COVID-19 vaccination in children and adolescents aged 5 years and older undergoing treatment for cancer and non-malignant haematological conditions: Australian and New Zealand Children’s Haematology/Oncology Group consensus statement

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Following the recommendation for coronavirus disease 2019 (COVID-19) vaccination in all children and adolescents aged 12 years and older, the Australian Technical Advisory Group on Immunisation (ATAGI) and the New Zealand Ministry of Health have extended the group to include all children from 5 years of age. This includes children and adolescents with immunocompromising conditions, such as cancer, haematopoietic stem cell transplant (HSCT) recipients, certain non-malignant haematological conditions, and survivors of childhood cancer.1-3

Initial reports of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in children and adolescents with cancer were suggestive of mild COVID-19,4-6 similar to children without significant comorbidities, where COVID-19-related mortality is estimated between 0.001% and 0.01%, rising to 0.7% in children with pre-existing medical conditions.7,8 A large international cohort study subsequently reported severe COVID-19 in 19.9% of children with SARS-CoV-2 undergoing treatment for cancer or following HSCT, with a 3.8% mortality rate.9 Notably, a large proportion of reported cases were from low income and lower middle income countries, and reporting bias may have occurred as cases were self-reported. Nonetheless, considered alongside adult data demonstrating a more than threefold increased risk of severe COVID-19 disease in immunocompromised people,10 the study suggests children receiving treatment for cancer or following HSCT are at increased risk of severe or fatal COVID-19.

There remains a paucity of data regarding the immune response to COVID-19 vaccine in children and adolescents receiving immunosuppressive therapy. In severely immunocompromised adults, COVID-19 vaccine immune responses are less pronounced and likely result in reduced effectiveness compared with the broader population.11,12 Considering the safety profile of mRNA COVID-19 vaccines and the potential to offer significant, albeit potentially reduced, protection against severe or fatal COVID-19 in children and adolescents undergoing immunosuppressive treatment, we recommend vaccination in this population where immunosuppressive, chemotherapeutic and/or targeted biological agents are used. These include the timing of vaccination in patients undergoing active treatment, management of specific situations where vaccination is contraindicated or recommended under special precautions, and additional vaccination recommendations for severely immunocompromised patients. Finally, we stress the importance of upcoming clinical trials to identify the safest and most efficacious vaccination regimen for this population.

Changes in management as a result of this statement: This consensus statement provides recommendations for COVID-19 vaccination in children and adolescents aged ≥5 years with cancer and immunocompromising non-malignant haematological conditions, based on evidence, national and international guidelines and expert opinion.

Endorsed by: The Australian and New Zealand Children’s Haematology/Oncology Group.

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treatment for cancer and non-malignant haematological conditions, the Australian and New Zealand Children's Haematology/Oncology Group (ANZCHOG) recommends vaccination in this vulnerable population. A summary of the key messages is provided in Box 1.

Methods

The ANZCHOG COVID-19 Clinical and Research Reference Group was established to provide COVID-19-related recommendations, including vaccination guidelines, based on review of publications and current international and national health advisory committee guidelines, and where evidence is lacking, to provide consensus recommendations. The following disciplines from different states and hospitals across Australia and New Zealand are represented: medical oncology, transplant and cellular therapy, haematology, infectious diseases, microbiology, and immunology. Input was sought from the Australian and New Zealand Cardio-Oncology Registry steering committee members.

We reviewed the following health organisations and advisory group position statements in detail: ATAGI; NZ Ministry of Health COVID-19 program; Canadian National Advisory Committee on Immunisation; Australia and New Zealand Transplant and Cellular Therapies; British Society of Blood and Marrow Transplantation and Cellular Therapy; European Society for Blood and Marrow Transplantation; Children’s Cancer and Leukaemia Group; Haematology Society of Australia and New Zealand; American Society of Hematology; Australasian Society of Clinical Immunology and Allergy; Cardiac Society of Australia and New Zealand; Centers for Disease Control and Prevention (CDC); European Medicines Agency; and United Kingdom Joint Committee on Vaccination and Immunisation.

