CLINICAL GUIDELINES ON COVID-19 VACCINATION FOR ADOLESCENTS (12-17 YEARS) IN MALAYSIA

Ministry of Health, Malaysia

Version 1.0

July 2021

Clinical Guideline on COVID-19 Vaccination for Adolescents (12 – 17 years)

1. Background

This guideline is based on review of available published literature and international guidelines on COVID-19 vaccination in adolescents age 12-17 years. At the time of writing, COVID-19 vaccine is not licensed for use in children below 12 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 30th June 2021, 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

- Adolescents with underlying medical conditions are at an increased risk for severe COVID-19 and should be prioritised to receive COVID-19 vaccine.
- Adolescents with no underlying medical conditions are still at risk for severe COVID-19, although the risk is lower. They may be offered COVID-19 vaccination. The timing of vaccination shall follow the national COVID-19 immunisation program schedule taking into consideration existing vaccine priorities in the country.
- At this time, Comirnaty (Pfizer-BioNTech) is the only approved COVID-19 vaccine in adolescents 12-17 years old. Two standard doses of the vaccine (30mcg) should be given at least 21 days apart.
- Prophylactic oral analgesics or antipyretics, such as paracetamol or ibuprofen, should not be routinely used before or at the time of vaccination, but may be considered for the management of pain or fever after vaccination.

3. Introduction

Children and adolescents have, so far, been relatively spared from the full brunt of the COVID-19 pandemic. Data from large epidemiological studies worldwide showed they were infected less commonly than adults.[1-6] Most of the children and adolescents that were infected, had no or mild, self-limiting symptoms. However, some children and adolescents have severe disease and a few have died. Many of them have underlying chronic medical conditions that predispose them to severe illness and are more likely to develop complications arising from COVID-19.[7]

In addition, children and adolescents with 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 features 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.[8-10]

Epidemiological data from the earlier part of the COVID-19 pandemic showed that children and adolescents constituted on average less than 10% of the total number of cases. More recently, the proportion of children and adolescents reported to have COVID-19 has increased.[11] Similar trend is seen in Malaysia with recent data from CPRC showing children < 18 years comprised of 15.3% of total cases, an increase from less than 10% at the end of 2020.[12] Several factors possibly contributed to the increase including more testing being done in children, and more worryingly, the spread of new, more infective variants of the virus.

Children and adolescents also suffer significantly from the indirect impact of COVID-19 pandemic. The pandemic has tremendously disrupted family and social life, interrupted schooling and education as well as social development of the children and adolescents; the impact of which may not be fully reversed.

4. Priority Groups for COVID-19 Vaccination

Although the data is still limited, children with underlying medical conditions are at a greater risk for severe COVID-19 including hospitalisation, ICU admission and death. A wide spectrum of underlying medical conditions associated with severe COVID-19 have been reported in the published literature including chronic respiratory diseases, cardiovascular diseases, hypertension, immunosuppression, diabetes mellitus, chronic kidney diseases, neurological conditions and obesity.[13-21] Due to the increase risk of severe COVID-19, this category of children and adolescents should be prioritised to receive COVID-19 vaccination as soon as possible. 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 and Adolescents (12-17 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***	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 ≥ 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 Appendix 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	**Severe mental illness**	Schizophrenia or bipolar disorder, or any mental illness that causes severe functional impairment.
14	**Adolescents in long-stay nursing and residential care settings**	Many adolescents 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. Younger residents in care homes for the elderly will be at high risk of exposure, and although they may be at lower risk of mortality than older residents should not be excluded from vaccination programmes.
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).
2	**Carers**	Those who are the sole or primary carer of a disabled person who is at increased risk of COVID-19 related mortality.

Adapted from Public Health England. Immunisation against Infectious Disease (Green Book). Chapter 14A COVID-19 - SARS-CoV-2 [22]

* Please refer to Appendix 1 for the optimal timing for COVID-19 vaccination in haemato-oncology patients.

5. COVID-19 Vaccines for Adolescents

Currently in Malaysia, only Pfizer-BioNTech COVID-19 vaccine is approved for use in adolescents 12 years and older. It is an mRNA vaccine that targets the spike proteins on the surface of the SARS-CoV-2.

