

**CLINICAL GUIDELINE ON
COVID-19 VACCINATION
FOR CHILDREN
(5 – 11 YEARS)
1ST EDITION**

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MINISTRY OF HEALTH MALAYSIA

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1. BACKGROUND

This guideline is based on review of available published literature and international guidelines on COVID-19 vaccination in children age 5-11 years. At the time of writing, COVID-19 vaccine is not licensed for use in children below 5 years of age. Therefore, to protect these young children, vaccination of all eligible household members, caregivers, teachers and other close contacts should be promoted.

DISCLAIMER

This statement is current as of 12th January 2022, and recommendations may change as more data become available. Please consult the treating clinicians before vaccination. For further update and information, please refer to the Guidelines for COVID-19 vaccination from MOH Malaysia.

2. RECOMMENDATIONS

- COVID-19 vaccination is recommended for all children aged 5-11 years.
- Children aged 5-11 years with underlying medical conditions are at an increased risk for severe illness and should be prioritised to receive COVID-19 vaccination.
- The Committee recommends Comirnaty® (Pfizer-BioNTech) vaccine paediatric formulation for COVID-19 vaccination of children 5-11 years. Two doses of the vaccine (10mcg per dose) should be given 8 weeks apart.

3. INTRODUCTION

Children with SARS-CoV-2 infection usually have no or mild, self-limiting symptoms. However, some children do progress to severe disease and a few have died.¹⁻⁴ Many have underlying chronic medical conditions that predispose them to severe illness and are more likely to develop complications arising from COVID-19. In Malaysia, a total of 278,383 cases of SAR-CoV-2 infection in children below 12 years were reported over a 6-month period from July to December 2021 with 63 deaths.⁵

In addition, children with recent COVID-19 are also at risk of developing a rare, but serious condition known as Multi System Inflammatory Syndrome in Children (MIS-C). The clinical presentations mimic those of Kawasaki Disease, Kawasaki Disease Shock Syndrome and Toxic Shock Syndrome. Clinical features include persistent fever, hypotension, gastrointestinal symptoms, rash, myocarditis, and laboratory findings associated with increased inflammation.⁶⁻⁷ It is estimated to affect 1 in 3200 cases in the United States.⁸ A large international study noted a higher incidence of 0.5% - 3.1% of all children with SARS-CoV-2 infection.⁹ An ongoing retrospective multicentre study

involving 14 hospitals in Malaysia reported 174 cases of MIS-C admitted to the hospitals where 100 (56%) were children aged 5-11 years. Mortality rate was 4% (7 deaths). (unpublished data)

Children are also at risk of developing “Long COVID” (post-acute COVID-19 syndrome). Limited data in children, however, suggest the risk to be lower compared to adults.¹⁰

Children also suffer significantly from the indirect impact of COVID-19 pandemic. The pandemic has disrupted family and social life, interrupted schooling and education as well as adversely affecting the psychological and social development of the children.

4. PRIORITY GROUPS FOR COVID-19 VACCINATION

Although the data is still limited, children with certain underlying medical conditions are at a higher risk for severe COVID-19 including hospitalisation, ICU admission and death. Risk factors for severe COVID-19 reported in the literature include chronic respiratory diseases, cardiovascular diseases, hypertension, immunosuppression, diabetes mellitus, chronic kidney diseases, neurological conditions and obesity.¹¹⁻¹⁹ A recent large meta-analysis reported a near 9-fold increase in the odds of death due to COVID-19 in children with underlying chronic pulmonary disease, congenital heart disease, neurological disease and obesity compared to those with no risk conditions.²⁰ Hence, this group of children should be prioritised to receive COVID-19 vaccination. The list of underlying medical conditions with increased risk of severe COVID-19 is given in Table 1 below. The list is not exhaustive, and, clinical judgement should be applied on risk-benefit of vaccination on case to case basis.