Most data on COVID-19 vaccination in populations without notable comorbidities was supported by high quality evidence according to the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) criteria, and included large international randomised controlled trials. Data on COVID-19 vaccination in people who are immunocompromised are sparse, based predominantly on observational studies of adults, and of moderate to poor quality. Some COVID-19 vaccination adverse effects data are supported by large observational cohort studies, surveillance programs and case studies (eg, myocarditis and pericarditis), whereas others have only been assessed in small cohort studies (eg, polyethylene glycol–asparaginase allergy) and for some, evidence is yet to be obtained (eg, COVID-19 vaccination following anthracyclines).

Recommendations

Cohort of patients

Recommendation

All children and adolescents in Australia and New Zealand with cancer and non-malignant haematological conditions, and all survivors of childhood cancer aged ≥ 5 years should receive at least two doses of an mRNA COVID-19 vaccine.

Children and adolescents with the following conditions are considered to be at the greatest risk of severe COVID-19 due to a high degree of immunosuppression, and should receive an augmented three-dose primary schedule (Box 2):

- any type of cancer including haematological, solid or brain cancer undergoing active treatment;
- recipients of autologous or allogeneic HSCT or chimeric antigen receptor (CAR) T-cell therapy within 2 years of treatment;
- those receiving immunosuppressive therapies including:
  ▶ high dose corticosteroids;
  ▶ biological and targeted therapies including anti-CD20 antibodies, anti-CD52 antibodies, anti-thymocyte globulin, Janus kinase inhibitors and anti-complement antibodies;
  ▶ conventional synthetic disease-modifying anti-rheumatic drugs including mycophenolate mofetil, methotrexate, cyclosporine, tacrolimus and cyclophosphamide;
- those receiving multiple immunosuppressants with an expected cumulative effect.

Comments

Children and adolescents with confirmed COVID-19 who have not yet received vaccination should proceed with vaccination as soon as they recover to boost their natural, albeit likely reduced, immune response.

This is in accordance with ATAGI and NZ Ministry of Health statements addressing COVID-19 vaccination in children aged 5–11 years and 12–15 years, and severely immunocompromised people, and is supported by recommendations set by the CDC and European Medicines Agency.

Type of vaccine

Recommendation

The recommended vaccine is Comirnaty (Pfizer), available in both Australia and New Zealand, or alternatively, Spikevax (Moderna), available for use in Australian adolescents ≥ 12 years of age.

1 Key messages

- The Australian Technical Advisory Group on Immunisation (ATAGI) and New Zealand Ministry of Health have extended their recommendation for COVID-19 vaccination to include children aged 5 years and older.
- Children and adolescents undergoing treatment for cancer and immunosuppressive therapy for non-malignant haematological conditions are among the most vulnerable.
- Children and adolescents with cancer demonstrate up to a 20% rate of severe COVID-19, with a 3.8% mortality compared with 0.001–0.7% in the general population.
- In adults, immunosuppression is estimated to increase the risk of severe COVID-19 threefold.
- Comirnaty (Pfizer) and Spikevax (Moderna) are mRNA-based non-live vaccines suitable for use in immunocompromised individuals. Both vaccines have an excellent safety profile and high efficacy in the general population, including children and adolescents.
- Immunogenicity of COVID-19 vaccines in the immunocompromised is reduced, leading to recommendations for an augmented primary schedule in severely immunocompromised people.
- Considering the safety profile of mRNA COVID-19 vaccines and the increased risk of severe COVID-19, the Australian and New Zealand Children's Haematology/Oncology Group strongly recommends COVID-19 vaccination.
- All children and adolescents with cancer and non-malignant haematological conditions, and all survivors of childhood cancer aged ≥ 5 years, except for those in whom vaccination is contraindicated, should receive COVID-19 vaccination.
- All household contacts, including parents, siblings ≥ 5 years of age, and grandparents, should be encouraged to receive a COVID-19 vaccine.