Efficacy, immunogenicity, and safety of the Pfizer-BioNTech COVID-19 vaccine have been reported in a large randomised control trial of individuals aged 16 years and older.[23] Data

from a smaller study of children and adolescents aged 12 to 15 years showed excellent vaccine efficacy (100%) and neutralising antibodies which were considered non-inferior to individuals of 16 to 25 years old. Neutralizing antibody levels were significantly higher than those observed in the 16- to 25-year-old group.

The vaccine was well tolerated in adolescents 12 to 15 years of age, with reactogenicity similar to that reported in individuals age 16 to 25 years. Local and systemic reactogenicity were mostly mild to moderate in severity and usually resolved in 1-2 days. Pain at injection site was the most common local reaction reported while fatigue, headache, chills, muscle pain, fever, and joint pain were the most common systemic reactions. There were no serious adverse events related to the vaccine and no deaths were reported.[24]

6. Contraindications and precautions

6.1 Allergy

Pfizer-BioNTech COVID-19 vaccine is contraindicated in individuals who have had an allergic reaction to a previous dose of the vaccine or to any of its components. The vaccine is also contraindicated in a person with a history of anaphylaxis which include severe angioedema, bronchospasm and/or hypotension, to other drugs, vaccines, food, insect stings, or unknown trigger (idiopathic). Please refer to the relevant section (Contraindication to COVID-19 vaccination) in the Clinical Guidelines for COVID Vaccination in Malaysia for further details.[25]

6.2 Acute illness

Vaccination of adolescents 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.[25]

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 adolescent defaulting subsequent appointment for vaccination is high), coadministration of routine childhood/adolescent vaccine and COVID-19 vaccine is allowed. If multiple vaccines are given at a single visit, give each injection in a different injection site. This advice may change as data become available.[25-28]

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.[26]

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 adolescents with co-morbidities will require PVA. In general, adolescents that require PVA include:

1. Immunocompromised individuals (e.g. adolescents with diseases or on medications that suppress their immune system)
2. Adolescents with increased bleeding tendency (e.g. haemophilia, ITP, or on anticoagulants)
3. Adolescents with history of severe allergy (e.g. anaphylaxis)

For further details, please refer to the section on Pre-vaccination Assessment in the national guidelines.[25]

8. Administration

Pfizer-BioNTech COVID-19 vaccine is administered by IM injection into the deltoid muscle, or alternatively, the anterolateral thigh. Each dose is 0.3 mL and contains 30 mcg of SARS-CoV-2 spike protein mRNA.

9. Consent

Information regarding the vaccine's efficacy, safety and possible adverse reactions should be clearly explained to the adolescents 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 adolescents.

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. 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 should follow the standard procedure as outlined in the main section of the national guidelines.[25]

Recently, there have been rare reports of cases of myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines in several countries. 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. Follow up is ongoing. At this moment, it is not known whether there is a causal relationship with receipt of the vaccine.[29-32]

Healthcare providers should consider myocarditis and pericarditis in adolescents presenting with acute chest pain, shortness of breath, or palpitations, and ask about prior COVID-19 vaccination if these symptoms are encountered. All cases of myocarditis and pericarditis post-COVID-19 vaccination should be reported promptly to MOH. Algorithm on diagnosis and management of these adolescents are as shown in Appendix 3.