Table 1 Priority Groups for COVID-19 Vaccination in Children (5 -11 years)

Underlying medical conditions that increased the risk for severe COVID-19 (Conditions listed here are in no order of priority)		
1	Immunocompromised due to disease or treatment (refer Annex 1 for optimal timing for COVID-19 vaccination in haemato-oncology patients)	Bone marrow or stem cell transplant recipients.
		Solid organ transplant recipients.
		Haematological malignancies.
		Cancer patients on active chemotherapy.
		Severe aplastic anaemia.
		Autoimmune or autoinflammatory disorders requiring long term immunosuppressive treatment.

		Receiving systemic steroids for > 1 month at a daily dose equivalent to prednisolone 20mg or more (for patient weighing < 10kg, prednisolone dose of > 2mg/kg/day for \geq 14 days).
		Receiving immunosuppressive or immune-modulating biological therapy such as anti-TNF, rituximab.
2	HIV Infection	HIV infection at all stages.
3	Asplenia or dysfunction of the spleen	Those who have undergone splenectomy and those with conditions that may lead to splenic dysfunction, such as thalassemia major and coeliac syndrome.
4	Chronic heart disease and vascular disease	Congenital heart disease, cardiomyopathy, individuals with arrhythmia, chronic rheumatic heart disease with valve involvement, pulmonary hypertension and right heart failure, chronic heart failure, individuals with aortic root dilatation.
5	Chronic kidney disease	Kidney transplantation, ESRD on haemodialysis and CAPD, chronic kidney disease stage 3 and 4. Glomerulonephritis e.g. lupus nephritis. Nephro-urological problems.
6	Chronic gastrointestinal/liver disease	Cirrhosis, biliary atresia. Inflammatory bowel disease, malabsorption syndrome.
7	Chronic neurological disease	Cerebral palsy, chronic neuromuscular disease, epilepsy, learning disabilities, autism spectrum disorder, chronic demyelinating disease, hereditary and degenerative disease of the nervous system or muscles, stroke; or neurological disability requiring assistance in activities of daily living.

8	Chronic respiratory disease	Chronic lung disease (e.g. BPD survivors, bronchiectasis, bronchiolitis obliterans, chronic aspiration pneumonia, cystic fibrosis and primary ciliary dyskinesia). Chronic restrictive lung disease (e.g. neuromuscular disorders, syndromic with hypotonia, skeletal disorders, metabolic disorders like mucopolysaccharidosis). Chronic upper and lower airway obstruction (e.g. severe OSAS, malacic, stenosis, asthma). Hypoventilation syndrome (e.g CCHS).
9	Chronic endocrine disease	Diabetes mellitus type 1, type 2, monogenic. Hypopituitarism, isolated growth hormone deficiency, diabetes insipidus, adrenal insufficiency.
10	Obesity	BMI at or above the 95th percentile for adolescents of the same age and sex (refer Annex 2).
11	Genetic conditions	Down syndrome. Genetic disorders affecting the immune system e.g. primary immunodeficiency disorders. Inherited metabolic diseases with risk of acute metabolic decompensation, respiratory or cardiac complications, and frequent exacerbation induced by infection.
12	Chronic dermatological disease	Chronic dermatoses requiring immunosuppressive drugs and/or biologics. Complex vascular anomalies including complex vascular malformations and complex vascular tumours. Genodermatoses including ichthyoses syndromes, epidermolysis bullosa and others that is associated with immunosuppression.

13	Children in long-stay nursing and residential care settings	Many children in residential care settings will be eligible for vaccination because they fall into one of the risk groups above (for example learning disabilities). Given the likely high risk of exposure in these settings, where a high proportion of the population would be considered eligible, vaccination of the whole resident population is recommended.
Other risk groups		
1	Household contacts of people with immunosuppression	Those who expect to share living accommodation on most days with individuals who are immunosuppressed (defined as above).

