

COVID-19 Vaccination in Haematology Patients: An Australia and New Zealand Consensus Position Statement

Introduction

Australia and New Zealand have achieved very good control of community spread of SARS-CoV-2 during the global pandemic due to highly effective public health interventions.(1, 2) As of 20 January 2021, Australia had recorded 22,201 local cases with 909 total fatalities(3) and New Zealand had reported 1044 local cases with 25 fatalities.(4) The availability of effective vaccines offers an opportunity to consolidate this successful control and requires consideration of their application to key vulnerable populations including those with haematological disorders.

Haematological malignancies account for approximately 11% of all cancers in Australia and New Zealand.(5) Patients with lymphoid malignancies, including chronic lymphocytic leukaemia (CLL) and multiple myeloma, recipients of allogeneic stem cell transplantation and of potent B- and T-cell depleting therapies are particularly vulnerable to serious viral infections.(6-9) Haematology patients are often severely immune compromised due to their underlying disease and/or associated therapy, and experience higher rates of infection than age-matched controls.

COVID-19 Morbidity and Mortality Risk Factors in Haematology Patients

Adults with haematological malignancies are reported to be at high risk of progression to severe disease and death from COVID-19 with an estimated mortality of 36% or greater, comparable to the mortality rate of aged care residents.(10-13) While mortality risk in paediatric patients (estimated at 4%) is lower, it is much higher than in healthy children.(11)

Patients with haematological malignancies, including lymphoid disorders, multiple myeloma, acute myeloid leukaemia and myelodysplastic syndrome appear to be at highest risk of mortality.(10, 11) Among those with lymphoid malignancies who acquire COVID-19, hospitalisation rates are up to 90% and intensive care admission rates 35%.(14) CLL patients who had previously received immunochemotherapy have a mortality of up to 60%. In a multi-national cohort of patients with multiple myeloma and COVID-19 infection, the COVID-19-related mortality rate was 33% with geographical variation from 27-57% of hospitalised patients.(12) In a myelofibrosis population study, the COVID-19 mortality was 48% (15). Limited data suggest that chronic phase chronic myeloid leukaemia patients on tyrosine kinase inhibitors with COVID-19 have mortality rates comparable to the general population.(16)(17) In myelofibrosis additional risk factors of mortality include discontinuation of ruxolitinib at COVID-19 diagnosis, possibly due to rebound inflammation.(15)

Patients with benign haematological disorders have varying outcomes depending on the underlying disease and associated co-morbidities (18-21). Patients with sickle cell disease appear to be at particular risk with an age standardised mortality ratio of 7.7 times (20).

In patients with haematological malignancies, COVID-19-related mortality is not always related to recent therapy of the underlying malignancy (11, 12, 14). Risk factors for mortality include age >60 years, active or progressive disease, ECOG performance score ≥ 2 , absolute lymphocyte count $\leq 0.6 \times 10^9/L$, platelet count $\leq 40 \times 10^9/L$, an elevated LDH, and a raised C-reactive protein.(10, 11) In multiple myeloma additional predictors of include high risk cytogenetics (del17p, t(4;14), amp 1q or t(14;16)

and renal disease.(12, 22) Furthermore, patients with haematological malignancies who recover from COVID-19 display distinct, prolonged immunological complications compared to those with solid organ malignancies who have similar rates to the general population.(23)

Impaired SARS-CoV-2 Clearance and Viral Evolution in Patients with Haematological Malignancies

Patients with haematological malignancies are unable to clear certain viruses (14, 24). Preliminary reports suggest that these patients when exposed to SARS-CoV-2 display heterogeneous humoral responses, an exhausted T cell phenotype and a high prevalence of prolonged virus shedding more so than patients with solid organ malignancies (23, 25). Therefore, these patients have an ongoing risk of recurrent infection and of onward transmission. Furthermore, preliminary data suggests that immunocompromised patients have the potential for accelerated viral evolution (25, 26).

Vaccine Considerations

These data should inform future preventative efforts as Australia and New Zealand commence their vaccination campaigns. At time of writing there are two vaccines of relevance in Australia and New Zealand. The Pfizer/BioNTech SARS-Cov-2 vaccine is a first-in-class mRNA vaccine which in an international phase 3 study was administered to 43,448 participants aged 16 or older in a two dose regimen 21 days apart. The vaccine was 95% effective against symptomatic COVID-19 from seven days after the second dose. Efficacy was consistent across age, gender and ethnicity, and no serious safety concerns were reported. This trial included a small number of patients (n=76) with leukaemia or lymphoma as a co-morbidity, 36 of whom received the vaccine (27).

The AstraZeneca ChAdOx1 nCoV-19 vaccine is a replication-deficient chimpanzee adenoviral vectored vaccine given in a two dose regimen. In a pooled analysis across four studies with varying dosing, overall vaccine efficacy was 70.4% with no serious safety concerns reported.(28) In a subgroup of 8,895 participants who received two standard doses (as will be administered in practice), vaccine efficacy was 62%. Experience with viral vectored vaccines is limited with no evidence in haematology patients.

An alternative vaccine available internationally is the Moderna mRNA SARS-CoV-2 vaccine (mRNA-1273) which is another two dose regimen vaccine administered 28 days apart, shown in a phase 3 study to have an overall efficacy of 94%.(29) Other vaccines with potential future relevance in Australia and New Zealand include the Novovax vaccine NVX-CoV2373, the Janssen vaccine Ad26Cov2S and access to the COVAX facility.

None of these studies included immunocompromised patients, and we await studies to evaluate these vaccines specifically in haematology patients. Despite the lack of data, none of these are live vaccines and therefore pose no risk of COVID-19 transmission.

Recommendations

Acknowledging the paucity of prospective data, representative experts from the Haematology Society of Australia and New Zealand, have collaborated with Infectious disease specialists on this consensus

position statement regarding COVID-19 vaccination in haematology patients in Australia and New Zealand. Broadly we consider that the following applies to all haematology patients:

1. Given the high mortality associated with COVID-19 infection in haematology patients, vaccination of these patients and health care workers delivering their care should be prioritised (22).
2. The benefits of vaccination outweigh possible unknown factors in haematology patients with no known contraindications to the contents of the vaccine (30).
3. Patients requiring treatment for a haematological malignancy should be vaccinated before treatment with chemotherapy, cellular therapies or T- or B-cell depleting treatments if possible, but this should not delay urgent treatment.
4. Vaccination should be timed with the aim of achieving optimal protection at the earliest opportunity without compromising disease treatment outcomes. Where possible, vaccination should be completed at least two weeks before immunosuppressive treatment (31).
5. For patients who have already commenced disease-specific therapies, we do not generally recommend interruption of treatment during vaccination. It is appropriate to delay vaccination for at least three months after B cell depleting therapy or stem cell transplantation (32). For such patients the vaccination of household contacts is an essential preventative measure.
6. Given the likelihood of reduced immunogenicity to COVID-19 vaccination in patients with haematological malignancies, particularly those who are on immunosuppressive therapies, vaccination should not replace other measures to reduce risk of COVID-19 infection (31, 33).
7. After vaccination, patients should be advised to continue to practice usual public health measures (e.g. masks, social distancing, ensuring good indoor ventilation, and hand hygiene) in accordance with national and regional guidelines, because the immunogenicity and efficacy of vaccination in haematology patients is unknown (34).
8. All haematology patients including those with haematological malignancies and recipients of cellular therapies, should also receive vaccinations against influenza, pneumococcus and other pathogens, as per standard guidance (35).
9. Patients with suspected or confirmed previous COVID-19 infection should be vaccinated as per international guidelines as immunity may wane (30, 36).
10. Household transmission is one of the most common mechanisms of SARS-CoV-2 transmission. Therefore, vaccination of household members and/or carers of haematology patients with high efficacy vaccines should be prioritised (37).
11. Acknowledging the lack of data for efficacy and safety of COVID-19 vaccines in haematology patients, we recommend the most efficacious vaccine in haematology patients, health care workers delivering their care and household members. This preference, however, should not delay vaccination with more immediately available vaccines.
12. Studies to determine the optimal vaccine safety, immunogenicity, timing, number of doses and schedule in haematology patients are urgently needed. In the interim, where feasible, assessment of vaccine response with post vaccination serology testing should be performed in these patients. This will be of clinical importance especially in patients who are on continuous anti-cancer therapies, hypogammaglobulinaemic and/or lymphopenic to identify

patients who do not achieve an adequate immunogenic response and who remain vulnerable to COVID-19 risks and may benefit from future revaccination.(38, 39)

Other disease specific considerations:

Vaccine Administration in Patients with Bleeding Risk Factors

Patients with bleeding disorders, those receiving antiplatelet or anticoagulant therapy and those with thrombocytopenia may have an increased risk of bleeding at the injection site given the intramuscular route of administration (40).

- Patients with severe haemophilia on prophylaxis with factor concentrate should have their normal prophylactic dose prior to the injection. Those receiving emicizumab who are in steady state will not require additional treatment prior to vaccination.
- While patients with mild inherited bleeding disorders can generally have an intra-muscular injection without any additional precautions, consultation with the patient's haematologist is advised.
- Patients on standard anticoagulation with warfarin can receive intra-muscular injections if the most recent INR is ≤ 3.0 . Patients requiring higher intensity anticoagulation should be managed on an individual basis but the risk of significant haematoma may be minimised by applying five minutes firm pressure at the vaccination site
- Patients on maintenance direct oral anticoagulants or therapeutic low-molecular weight heparin can delay the dose on the day of vaccination until after the intra-muscular injection but do not need to miss anticoagulant doses.
- Patients on single agent anti-platelet therapy (e.g., aspirin or clopidogrel) can continue on these medications without adjustment.
- Patients with thrombocytopenia may bleed or bruise at the site of the injection site. To reduce this risk, we recommend the platelet count should be kept $\geq 30 \times 10^9/L$ and that prolonged pressure at the injection site should be applied for five minutes.
- If patients are receiving regular platelet transfusions the vaccine should be given as soon as feasible after a platelet transfusion.
- If patients have a platelet count $\leq 30 \times 10^9/$ consultation with a haematologist is recommended regarding the need for platelet transfusion support.

Immune Thrombocytopenia

Both viral infections, and immunisations against viruses have been implicated as potential "triggers" of immune thrombocytopenia (ITP)(41, 42). But immunisation induced ITP is very rare, and for most ITP patients the benefits of avoiding COVID-19 infection far outweigh the risks of disease flare from vaccination. Although treatments for ITP such as high dose steroids and anti-CD20 monoclonal antibodies may impair humoral responses to immunisation, no data exist specifically for this cohort. It is recommended that vaccination of ITP patients should be done in consultation with and under the supervision of a haematologist.

Splenectomised Patients

Splenectomised patients should be encouraged to stay on antibiotic prophylaxis as per standard recommendations. However, consideration must be given to the indication for splenectomy including haematological malignancies, sickle cell disease and thalassemia which are associated with increased mortality with COVID-19.

Lymphoma, Chronic Lymphocytic Leukaemia and Multiple Myeloma

Some patients with these lymphoproliferative disorders may not necessarily require immediate chemotherapy or immunotherapy. However, significant delay in interventions in an attempt to achieve a potential increased immunological response is not recommended. This should be based on clinical discretion considering the risks and benefits to the patient (35).

Acute Leukaemias, Myelodysplastic Syndrome and Myeloproliferative disorders

Given the acute and urgent nature of a diagnosis of acute leukaemia, vaccination should not delay definitive therapy. For patients in remission, vaccination should be facilitated as soon as possible with consideration for thrombocytopenia and the associated risk of bleeding.

Aplastic Anaemia

There are case reports of aplastic anaemia (AA) post-vaccination, and of recovered AA patients relapsing post vaccination.(43, 44) Conversely, it is likely that viral insults are a key trigger in the pathogenesis of many cases of AA.(45, 46)

Recent immunosuppressive treatment in the setting of AA (typically anti-thymocyte globulin (ATG) and cyclosporin) is likely to markedly impair host immune response to vaccination. However, patients on maintenance cyclosporin more than six months post ATG and/or allogeneic haematopoietic stem cell transplantation do demonstrate responses to other routine vaccinations.(47)

The risk of COVID-19 infection still favours vaccination in AA, particularly those with additional risks for severe COVID-19 disease.(48)

Haematopoietic stem cell transplantation and CART therapy

Refer to the ANZTCT position statement available at www.anztct.org.au for guidance.

These statements will be regularly reviewed and updated as appropriate as further data on vaccines emerge (www.hsanz.org.au).

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