References

1. Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. JAMA. 2020;323(13):1239.
2. Docherty AB, Harrison EM, Green CA, Hardwick HE, Pius R, Norman L, et al. Features of 20 133 UK patients in hospital with covid-19 using the ISARIC WHO Clinical Characterisation Protocol: prospective observational cohort study. BMJ. 2020;369:m1985. Epub 2020 May 22.
3. Stokes EK, Zambrano LD, Anderson KN, Marder EP, Raz KM, El Burai Felix S, et al. Coronavirus Disease 2019 Case Surveillance - United States, January 22-May 30, 2020. MMWR Morb Mortal Wkly Rep. 2020;69(24):759. Epub 2020 Jun 19.
4. Dong Y, Mo X, Hu Y, Qi X, Jiang F, Jiang Z, Tong S. Epidemiology of COVID-19 Among Children in China. Pediatrics. 2020;145(6) Epub 2020 Mar 16.
5. CDC COVID-19 Response Team. Coronavirus Disease 2019 in Children - United States, February 12-April 2, 2020. MMWR Morb Mortal Wkly Rep. 2020;69(14):422. Epub 2020 Apr 10.
6. Viner RM, Mytton OT, Bonell C, Melendez-Torres GJ, Ward J, Hudson L, et al. Susceptibility to SARS-CoV-2 Infection Among Children and Adolescents Compared With Adults: A Systematic Review and Meta-analysis. JAMA Pediatr. 2021;175(2):143.
7. Bixler D, Miller AD, Mattison CP, Taylor B, Komatsu K, Peterson Pompa X, et al. SARS-CoV-2-Associated Deaths Among Persons Aged<21 Years - United States, February 12-July 31, 2020. MMWR Morb Mortal Wkly Rep. 2020;69(37):1324. Epub 2020 Sep 18.
8. Riphagen S, Gomez X, Gonzalez-Martinez C, Wilkinson N, Theocharis P. Hyperinflammatory shock in children during COVID-19 pandemic. Lancet. 2020;395(10237):1607. Epub 2020 May 7.
9. Whittaker E, Bamford A, Kenny J, Kaforou M, Jones CE, Shah P, et al. Clinical Characteristics of 58 Children With a Pediatric Inflammatory Multisystem Syndrome Temporally Associated With SARS-CoV-2. JAMA. 2020;324(3):259.
10. Feldstein LR, Rose EB, Horwitz SM, Collins JP, Newhams MM, Son MBF, et al. Multisystem Inflammatory Syndrome in U.S. Children and Adolescents. N Engl J Med. 2020;383(4):334. Epub 2020 Jun 29.
11. Leidman E, Duca LM, Omura JD, Proia K, Stephens JW, Sauber-Schatz EK. COVID-19 Trends Among Persons Aged 0-24 Years - United States, March 1-December 12, 2020. MMWR Morb Mortal Wkly Rep. 2021;70(3):88. Epub 2021 Jan 22.
12. CPRC, MOH. Infographics 28 April 2021.
13. Williams N, Radia T, Harman K, Agrawal P, Cook J, Gupta A. COVID-19 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in children and adolescents: a systematic review of critically unwell children and the association with underlying comorbidities. Eur J Pediatr. 2021;180(3):689. Epub 2020 Sep 10
14. Graff K, Smith C, Silviera L, Jung S, Curran-Hays S, et al. Risk Factors for Severe COVID-19 in Children. Pediatr Infect Dis J 2021;40:e137–e145

15. Tsabouri S, Makis A, Kosmeri C, Siomou E. Risk Factors for Severity in Children with Coronavirus Disease 2019: A Comprehensive Literature Review. Pediatr Clin N Am 68 (2021) 321–338
16. Shekerdemian LS, Mahmood NR, Wolfe KK, et al. Characteristics and outcomes of children with coronavirus disease 2019 (COVID-19) infection admitted to US and Canadian pediatric intensive care units. JAMA Pediatr. 2020;174:868–873.
17. Zachariah P, Johnson CL, Halabi KC, et al. Epidemiology, clinical features, and disease severity in patients with coronavirus disease 2019 (COVID- 19) in a Children's Hospital in New York City, New York. JAMA Pediatr. 2020;174:e202430
18. DeBiasi RL, Song X, Delaney M, et al. Severe COVID-19 in children and young adults in the Washington, DC Metropolitan Region. J Pediatr. 2020;223:199–203.e1.
19. Götzinger F, Santiago-García B, Noguera-Julián A, Lanaspa M, Lancella L, Calò Carducci FI, et al. COVID-19 in children and adolescents in Europe: a multinational, multicentre cohort study. Lancet Child Adolesc Health. 2020 Sep;4(9):653-661.
20. Leon-Abarca JA. Obesity and immunodeficiencies are the main pre-existing conditions associated with mild to moderate COVID-19 in children. Pediatr Obes. 2020 Dec;15(12):e12713.
21. Tsankov BK, Allaire J, Irvine MA, Lopez AA, Sauvé LJ, Vallance BA, Jacobson K. Severe COVID-19 Infection and Pediatric Comorbidities: A Systematic Review and Meta-Analysis. Int J Infect Dis. 2021 Feb; 103: 246–256.
22. Public Health England. Immunisation against Infectious Disease. Green Book. Chapter 14A COVID-19 - SARS-CoV-2. 7 May 2021.
23. Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med 2020;383(27):2603-2615.
24. Frenck RW Jr, Klein NP, Kitchin N, Gurtman A, Absalon J, Lockhart S, et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. N Engl J Med. 2021 May 27:NEJMoa2107456.
25. Clinical Guidelines on COVID-19 Vaccination in Malaysia. 3rd Edition. Ministry of Health, Malaysia.
26. Moore DL. Canadian Paediatric Society Position Statement. COVID-19 vaccine for children. (https://www.cps.ca/) 21 May 2021.
27. Committee on Infectious Diseases. COVID-19 vaccines in children and adolescents. Pediatrics 2021; doi:10.1542/peds.2021-052336.
28. CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html. Accessed 21 June 2021.
29. Abu Mouch S, Roguin A, Hellou E, Ishai A, Shoshan U, Mahamid L, et al. Myocarditis following COVID-19 mRNA vaccination. Vaccine 2021;39:3790-3.
30. Marshall M, Ferguson ID, Lewis P, et al. Symptomatic acute myocarditis in seven adolescents following Pfizer-BioNTech COVID- 19 vaccination. Pediatrics. 2021 1; doi: 10.1542/peds.2021-052478