Adapted from Public Health England. Immunisation against Infectious Disease (Green Book). Chapter 14a COVID-19 - SARS-CoV-2 ²¹

5. COVID-19 VACCINES FOR CHILDREN (5 – 11 years)

In Malaysia, Comirnaty® (Pfizer-BioNTech) COVID-19 vaccine is currently the only approved vaccine for children 5-11 years of age. It is expected that additional COVID-19 vaccine suitable for paediatric population may become available in the future.

Comirnaty is an mRNA vaccine that targets the spike proteins on the surface of the SARS-CoV-2. Efficacy, immunogenicity, and safety of the vaccine in adolescents and adults have been previously reported. ^{22,23} A recent phase II/III randomised clinical trial involving children 5 – 11 years old demonstrated excellent vaccine efficacy (90.7%) and non-inferior neutralising antibodies response in trial participants compared to individuals aged 16-25 years old. However, the clinical trial was conducted before the emergence of the Omicron variant. Vaccine efficacy against the Omicron is still unknown.

The vaccine was well tolerated with reactogenicity and adverse events profile comparable to individuals age 16-25 years. Pain at injection site, redness and swelling are common local reactions. Common systemic reactions include fatigue, headache, muscle pain, chills and fever. The adverse reactions were mostly mild to moderate, and short lived. No severe adverse events related to the vaccine or deaths were reported. ²⁴

Rare adverse events may not be detected in the clinical trial due to the limited number of the study population. However, real-world data are rapidly emerging confirming the

low rate of rare severe adverse events following immunisation. As of 19 December 2021, a total of 8.7 million children 5-11 years have received COVID-19 vaccination in the United States.²⁵

Myocarditis and pericarditis following mRNA COVID-19 vaccination

Cases of myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines in individuals \geq 12 years old have been reported in several countries.^{26,27} However, the incidence is extremely low and risk is considered rare. Symptoms of myocarditis/pericarditis include shortness of breath, chest pain and palpitation. Cases have involved predominantly male adolescents and young adults below 30 years and have occurred more often after the second dose of the vaccine. Most cases appeared to be mild, responded well to medications and rest and showed prompt improvement of symptoms.²⁸⁻³⁰ At this moment, the exact mechanism of myocarditis/pericarditis following COVID-19 vaccination is still uncertain.

The risk of myocarditis/pericarditis in children following immunization with the 10 mcg dose of the Pfizer-BioNTech vaccine is still unknown. Early adverse events surveillance data from United States suggest that the risk in children 5-11 years is substantially lower than that for adolescents 12-17 years old.²⁵

6. CONTRAINDICATIONS AND PRECAUTIONS

6.1. Allergy and Severe Adverse Reactions

Pfizer-BioNTech COVID-19 vaccine is contraindicated in individuals who have had severe allergic reactions after a previous dose of the vaccine or to any of the vaccine ingredients. The vaccine is also contraindicated in individuals who develop allergic reaction of any severity within 72 hours after a previous dose or any known allergy to any of the vaccine ingredient. Please refer to the relevant section (Contraindication to COVID-19 vaccination) in the Clinical Guidelines for COVID Vaccination in Malaysia for further details.³¹

6.2. Acute illness

Vaccination of children with an acute illness should be deferred until the acute symptoms have resolved. Individuals with symptoms compatible with COVID-19 should be tested for SARS-CoV-2.³¹

6.3 Other vaccines

COVID-19 vaccine should preferably not be given simultaneously with other vaccines to avoid confounding possible adverse events. Evidence regarding possible immune interference is also lacking currently. Defer the vaccination for at least 2 weeks, if possible. In circumstances where the vaccination could not be deferred (e.g. the risk of the child defaulting subsequent appointment for vaccination is high), coadministration of routine childhood vaccine and COVID-19 vaccine is allowed. If multiple vaccines are given at a single visit, give each injection in a different injection site.³¹⁻³³ This advice may change as data become available.