* A large proportion of reported cases were from low income and lower middle income countries and reporting bias may have occurred as cases were self-reported.
Comments

Currently, Comirnaty is the only COVID-19 vaccine approved for use in children and adolescents aged ≥ 5 years in both Australia and New Zealand. Spikevax has been approved, in addition to Comirnaty, in the ≥ 12 years age group in Australia only. Vaxzevria (AstraZeneca), Ad26.COV2.S (Janssen) and Nuvaxovid (Novavax) are registered in both Australia and New Zealand for use in people aged ≥ 18 years, with either Comirnaty or Spikevax being preferred in younger adults.

The safety of both Comirnaty and Spikevax vaccines is supported by a number of large clinical trials conducted in people aged ≥ 16 years, in addition to real world data on hundreds of millions of people vaccinated worldwide to date. The two largest placebo-controlled trials conducted on 43 548 and 30 420 participants studying safety and efficacy of Comirnaty and Spikevax demonstrated 95% and 94% efficacy in preventing COVID-19, respectively, and an excellent safety profile for both. The safety of these vaccines is also supported by local post-marketing safety surveillance data.

Both vaccines are mRNA-based lipid nanoparticle-encapsulated vaccines that encode the full-length spike glycoprotein of SARS-CoV-2. They are non-live vaccines and therefore safe for use in immunocompromised people.

Safety, immunogenicity and efficacy of both Comirnaty and Spikevax were studied in placebo-controlled trials of 2260 and 3732 adolescents aged 12–15 and 12–17 years, respectively. Favourable vaccine safety profiles were demonstrated, with mainly transient mild to moderate reactions, the most common after the first and second doses being injection site pain (in 86% and 79% of participants after Comirnaty, and 93% and 92% after Spikevax), fatigue (in 60% and 66% after Comirnaty, and 48% and 68% after Spikevax), and headache (in 55% and 65% after Comirnaty, and 45% and 70% after Spikevax). No vaccine-related serious adverse events were observed in either study. Both Comirnaty and Spikevax were efficacious, with no breakthrough infections in vaccine recipients. For Comirnaty, immunogenicity was greater than previously observed in young adults aged 16–25 years, and for Spikevax, immunogenicity was similar to that observed in young adults.

Safety, immunogenicity and efficacy of COVID-19 vaccine in children aged 6 months to 11 years are being studied in an ongoing placebo-controlled trial. Results for the 5–11 years group have recently been published, showing efficacy of 90.7% after two paediatric doses of Comirnaty, with a similar safety profile to that observed in older children and adolescents among 2186 study participants.

An association between COVID-19 vaccination and myocarditis or pericarditis had been reported but not observed in the initial Comirnaty and Spikevax clinical trials in adults, or in the corresponding adolescent trials, likely due to inadequate participant numbers to detect such rare events. Safety data has indicated a number of cases of myocarditis or pericarditis linked to mRNA COVID-19 vaccines have been reported in the literature, and investigated by national vaccine safety programs. Symptoms typically appear 1–5 days after vaccination and are more frequent after the second dose. The condition seems to occur more frequently in male adolescents and young adults at an estimated incidence of 1 to 5 per 100 000 individuals, and appears to be extremely rare in the 5–11 years age group. Most cases have required hospitalisation; however, the majority responded well to standard treatment with a mild and self-limiting course and no associated deaths. Notably, in comparison, SARS-CoV-2 infection-associated myocarditis occurs at an incidence of 11 per 100 000 individuals.

Vaccination schedule

Recommendation

COVID-19 vaccination schedule should vary depending on a child’s age, the level of immunosuppression, and vaccine availability (Box 2).

Comments

Increasing evidence suggests reduced vaccine response in immunocompromised patients compared with the broader population. Lower post-vaccination antibody geometric mean titres have been found in recipients of solid organ transplants and adult patients with haematological malignancies. A study identified reduced cellular immunity in patients immunosuppressed after solid organ transplants, however, the majority of studies did not evaluate T-cell vaccine responses. Although immunogenicity data cannot directly predict protection from infection, observational studies finding a high

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| 2 Primary vaccination schedule for children and adolescents, based on age and level of immunosuppression* |
|---|
| Eligible to receive COVID-19 vaccine |
| Level of immunosuppression |
| Mild to moderate |
| Age | 5–11 years | Comirnaty 10 μg 2 doses 8 weeks apart |
| ≥ 12 years | Comirnaty 30 μg 2 doses 3 weeks apart or Spikevax 100 μg 2 doses 4 weeks apart |
| Severe |
| Age | 5–11 years | Comirnaty 10 μg 3 doses 3 and 8 weeks apart or Spikevax 100 μg 3 doses 4 and 8 weeks apart |
| ≥ 12 years |

* Comirnaty (Pfizer) is available in Australia and New Zealand; Spikevax (Moderna) is available in Australia only. Note the primary vaccination schedule is regularly updated to reflect latest changes.
and have been endorsed by the Australasian Society of Clinical Immunology and Allergy.\textsuperscript{50}

**Recommendation**

Children and adolescents with myocarditis attributed to a previous dose of an mRNA COVID-19 vaccine, and those with pericarditis associated with a previous mRNA COVID-19 vaccine and abnormal investigations, should not receive further mRNA vaccines.

**Comments**

This recommendation is in keeping with Cardiac Society of Australia and New Zealand guidance regarding mRNA COVID-19 vaccination-associated myocarditis and pericarditis in individuals aged \( \geq 12 \) years.\textsuperscript{54}

**Recommendation**

According to the Cardiac Society of Australia and New Zealand guideline:\textsuperscript{54}

- Children and adolescents who have developed pericarditis possibly associated with a previous dose of an mRNA COVID-19 vaccine but with normal investigation results (electrocardiography, troponin and inflammatory markers), and who have been symptom-free for at least 6 weeks, may receive further doses of an mRNA COVID-19 vaccine.
- Children and adolescents with current or recent (within the past 3 months) myocarditis or pericarditis due to causes other than the mRNA vaccination, including rheumatic heart disease and acute rheumatic fever, can receive an mRNA COVID-19 vaccine after consultation with a general practitioner, immunisation specialist or cardiologist.

**Comments**

ANZCHOG recommends that all children and adolescents with cancer and non-malignant haematological conditions with myocarditis or pericarditis considered for COVID-19 vaccination should receive specialist consultation.

**Recommendation**

Children and adolescents who have received anthracyclines as part of their treatment are not considered at higher risk of developing side effects from mRNA COVID-19 vaccination, and should therefore receive either of the mRNA vaccines.

**Comments**

Survivors of childhood cancer treated with anthracyclines, such as doxorubicin, daunorubicin, idarubicin and mitoxantrone, are at an increased risk of developing cardiomyopathy and congestive heart failure.\textsuperscript{55,56}

Currently, there is no evidence to suggest long term sequelae in people who have developed mRNA vaccine-related myocarditis or pericarditis. Similarly, there is no evidence to suggest poor cardiac outcomes in patients who have received anthracyclines and mRNA vaccination.

Further support for mRNA COVID-19 vaccination in children and adolescents with cancer who have been exposed to anthracyclines can be garnered from Cardiac Society of Australia and New Zealand guidance recommending mRNA COVID-19 vaccination without specific precautions in individuals aged...
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≥ 12 years with most pre-existing cardiac conditions, including dilated cardiomyopathy and stable heart failure.54

Vaccine timing

Recommendation

mRNA COVID-19 vaccines can be given during treatment, providing that scheduling of the vaccine has been discussed with the treating haematology/oncology team.

Comments

It has been shown that some drugs, such as the antimetabolites (ie, methotrexate, mycophenolate mofetil) and corticosteroids, have a negative impact on humoral vaccine response in adult patients.38,57,58 In a study of Comirnaty and Vaxzevria in adult patients with multiple myeloma, patients on treatment showed a significantly lower vaccine response compared with those off treatment;59 and a blunted antibody response was found after two doses of Comirnaty in another study of adults with haematological malignancies.60 Immunogenicity was significantly higher in patients with solid tumours compared with haematological malignancies in a study of Comirnaty in adult patients undergoing treatment for cancer.61 Despite emerging evidence of a poorer vaccine response in the setting of immunosuppressive therapy, there are currently no guidelines regarding ideal timing of vaccination during treatment for cancer and other conditions requiring immunosuppressive therapy. Given the demonstrated safety of vaccination and the higher risk of severe disease in the setting of immunosuppression, vaccination should proceed during cancer therapy as soon as practicable.

Recommendation

Children and adolescents who have received anthracyclines, high dose cytarabine (> 6000 mg/m²) or immune checkpoint inhibitors should receive mRNA COVID-19 vaccination at the following time points: at least 1 week after anthracycline administration; at least 4 weeks after high dose cytarabine administration; and at least 6 weeks after the first dose of immune checkpoint inhibitors, and only if they did not develop myocarditis or pericarditis.

Comments

Anthracyclines, high dose cytarabine and immune checkpoint inhibitors have all very rarely been associated with acute pericarditis.62-67 Acute pericarditis following anthracyclines occurs within the first week after administration.65 Conversely, high dose cytarabine has been shown to cause pericarditis up to 28 days after exposure, supporting a hypothesis of this adverse event being a type IV delayed hypersensitivity reaction.66 For immune checkpoint inhibitors, the median time for development of pericarditis is longer (usually 6–8 weeks) with wide inter-patient variability.69-72

Recommendation

Children and adolescents who are being treated with rituximab, CD19-targeted CAR T-cells or HSCT should receive mRNA COVID-19 vaccination before the treatment begins or, if the treatment has already been administered, at least 3 months after completion of the treatment.

Comments

Rituximab, a humanised chimeric anti-CD20 monoclonal antibody, is widely used for the treatment of B-cell lymphoproliferative disease and refractory auto-immune conditions. The profound effect on B-cell depletion following rituximab has been found to have a significantly negative effect on immune response to other vaccines, and it is therefore expected that the mRNA COVID-19 vaccine response would be reduced in a similar manner.73 CAR T-cells, currently licensed in Australia for the treatment of refractory, relapsed post-HSCT, or second or greater relapse CD19-positive B-cell acute lymphoblastic leukaemia in children and young adults ≤ 25 years of age,74 induce a long-lasting and profound hypogammaglobinaemia, which is likely to affect the serological response to mRNA COVID-19 vaccines.75-76 Patients who have received HSCT experience a state of profound immune dysfunction for weeks to months, with a gradual recovery to full immune function about 2 years after HSCT.77 Current international guidelines for vaccination of HSCT recipients recommend administration of inactivated vaccines from 6 months following HSCT, and from 3 months in community outbreaks.78 Although it is acknowledged that optimal response to mRNA COVID-19 vaccines is more likely to develop ≥ 6 months after HSCT, introducing vaccination as early as 3 months after HSCT in the context of the COVID-19 pandemic has been endorsed by the British Society of Blood and Marrow Transplantation and Cellular Therapy, European Society for Blood and Marrow Transplantation, and Australia and New Zealand Transplant and Cellular Therapies in their COVID-19 vaccination consensus statements.79-81 A recent report revealed a good humoral response to COVID-19 vaccination in allogeneic recipients < 12 months after HSCT; however, the report did not specify if a good response was observed in those who received COVID-19 vaccination 3 months after HSCT.82

Infection prevention and control

Recommendation

COVID-19 vaccination should not replace public health measures reducing the risk of SARS-CoV-2 infection.

Comments

Measures such as wearing masks, social distancing, good hand hygiene and optimal indoor ventilation should continue.55 These are of particular importance in children and adolescents undergoing treatment for cancer and those on immunosuppressive therapies, given the likelihood of reduced immunogenicity to COVID-19 vaccination.

All household contacts, including parents, siblings aged ≥ 5 years, and grandparents with no contraindication to COVID-19 vaccination, should receive COVID-19 vaccination.

Conclusion

In this consensus statement, ANZCHOG provides current recommendations for COVID-19 vaccination in children and adolescents aged ≥ 5 years with cancer and immunocompromising non-malignant haematological conditions (Box 3). The recommendations are based on evidence-based knowledge of the safety, immunogenicity and efficacy of the vaccines in the general population, in addition to emerging data regarding COVID-19 vaccination in immunocompromised individuals. Large international trials and collection of real world data are essential to provide best evidence to identify the ideal timing, schedule, efficacy and safety of COVID-19 vaccines in this vulnerable population.84
3 Key recommendations

- All children in Australia and New Zealand with cancer and non-malignant haematological conditions, and all survivors of childhood cancer aged ≥ 5 years, should receive COVID-19 vaccination.
- Children and adolescents with the following conditions are considered to be at the highest risk of severe COVID-19, and should receive an augmented primary vaccine schedule:
  - any type of cancer including haematological, solid or brain cancer undergoing active treatment;
  - recipients of autologous or allogeneic haematopoietic stem cell transplantation (HSCT) or chimeric antigen receptor (CAR) T-cell therapy within 2 years of treatment;
  - those receiving immunosuppressive therapies including high dose corticosteroids, biological and targeted therapies such as rituximab, or conventional synthetic disease-modifying anti-rheumatic drugs;
  - those receiving multiple immunosuppressants.
- Children and adolescents with confirmed COVID-19 should proceed with vaccination after they have recovered from COVID-19.
- Recommended COVID-19 vaccines are:
  - Comirnaty (Pfizer), available in both Australia and New Zealand; and
  - Spikevax (Moderna), available in Australian adolescents ≥ 12 years old.
- COVId-19 vaccination schedule varies depending on child’s age, level of immunosuppression, and vaccine availability.
- Vaccine contraindications:
  - anaphylaxis to an mRNA COVID-19 vaccine;
  - anaphylaxis to polyethylene glycol (PEG), but not PEG–asparaginase;
  - myocarditis attributed to an mRNA COVID-19 vaccine;
  - pericarditis associated with an mRNA COVID-19 vaccine and abnormal investigations.
- Vaccine precautions:
  - generalised allergic reaction other than anaphylaxis to an mRNA COVID-19 vaccine;
  - anaphylaxis to PEG–asparaginase;
  - current or recent (within the past 3 months) myocarditis or pericarditis due to causes other than an mRNA COVID-19 vaccine;
  - acute decompensated heart failure.
- Treatment with anthracyclines is not a contraindication to COVID-19 vaccination.
- COVID-19 vaccines can be administered during treatment as soon as practicable, with the exception of the following:
  - at least 1 week after anthracycline administration;
  - at least 4 weeks after high dose cytarabine administration;
  - at least 6 weeks after the first dose of immune checkpoint inhibitors, and only if there has been no development of myocarditis or pericarditis;
  - before the treatment, or at least 3 months after the completion of treatment in those receiving rituximab, CAR T-cell therapy or HSCT.
- COVID-19 vaccination should not replace public health measures reducing the risk of SARS-CoV-2 infection.
- All household contacts ≥ 5 years of age with no COVID-19 vaccine contraindication should receive COVID-19 vaccination.

Endorsement: These recommendations have been endorsed by ANZCHOG, and are regularly updated by the ANZCHOG COVID-19 Clinical and Research Reference Group. A lay summary, produced in consultation with consumers, can be found on the ANZCHOG organisational webpage: https://anzchog.org/covid-19-vaccination-guide-nc-for-children-5-years-and-older-undergoing-cancer-treatment-and-children-with-non-cancerous-blood-disorders-updated/

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