31. CDC. Myocarditis and Pericarditis Considerations. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html. Accessed on 23 June 2021.
32. CDC. Selected Adverse Events Reported after COVID-19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html. Accessed on 30 June 2021.

Appendix 1

PAEDIATRIC HAEMATO-ONCOLOGY PRIORITY GROUPS FOR COVID-19 VACCINATION

1. HSCT – patients who are planned for HSCT e.g.: 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.

Appendix 2

BODY MASS INDEX CHART FOR BOYS 2 TO 20 YEARS

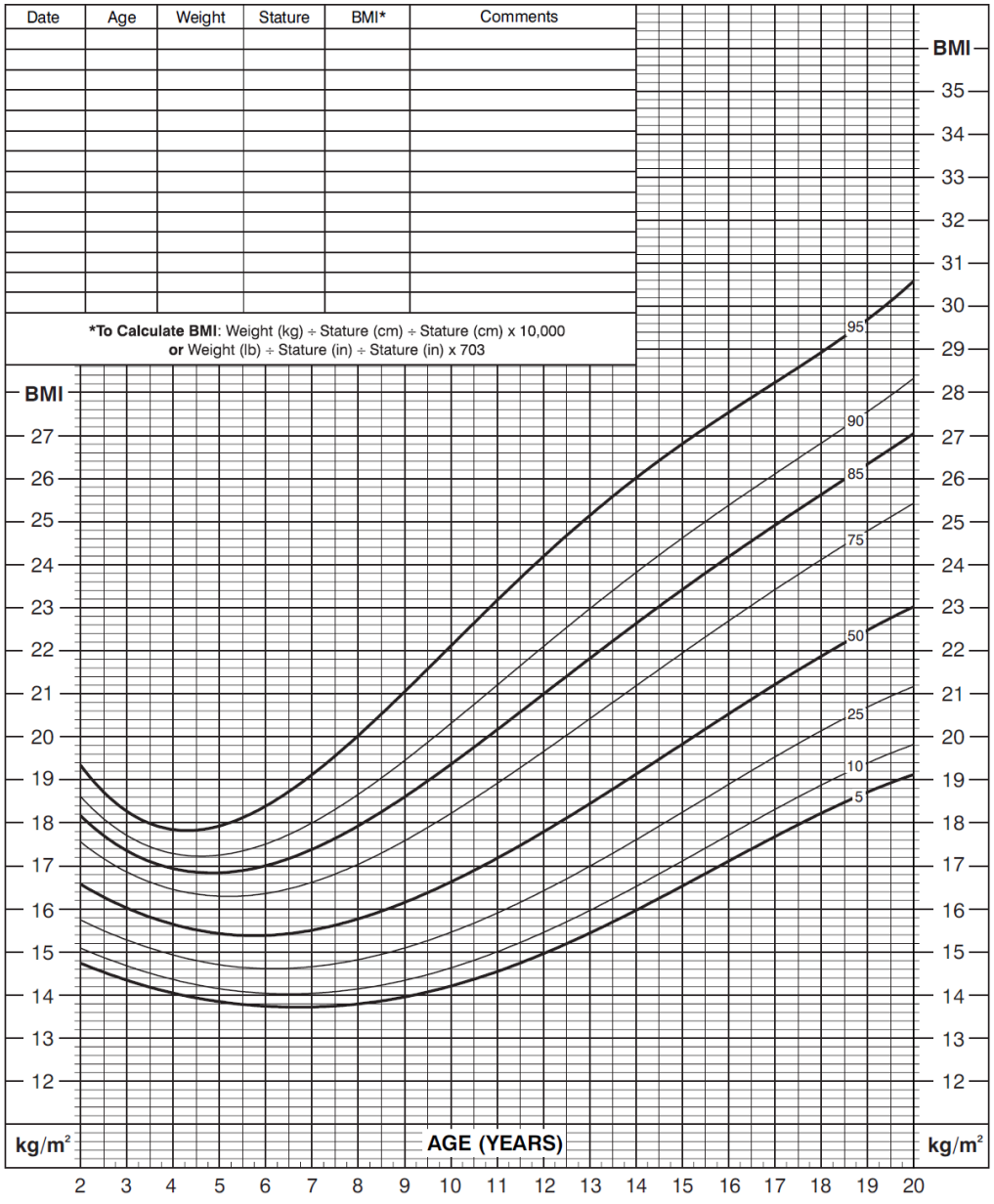
2 to 20 years: Boys
Body mass index-for-age percentiles