6.4 Medications

Prophylactic oral analgesics or antipyretics, such as paracetamol or ibuprofen, should not be routinely used prior to or during vaccination as the medications may interfere with the immune response. However, they may be considered for the management of pain or fever after vaccination.^{32,33}

6.5 Children with MIS-C

Children with a prior history of MIS-C may receive COVID-19 vaccine. However, it should be deferred until clinical recovery has been achieved or until it has been more than 90 days since diagnosis, whichever is longer.^{32,33}

6.6 Children with SARS-CoV-2 infection

Children with previous history of SARS-CoV-2 infection can receive COVID-19 vaccination. The vaccine can be given after the child has recovered from his/her illness and has met criteria to discontinue isolation.^{32,33}

7. PRE-VACCINATION ASSESSMENT

Pre-vaccination assessment (PVA) is an assessment conducted preferably by the treating doctor to determine the suitability of individual to receive the vaccine, the timing of receiving the vaccine and the appropriate facility for he/she to receive the vaccine (i.e. hospitals, health clinics or other vaccination centres).

Not all children with co-morbidities will require PVA. In general, children that require PVA include:

1. Immunocompromised individuals (e.g children with diseases or on medications that suppress their immune system).

2. Children with increased bleeding tendency (e.g. haemophilia, ITP, or on anticoagulants).
3. Children with history of severe allergy (e.g. anaphylaxis).

For further details, please refer to the section on Pre-vaccination Assessment in the national guidelines.³¹

8. VACCINE FORMULATION AND ADMINISTRATION

8.1 Formulation and Dose

The paediatric formulation of Comirnaty® (Pfizer-BioNTech) COVID-19 vaccine **DIFFERS** from adolescents/adult formulation. It is supplied in a 10-dose vial (orange cap) and requires dilution with 1.3ml of normal saline. Each dose administered is 0.2ml containing 10mcg of mRNA vaccine. It is administered by IM injection into the deltoid muscle, or alternatively, the anterolateral thigh.

Table 2 Formulation of Comirnaty® Pfizer-BioNTech COVID-19 Vaccine

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use
Age Group	12 years and older ^{1,2}	12 years and older ³	5 through 11 years ⁴ ("Age 5y to <12y" on vial label)
Vial Cap Color			
Dose	30 mcg	30 mcg	10 mcg
Dose Volume	0.3 mL	0.3 mL	0.2 mL
Amount of Diluent Needed per Vial [†]	1.8 mL	NO DILUTION	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)
Storage Conditions			
Ultra-Low-Temperature (ULT) Freezer [-90°C to -60°C (-130°F to -76°F)]	9 months [†]	6 months [†]	6 months [†]
Freezer [-25°C to -15°C (-13°F to 5°F)]	2 weeks	DO NOT STORE	DO NOT STORE
Refrigerator [2°C to 8°C (35°F to 46°F)]	1 month	10 weeks	10 weeks
Room Temperature [8°C to 25°C (46°F to 77°F)]	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to dilution (including any thaw time)
After First Puncture [2°C to 25°C (35°F to 77°F)]	Discard after 6 hours	Discard after 12 hours	Discard after 12 hours

Image Credit: Pfizer-BioNTech, Vaccine Formulation Presentation Guide

8.2 Dosing Schedule

The manufacturer's recommended dosing schedule is 2 doses, 3 weeks apart. However, **the Committee recommends the vaccine to be given 2 doses, 8 weeks apart.**

The longer interval of 8 weeks between the 2 doses is recommended based on emerging data in adults suggesting a stronger immune response, higher vaccine effectiveness and potentially longer duration of protection in those receiving longer interval of the primary series.³⁴⁻³⁵ Data in adults also suggests that a longer interval may be associated with reduced risk of myocarditis/pericarditis following a second dose of the vaccine.³⁶ Extended dosing intervals have not yet been directly studied in children.

8.3 Other considerations

Children should receive the age-appropriate vaccine formulation and dose regardless of their size or body weight.

The dosage recommendation is according to birth date. Children who turn 12 after their first dose may be given adolescent/adult Comirnaty® (Pfizer-BioNTech) vaccine formulation and dose (30mcg) to complete their primary vaccine course. If the second dose of 10mcg is inadvertently given, the dose should still be considered valid and the series complete.³²⁻³³

9. CONSENT

Information regarding the vaccine's efficacy, safety and possible adverse reactions should be clearly explained to the children and to their parents/ caregivers prior to the vaccination. Parents or caregivers will be required to sign the informed consent form on behalf of the children.

10. MONITORING OF ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

Surveillance data on AEFI are essential and an integral part of any immunisation program especially when new vaccines are introduced. Most COVID-19 vaccines are currently approved for use under conditional registration following rigorous controlled trials that have demonstrated excellent efficacy and safety profiles in the short term. Many of these studies are still ongoing to monitor the long-term efficacy and safety of the vaccines on recipients. All health care providers should be alert and report any AEFI to National Pharmaceutical Regulatory Agency (NPRA). Monitoring and

reporting of adverse events including myocarditis/pericarditis should follow the standard procedure as outlined in the main section of the national guidelines.³¹ Algorithm on diagnosis and management of children with myocarditis/pericarditis following COVID-19 vaccination are shown in Annex 3.

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Annex 1 Paediatric Haemato-Oncology Priority Groups for COVID-19 Vaccination

- 1) HSCT – patients who are planned for HSCT eg: Thalassaemia /cancer patients. It is best to give the vaccine prior to the procedure (at least 2 weeks before).

Post HSCT – recommended to give the vaccine at least 3 months post procedure OR between 3-6 months post procedure for area with high infectivity rate and > 6 months for area with low infectivity rate.

Post HSCT with GVHD – patients in stage III-IV, it is recommended to defer giving the vaccine until the GVHD illness has been well controlled. The mild form of GVHD stage I-II can receive the vaccine.

- 2) Cancer patients on active chemotherapy

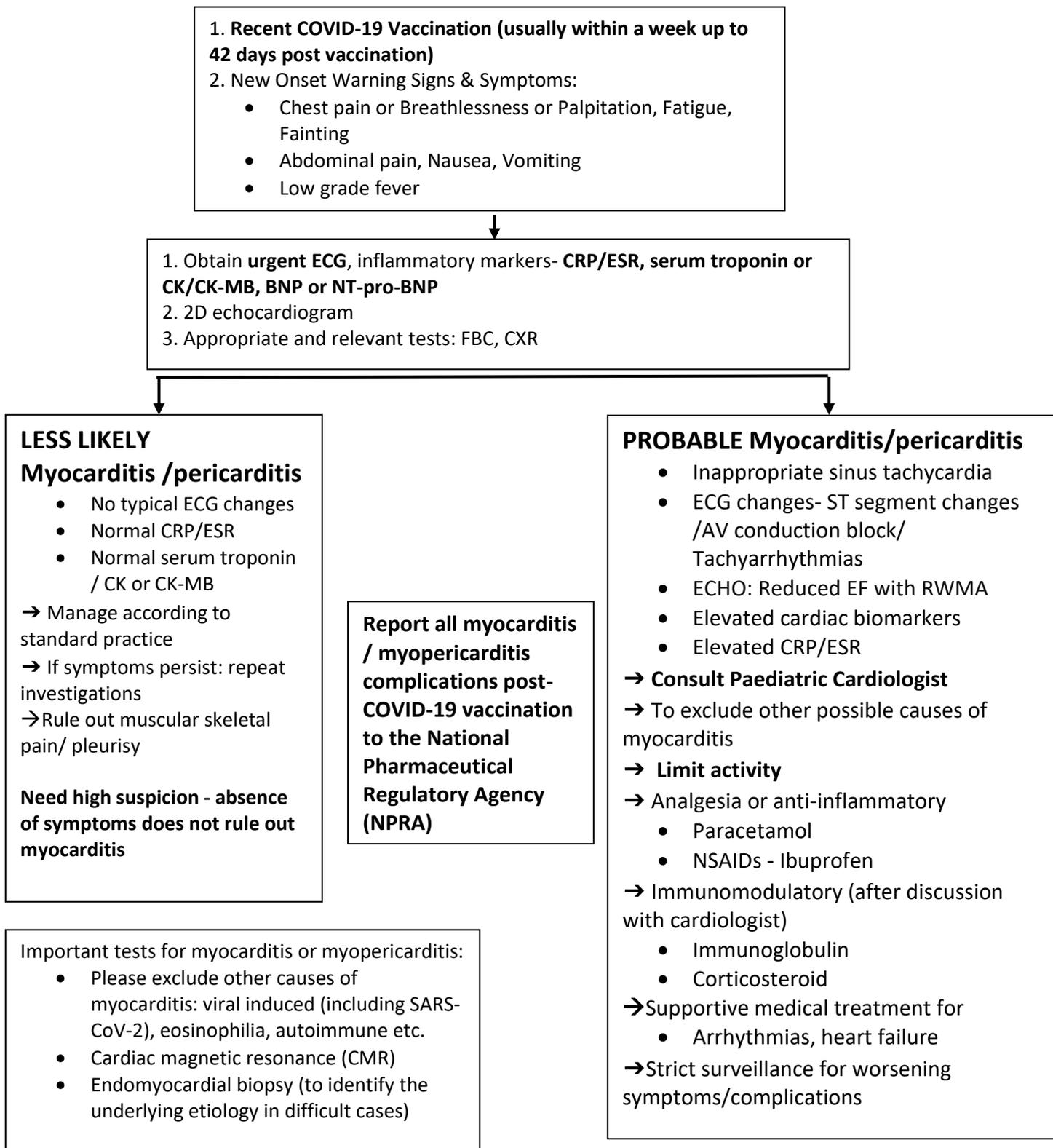
International recommendation – delay the vaccination until absolute neutrophil count (ANC) recovers. In patients with limited marrow recovery, it is recommended to give the vaccine at any time once vaccine is available to them. Therefore, this is at the discretion of the resident haemato-oncologist with regards to the timing of the vaccination

Cancer patients who are towards completion or who have just completed treatment, it is probably best to give the vaccine at 3 months after the last chemotherapy.

Cancer patients who are on maintenance phase (less intensive chemotherapy) eg: Acute Lymphoblastic Leukemia (ALL) patients, the vaccine can be considered to be given during this period.

- 3) Chronic Myeloid Leukemia (CML) on tyroxine kinase inhibitors can receive the vaccine at any time.
- 4) Patients with autoimmune disease eg : AIHA, ALPS on immunosuppressive therapy such as steroid, MMF or Sirolimus, can receive the vaccine at any time.
- 5) Patients with autoimmune disease who received monoclonal antibody eg: rituximab, the vaccine should be deferred for 6 months.
- 6) Patients with Severe Aplastic Anaemia (SAA) who received Anti-Thymocyte Globulin (ATG), vaccination should be deferred for 6 months.
- 7) The committee also recommend vaccination of the carers who are eligible for the vaccines for optimum protection.

Annex 3 Diagnosis and Management Algorithm for Myocarditis / Myopericarditis following COVID-19 Vaccination in Children and Adolescents



ECG: electrocardiogram, BNP: Brain natriuretic peptide, NT-pro-BNP: N-terminal pro-brain natriuretic peptide, NSAIDs: non-steroidal anti-inflammatory drugs, ANA: antinuclear antibody, COROS: Coronary Study, EF: Ejection fraction, RWMA: Regional wall motion abnormalities, AV: atrioventricular.