NAME _____

RECORD # _____

Date	Age	Weight	Stature	BMI*	Comments

***To Calculate BMI**: Weight (kg) ÷ Stature (cm) ÷ Stature (cm) x 10,000
or Weight (lb) ÷ Stature (in) ÷ Stature (in) x 703



Published May 30, 2000 (modified 10/16/00).
SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).
http://www.cdc.gov/growthcharts

SAFER · HEALTHIER · PEOPLE™

BODY MASS INDEX CHART FOR GIRLS 2 TO 20 YEARS

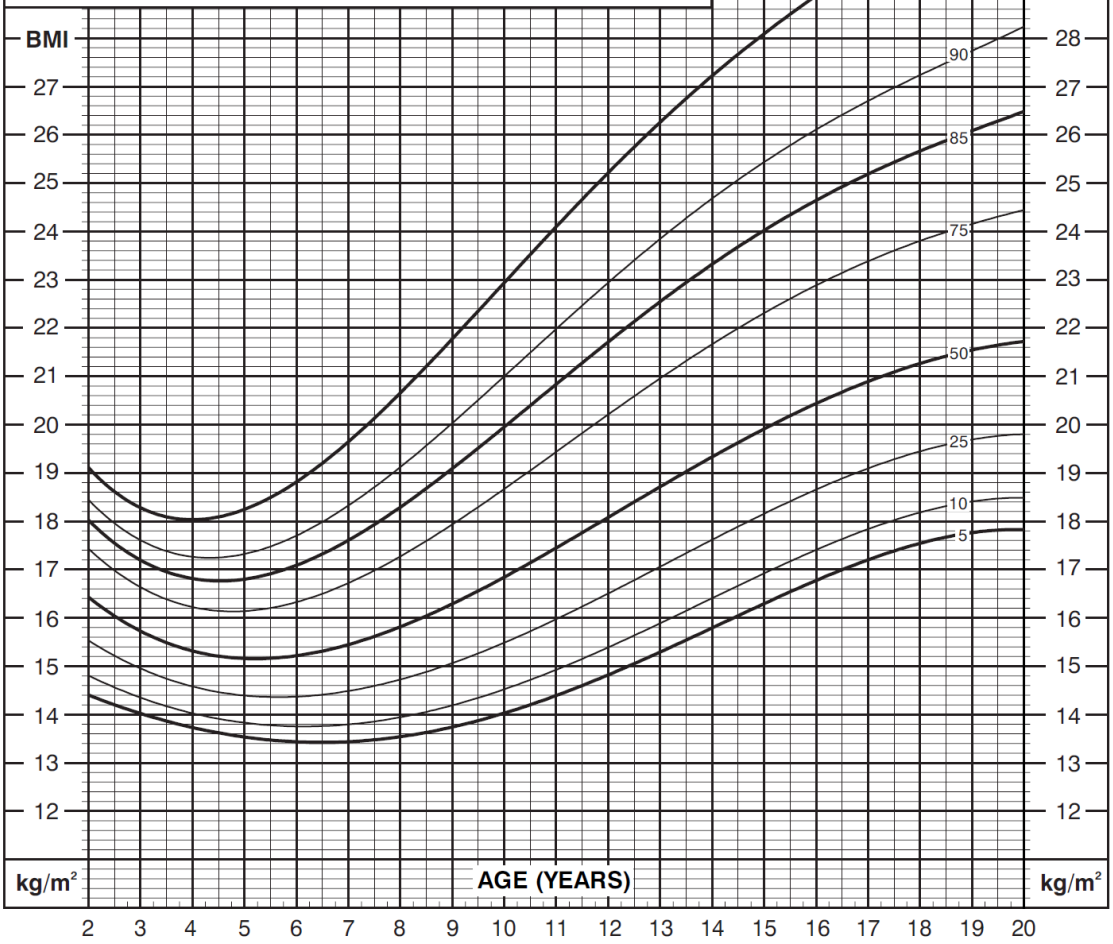
2 to 20 years: Girls
Body mass index-for-age percentiles

NAME _____

RECORD # _____

Date	Age	Weight	Stature	BMI*	Comments

***To Calculate BMI**: Weight (kg) ÷ Stature (cm) ÷ Stature (cm) x 10,000
or Weight (lb) ÷ Stature (in) ÷ Stature (in) x 703



Published May 30, 2000 (modified 10/16/00).
SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).
http://www.cdc.gov/growthcharts

CDC
SAFER • HEALTHIER • PEOPLE™

SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000). http://www.cdc.gov/growthcharts

Appendix 3

DIAGNOSIS AND MANAGEMENT ALGORITHM FOR MYOCARDITIS / MYOPERICARDITIS FOLLOWING COVID-19 VACCINATION IN CHILDREN AND ADOLESCENTS

1. **Recent COVID-19 Vaccination (usually within a week)**
2. New Onset Warning Signs & Symptoms:
   - Chest pain or Breathlessness or Palpitation, Fatigue, Fainting
   - Abdominal pain, Nausea, Vomiting
   - Low grade fever
   - Or a combination of symptoms
   - or combination of these symptoms

↓

1. Obtain **urgent ECG**, inflammatory markers- **CRP/ESR, serum troponin or CK/CK-MB, BNP or NT-pro-BNP**
2. 2D echocardiogram
3. Appropriate and relevant tests: FBC, CXR

↓

LESS LIKELY Myocarditis /pericarditis

- No typical ECG changes
- Normal CRP/ESR
- Normal serum troponin / CK or CK-MB

➔ Manage according to standard practice

➔ If symptoms persist: repeat investigations

→Rule out muscular skeletal pain/ pleurisy

Need high suspicion - absence of symptoms does not rule out myocarditis

Report all myocarditis or myopericarditis complications post-COVID-19 vaccination to the National Pharmaceutical Regulatory Agency (NPRA)

PROBABLE Myocarditis/pericarditis

- Inappropriate sinus tachycardia
- ECG changes- ST segment changes /AV conduction block/ Tachyarrhythmias
- ECHO: Reduced EF with RWMA
- Elevated cardiac biomarkers
- Elevated CRP/ESR

➔ **Consult Paediatric Cardiologist**

➔ To exclude other possible causes of myocarditis

➔ Limit **activity**

➔ Analgesia or anti-inflammatory
- Paracetamol
- NSAIDs

➔ Immunomodulatory
- Immunoglobulin
- Corticosteroid

→Supportive medical treatment for
- Arrhythmias, heart failure

➔Strict surveillance for worsening symptoms/complications

Important tests for myocarditis or myopericarditis:
- Please exclude other causes of myocarditis: viral induced (including SARS-CoV-2), eosinophilia, autoimmune etc.
- Cardiac magnetic resonance (CMR)
- Endomyocardial biopsy (to identify the underlying etiology in difficult cases)

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 .ST: