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சுகாதார அமைச்சு
Ministry of Health

මගේ අංකය)EPID/400/n-CoV/Vaccine
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Date) 22/09/2021

DDG/NHSL
Provincial Directors of Health Services : Western Province, North Western, North Central
Regional Directors of Health Service : Colombo, Kalutara, Gampaha, Kurunegala, Anuradhapura
Directors/ Teaching, Provincial General, General, Base hospitals-Western Province
Directors/ Teaching hospitals Kurunegala, Kuliyapitiya, Anuradhapura and Base hospitals Nikaweratiya, Dambadeniya, Galgamuwa, Thambuththegama

COMIRNATY : Covid 19 mRNA Vaccine (Nucleoside modified -Pfizer BNT) vaccination campaign for Children aged 12 -19 years with specified comorbid conditions

COMIRNATY Covid 19 mRNA (Nucleoside modified-Pfizer BNT) vaccine implementation will commence from 24/09/2021 in selected districts for children with specified comorbid conditions, aged 12-19 years.

The Ministry of Health has taken the decision to vaccinate children aged 12-19 years with underlying specified comorbid conditions against COVID-19. The vaccine which recommends to vaccinate these children is COMIRNATY, Covid 19 mRNA Vaccine (Nucleoside modified-Pfizer BNT).

The procedure to be followed are as follows:

- An in-charge Paediatrician / Physician needs to be identified for the vaccination centre by the hospital Director to endorse the eligibility of vaccination and closely monitor the vaccination process.
- Children with underlying medical conditions (specified comorbid conditions) recommended by Consultant Paediatricians/ Physicians should be considered for the vaccination.
- All Consultant Paediatricians, Physicians and Consultants in other relevant specialities are advised to make a list of children aged 12 to 19 years under their care with underlying specified comorbid conditions (government and private) to send for required vaccination to the nearest hospital where Covid-19 vaccination centre for children is functioning in the district (Annexure 1).
    - This list of the children should include child's name, age, underlying predominant comorbid condition/s, and contact number of the parent/guardian.
- Regional Epidemiologists, MO/MCH, MOOH and all field level public health staff are advised to refer eligible children with specified comorbid conditions under treatment (already under specialist care) and / or specified comorbid children in child disability homes and probational institutions in their respective areas to the nearest Covid-19 vaccination centre for children in a hospital for the vaccination (in the attached list in Annexure 1).

- As the initial step, the Covid-19 vaccination campaign for children will be started in the selected districts of Colombo, Kalutara, Gampaha, Kurunegala and Anuradhapura. A stepwise scaling up to other provinces/districts will be done in due course.
- Specified comorbid conditions which are having significant high risks for complications and mortality by Covid-19 disease are identified and recommended by Paediatricians and Physicians for the vaccination. These specified conditions are given below for the Covid-19 vaccination for children.

Indications with underlying health conditions for vaccination against COVID-19 with COMIRNATY Covid 19 mRNA (Nucleoside modified – Pfizer BNT) vaccine for children aged 12 -19 years:

1. Primary immune deficiency disorders
2. Acquired immune suppression due to disease or treatment:
   - Haematological malignancies, including leukaemia and lymphoma
   - Any other malignancy on radiotherapy or chemotherapy
   - On biological therapy
   - On high or moderate doses of corticosteroids
   - On any other immune modulating or suppressant drug like methotrexate, azathioprine, MMF, tacrolimus, cyclophosphamide
   - Any transplant recipient
   - Any condition which requires a long-term immunosuppressive treatments
3. Haematological conditions or other causes leading to asplenia or splenic dysfunction:
   - Thalassemia major and intermedius,
   - Hereditary spherocytosis
   - Sickle cell disease
   - Any other haematological diseases requiring long term treatment, other than Iron deficiency anaemia
4. Endocrine disorders:
   - Diabetes mellitus
   - Addison's disease
   - Congenital Adrenal Hyperplasia
   - Hypopituitary syndrome
   - Other significant hormonal dysfunction
5. Chronic neuro-disability:
   - Cerebral palsy
   - Autism
   - Epilepsy,
   - Neuro-degenerative diseases
   - Neuro-muscular disorders
6. Congenital genetic syndromes with any chronic disability or disorder and learning disabilities
   - Down syndrome
   - Severe or profound and multiple learning disabilities due to any aetiology
7. Any other significant genetic and/or metabolic abnormalities that affect a number of systems
8. Chronic heart disorders
   - Unrepaired congenital heart diseases
   - Repaired heart diseases with significant residual diseases or shunts
   - Haemodynamically significant acquired heart diseases
   - Chronic hypertension
9. Chronic respiratory disorders
   - Poorly controlled asthma which requires long term oral steroids or a history of severe asthma which required an ICU care
   - Cystic fibrosis
   - Bronchopulmonary dysplasia

- Interstitial lung diseases
- Significant bronchiectasis due to any aetiology
- Pulmonary hypertension

10. Chronic diseases involving Genito -Urinary tract
    - Chronic kidney diseases due to any cause
    - Nephrotic syndrome on regular follow up
    - On treatment for glomerulonephritis
    - Any other chronic condition involving Genito-Urinary tract
11. Chronic diseases involving Gastrointestinal tract
    - Chronic liver cell diseases due to any cause
    - Chronic gastrointestinal disorders including inflammatory bowel disease
    - Malabsorption syndrome
12. Chronic Rheumatological diseases
    - Presence of active connective tissue diseases
    - Presently being on long term prophylaxis rheumatic fever
    - Any other rheumatological or surgical condition with disability, requiring long term treatment
13. Being on long term treatment for chronic psychiatric diseases
14. Any other child with significant comorbid condition as recommended by the treating Consultant in relevant speciality and endorsed by the Paediatrician and Physician in the vaccination centre.

- The list of hospitals expected to conduct vaccination centres at the initial phase is attached herewith as **Annexure 1**
- Advise strictly adhere only to given comorbid conditions in this phase. These recommendations are given based on the risks of developing severe COVID-19 complications clearly outweigh the potential adverse events of the vaccine (AEFI) in this group.
- Directors in hospital are advised to make vaccine estimates in advance based on the recommendations of relevant Consultants in the hospital.
- It is advised to request minimum required vaccine stocks with the plan to get down additional stocks as with the requirement.
- Vaccine request needs to be forwarded to the Epidemiology Unit with a copy to Regional Epidemiologist in respective districts.
- The vaccines taken out from the Ultra-Low Temperature (ULT) freezer (from -70^{0}C) will not be able to re-freeze in ULT freezer.
- Vaccines supplied to the hospital should be stored only in the 2^0-8^{0}C in the Ice Lined Refrigerator (ILR) adhering to the national vaccine storage guidelines issued by the Epidemiology Unit. Even though hospital has ULT freezer (-70^{0}C) , Comirnaty-Pfizer vaccine should not be stored at ULT freezer as it is transported in 2^0-8^{0}C.
- Advised strictly to follow the COMIRNATY, Covid 19 mRNA (Nucleoside modified -Pfizer BNT) vaccination guidelines issued on 05/07/2021 by the Epidemiology Unit, Ministry of Health (attached here with as **Annexure 2** and find in www.epid.gov.lk) for vaccine storage, vial preparation, administration, prepare, follow up and surveillance of Adverse Events Following Immunization(AEFI).
- Consent form for children is attached herewith and it needs to be completed and signed by the guardian before vaccination. (**Annexure 3**)
- Hospital Directors are advised to get all measures to minimize vaccine wastage and ensure all eligible children will get the vaccination as planned for the day.
- Each vial of COMIRNATY, Covid 19 mRNA (Nucleoside modified -Pfizer BNT) has 6 doses to vaccinate (follow the guidelines issued on 05/07/2021 by the Epidemiology Unit, Ministry of Health-Annexure 2.
- Need to maintain regular communications with the Consultant Epidemiologists at the Epidemiology Unit (Dr. Deepa Gamage 0777295158 and Dr Manjula Kariyawasm 0767187301) and Regional Epidemiologists in respective districts on the vaccination process

to receive required vaccine supply to ensure minimum wastage, storage and achieving maximum coverage of eligible children.

- Directors are responsible for the vaccination clinic organization with Consultant Paediatricians, Physicians and other relevant specialities:
  - Prevent unnecessary gathering in and outside the hospital and preferably an appointment system based on the planned lists, needs to be executed at hospital level.
  - Seating arrangements needs to be planned to prevent overcrowding.
  - More than one registration desks should be arranged for registration procedure to prevent standing time and queues. Comorbid children and their parents should not allow to stand in queues.
  - Identify vaccination in-charge focal point in the hospital, preferably a Consultant Paediatrician to get approval and advices for the vaccination
  - Need to deploy adequate trained and competent staff for vaccination (vaccine vial preparation and vaccination)
  - Identify vaccination data entry team in the hospital to enter vaccination data in to the vaccine tracker.

- The individual vaccination data should be entered in to the web based "Vaccine tracker" system.
  - National Identity Card (NIC) number to be entered to the vaccine tracker
    - If the child is 16 years of age and above and having a NIC
    - Those who are not having a NIC and below 16 years advised to enter the parent/guardian NIC and then enter the "C" to indicate the "child" and then order of the child in the family. (e.g. for the 2nd child in the family: 778260893V , C, 2)
- At the end of each day, total number vaccinated needs to be provided to the Epidemiology Unit, copying to Regional Epidemiologist in respective districts.

If you need any further clarification, please contact the Chief Epidemiologist of the Epidemiology Unit.

Thank you,

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Director General of Health Services
Ministry of Health
"Suwasiripaya"
385, Rev. Baddegama Wimalawansa Thero Mawatha,
Colombo 10.

Dr. Asela Gunawardena
Director General of Health Services

Cc:

i. Hon. Minister of Health
ii. Secretary, Ministry of Health
iii. Additional Secretary (Public Health Services)
iv. Deputy Director General (PHS) -1
v. Deputy Director General (MS)
vi. Chief Epidemiologist
vii. Director/MCH/FHB
viii. Presidents/ College of Paediatricians, Physicians, Internal Medicine
ix. Provincial and district CCPs
x. Regional Epidemiologists
xi. MOO/MCH

Annexure I

List of hospitals for COVID-19 vaccinations for children with specified comorbidities

District	Hospital
Kalutara	Pandura Base Hospital
	Horana Base Hospital
	Pimbura Base Hospital
	Kalutara District General Hospital
	Beruwala Base Hospital
Colombo	Colombo South Teaching Hospital, Kalubowila
	Maharagama Apeksha Hospital
	Lady Ridgeway Hospital (LRH)
	Infectious Disease Base Hospital (IDH)
	Mulleriyawa (Colombo East) Base Hospital
	Neville Fernando Hospital
	Sri Jayawardenepura Teaching Hospital
	Sri Lanka Military Hospital
	Police Hospital
	Navy Hospital, Welisara
	Kothalawala Defence Teaching Hospital
	Awissawella Base Hospital
	Homagama Base Hospital
Gampaha	Colombo North Teaching Hospital, Ragama
	Gampaha District General Hospital
	Negambo District General Hospital
	Wathupitiwala Base Hospital
	Mirigama Base Hospital
	Minuwangoda Base Hospital
	Kiribathgoda Base Hospital
Anuradhapura	Anuradhapura Teaching Hospital
Kurunegala	Kurunegala Teaching Hospital

Annexure II

Guidelines for Covid-19 Vaccine

COMIRNATY : Covid 19 mRNA Vaccine (Nucleoside modified)

(05/07/2021)

"COMIRNATY" is the "Pfizer-BioNTech COVID-19 Vaccine" (BNT162b2) for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older as recommended by the manufacturer .(https://www.comirnatyglobal.com/- select country as Sri Lanka).

(Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2-WHO, under Emergency Use Listing updated on 15 June 2021: Age intended to use updated as persons aged 12 years and above) https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1

Important information:

- "COMIRNATY" is a messenger RNA (mRNA) based vaccine against coronavirus disease 2019 (COVID-19). The mRNA instructs the cell to produce proteins of the S antigen (a piece of the spike protein unique to SARS-CoV-2) to stimulate an immune response.
- Efficacy shown in clinical trials in participants with or without evidence of prior infection with SARS-CoV-2 and who received the full series of vaccine (2 doses) was approximately 95% based on a median follow-up of two months.
- "COMIRNATY" is a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles), which needs to be dissolved using 0.9% normal saline.
- The vaccine can be given 16 years of age and older. The safety and efficacy of COMIRNATY in children and adolescents aged less than 16 years of age have not yet been established though limited data are available to date. (However, WHO interim recommendations updated in June 2021, recommend to use 12 years and above)
- It is currently recommended that the same product should be used for both doses if start the vaccination with COMIRNATY-Pfizer-BioNTech vaccine. (Heterologous (mix-and-match) studies are ongoing with regards to the interchangeability of this vaccine with other COVID-19 vaccines.)
- Preliminary results from a heterologous priming schedule where BNT162b2 (COMIRNATY) was given as the second dose following a first dose of ChAdOx1- S [recombinant] vaccine showed a slightly increased but acceptable reactogenicity with superior or similar immunogenicity results.
- WHO interim guidelines recommend the use of Pfizer –BioNTech COVID-19 vaccine as the 2nd dose for those who have received the 1st dose (priming dose) from COVISHIELD vaccine (ChAdOx1-S [recombinant] vaccine) in settings where the second dose for the ChAdOx1-S [recombinant] vaccine is not available due to vaccine supply constraints.
- COMIRNATY vaccine vials (received on 05/07/2021) is a muti-dose vial, after dissolved using the diluent, the vial contains 2.25 mL from which advised to withdraw 6 doses of 0.3 mL, using a low dead volume needle and syringes.
    - *The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.*

check web site : ~~epid~~
www.epid.gov.lk

- The vaccine is a frozen component required to be dissolved using the diluent 0.9% (9 mg/mL) sodium chloride
- Normal saline (preservative free) - 5 ml normal saline diluent vial can be used only 2 withdrawals to be used to dissolve 2 vaccine vials at one time, under strict aseptic conditions, to prepare 12 doses in 2 vials at one time. (This will minimize the wastage). However, normal saline 5 ml vial can be used for one vial preparation once 2 vials are not required to be dissolved.
    - Other normal saline containers are not advised to use for multiple withdraws for the dilution of the vaccine vials at one time.
- Same vaccine needs to be given as 0.3 mL, 2 doses, keeping 3-4 weeks interval between 2 doses (when the COMIRNATY is been given as the 1st dose).
- Advise to vaccinate intramuscularly preferably to the upper part of the deltoid muscle on the left side.
- There are no data available to date on the interchangeability of COMIRNATY with other COVID-19 vaccines to complete the vaccination course. Individuals who have received 1 dose of COMIRNATY is advised to receive a second dose of COMIRNATY to complete the vaccination course.
- One dose of 0.3 mL contains 30 micrograms of COVID-19 mRNA Vaccine, embedded in lipid nanoparticles and contain following excipients;
    - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
    - Cholesterol
    - Potassium chloride
    - Potassium dihydrogen phosphate
    - Sodium chloride
    - Disodium hydrogen phosphate dihydrate
    - Sucrose
    - Water for injections
- The "COMIRNATY" vaccine vials are stored at ultra-cold temperature of minus 90 °C to minus 60 °C (-90 °C to -60 °C) for 6 months.
- If unopened, not exposed to direct sunlight and handled carefully without exposing to thawing temperature, the vaccine is stable for 6 months (6 months shelf life).
- Vaccines stored at -90 °C to -60 °C, can be transported at -25 °C to -15 °C for a single period of up to 2 weeks and can be returned to -90 °C to -60 °C to re-store.
- The frozen multidose vial must be thawed prior to dilution.
- Frozen vials should be transferred to an environment of +2 °C to +8 °C to thaw; a 195 vial pack may take 3 hours to thaw before use.
- Alternatively, frozen vials may also be thawed for 30 minutes at room temperatures up to 30 °C for immediate use.
- The unopened vial can be stored for up to 1 month at +2 °C to +8 °C,
- Within the 1-month shelf-life at +2 °C to +8 °C, up to 12 hours may be used for transportation if need.
- The chemical and physical in-use stability has been demonstrated 6 hours at +2 °C to +30 °C after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection. In fact, diluted vial is not recommend to use after 6 hours.

Additional information : https://www.comirnatyglobal.com/ (select the country as Sri Lanka)

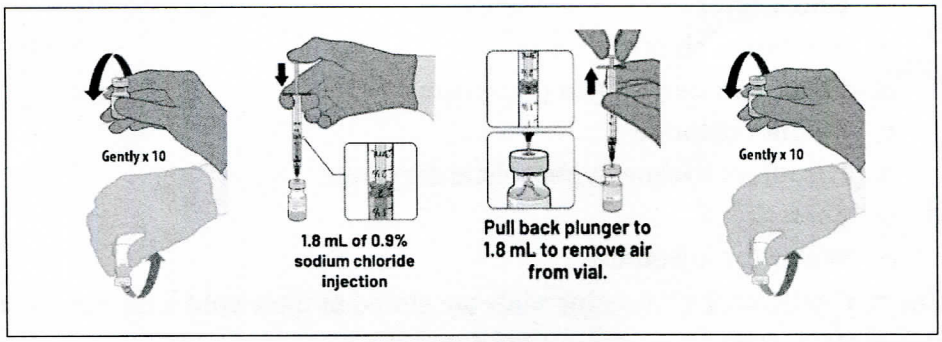
Product presentation:

Vaccine vial : Frozen, sterile, preservative-free, multi-dose concentrate for dilution before administration.

Diluent : 9% normal saline (preservative free)-5 ml vial presentation

Preparation of the vaccine vial for use: Vaccine vial dilution should be done by well-trained health care staff under the supervision of healthcare professional using aseptic technique to ensure the sterility and to ensure the correct composition of the prepared dispersion.

- The vaccine vial needs to be diluted with 0.9% normal saline before use.
- Before dilution, the thawed vaccine vial needs to be inverted gently 10 times, do not shake.
- Diluent syringe (mixing syringe) -recommend 2-3 ml syringe with a needle: 1.8 mL of diluent (0.9% normal saline), needs to draw into the mixing syringe.
- Add this amount of 1.8 mL of diluent (0.9% normal saline) into the vaccine vial; level and need to equalize the pressure in the vial before removing the needle by withdrawing 1.8 mL of air into the empty diluent syringe (mixing syringe).
- Discard diluent syringe in to the safety box (do not reuse)
- Same diluent normal saline 5 ml vial can be carefully used at the same time for a 2nd vial dilution (using a fresh needle and syringe) under careful aseptic conditions. Recommend to discard diluent vial after one time use for a single or 2 vial dilutions.
- Gently invert the vial with diluted vaccine 10 times to mix; do not shake.



- Inspect to make sure that the vaccine is an off-white uniform suspension; do not use if discoloured or if containing particles.
- Record, date and time of dilution on the vaccine vial label and it can be used for the maximum time of 6 hours after dilution.
- Vaccination syringe: 1 ml low dead volume syringe (and a needle) : Recommend to use 1 ml syringe with calibrations to draw 0.3 ml, using a 23 G needle with 24 mm in length.
- From a single vial, manufacturer recommend that 6 doses can be easily withdrawn by using low dead volume syringes and needles for vaccination.
- Draw up the vaccine dose at the time of administration, pre-loading of vaccines in syringes are not recommended.
- Use all vaccine doses in the diluted vaccine vial within 6 hours after dilution.
- After final dose withdrawal from the diluted vaccine vial, if any remaining vaccine solution of less than 0.3 ml in the vial, is not recommended to pool with other remaining doses from other vials for further vaccinations.

Target group:

1. Target groups to be vaccinated will be informed by the Ministry of Health as with the vaccine supply and considering the epidemiological assessment for the best impact for prevention of transmission and prevention of the mortality.
   This product can be used for people aged 16 years of age and above as with the manufacturer guidelines (WHO updated in June 2021 as 12 years and above), but the vaccination category and the age will be informed by the Epidemiology Unit, Ministry of Health after the final decision by the higher authorities of the Ministry of Health.

2. Recommend to use of Pfizer –BioNTech COVID-19 vaccine as the 2nd dose for those who have received the 1st dose (priming dose) from COVISHIELD vaccine (ChAdOx1-S [recombinant] vaccine) and missed the 2nd dose of ChAdOx1-S [recombinant] vaccine due to unavailability as with vaccine supply constraints.

   It is recommend to provide the 2nd dose from Pfizer–BioNTech COVID-19 vaccine at the first opportunity on completion of 8 weeks after the 1st dose or at any time without considering the default time duration in vaccine supply constraint situation.

   This provision of 2nd dose from Pfizer–BioNTech COVID-19 vaccine is recommended only in COVISHILD/ASTRAZENECA/ChAdOx1-S [recombinant] vaccine supply constraint situations.

Vaccine stock requirement:
Number of vaccine doses in a single vial, after accurate dilution and by using low dead volume syringes and needles, is informed as 6 doses (by the Manufacturer).

Method of Administration: The recommended administration is through intramuscular route (IM), preferably to the upper part of the left arm.

Active composition: excipients of the vaccine are given above.

Dosage schedule: recommend to vaccinate each of 0.3 ml per dose into the deltoid muscle (preferably left side), at 3 -4 weeks interval for the 2nd dose.
(as with the information to date : https://www.comirnatyglobal.com , COMIRNATY® (Tozinameran), COVID-19 mRNA vaccine (nucleoside modified) WHO updated information as of 10th May 2021).

Please note: 0.3 ml AD syringes are not available in the country at the moment and advised to use 1 ml low dead volume syringes and needle combination for intramuscular injection. The needle recommended is 23G x 24 mm in length. (Advise all precautions to be taken to minimize the contamination and vaccine wastage during handling of dilution and vaccination)

Storage

- Vaccine vials can be stored at +2^{0}C to +8^{0}C for a period of 1 month
  - After dilution with sodium chloride 9 mg/mL (0.9%) solution for injection (once opened the vial), it can be used only for 6 hours.

- If vials are kept un opened and kept at $+2^0$C to $+8^0$C and not exposed to room temperature, it can be re-store at ILR. But, strongly advise to take only required amount vaccines from the ILR during the vaccination session and should not expose unopen vials to room temperature.

- Advised to store vaccines preferably in Ice Lined Refrigerators with close monitoring of temperature using fridge tags (24 X 7). Careful temperature monitoring and early intervention is strongly advised.
- The frozen multidose vial must be thawed prior to dilution.
- Frozen vials should be transferred to an environment of +2 °C to +8 °C to thaw; a 195 vial pack may take 3 hours to thaw before use.
- Alternatively, frozen vials may also be thawed for 30 minutes at room temperatures up to 30 °C for immediate use.

Discard any unused vaccine 6 hours after dilution, or at the end of the immunization session, whichever comes first. Take maximum measures to optimally use the vaccine vial diluted to vaccinate 6 person at a time and advise to minimize vaccine wastage.

Indication to use: it can be given to adults over the age of 16 years (12 years as with updated June 2021 WHO recommendations).

The geographic areas and population category selection should be based on the decision taken by the Ministry of Health authorities and informed by the National Immunization Programme, Epidemiology Unit, Ministry of Health.

Indicated to use as the 2nd dose for those who have received COVISHILD/ASTRAZENECA/ChAdOx1-S [recombinant] vaccine as the 1st dose.

Contra indications

- Known history of a severe allergic reaction (e.g. anaphylaxis) to any component of COMIRNATY vaccine (components are mentioned above).
- In particular, COMIRNATY should not be administered to individuals with a known history of severe allergic reaction to polyethylene glycol (PEG) or related molecules.
- Persons with an immediate allergic reaction (e.g. anaphylaxis, urticaria, angioedema, respiratory distress) to the first dose of COMIRNATY should not receive additional doses.
- Immediate or delayed onset anaphylactic or severe allergic reaction to vaccines or injectable therapies, pharmaceutical products, food-items etc (unless proper risk benefit assessment done by an emergency care physicians or similar experts)

Special precautions: following conditions to be considered before intramuscular injection

- Should take caution in persons with a history of any bleeding or coagulation disorders (e.g. clotting factor deficiency, coagulopathy, platelet disorders). Need to get specialized opinion of the disease or understanding of the medical condition before vaccination.
- Chronic liver and kidney diseases, endocrine disorders (apparent thyroid function abnormalities and diabetes mellitus in decompensation stage), serious diseases of the hematopoietic system, epilepsy and other CNS diseases, acute coronary syndrome and acute cerebrovascular event, myocarditis, endocarditis, pericarditis (can be given with caution only if the treating clinician or a Consultant Physician/ emergency care Physician assessed the individual and recommended vaccinating under his/her care).

- Due to lack of data not indicated for persons with:
    - autoimmune diseases (stimulation of the immune system can lead to an exacerbation of the disease, special caution should be exercised with patients with an autoimmune disorder that tend to lead to severe and life-threatening conditions)
    - malignant neoplasms

  (decision to vaccinate for any person not indicated for vaccination or special precautions should be based on the proper risk-benefit assessment by the treating physician or by the recommendations of an expert from the relevant speciality under his/her guidance).

Temporary postponement of vaccination: following conditions are required temporary postponement of the vaccination (vaccination should be postponed for 4-8 weeks)

- Any signs and symptoms suggestive of acute SARS-CoV 2 infection or suffering from any other acute illness who are not fit for the vaccination.
- Already diagnosed SARS-CoV 2 patient who have received anti-CoV 2 monoclonal antibodies or convalescent plasma as a treatment option.

Following conditions are not contraindications for vaccination

- Persons with a past history of SARS-CoV 2 infection (by patient history, RT PCR positive report or sero positivity) : vaccination should be done irrespective of the previous COVID-19 disease conditions (COVID-19 confirmed cases can be vaccinated 2 weeks after the recovery)
- Co-morbidities such as hypertension; diabetes; asthma; and pulmonary, liver and kidney disease; as well as chronic (stable and controlled) infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV) and hepatitis B virus (HBV) are not contra indications and need to be vaccinated for better protection. However, immune response may be less in these patient categories.
- Lactation (at any time including post-partum period) : stop or delaying of breast feeding before or after vaccination is not required.
- The use of BNT162b2 vaccination in pregnant women has shown benefits outweighing the potential risks (as with updated WHO recommendations).
- In fact, to help pregnant women to get adequate benefits of the vaccination, it should be provided to get the likely benefits of vaccination during 2nd or 3rd trimester after 35 years or at any age for those who are with comorbidities during the 2nd or 3rd trimester.
- Take all precautions in contact with Consultant obstetricians, for any further decisions in identifying eligibility of pregnant women are needed.

Adverse events

- Mild local : tenderness or swelling in your arm at the injection site
- Short term general : feeling tired, headache, muscle pain, joint pain, diarrhoea, fever
- Rare: Itchiness in general, rash, swelling of the lymph nodes, sleeplessness, Bell's palsy (1 in 10,000)
- Serious allergic reactions and anaphylaxis can occur for any pharmaceutical product and need to take maximum precautions

Vaccine safety surveillance suggest close monitoring of ;

- Serious adverse events including myocarditis
- thromboembolic events, thrombosis with thrombocytopenia syndrome (TTS),
- anaphylaxis and other serious allergic reactions,
- Bell`s palsy, and transverse myelitis
- maternal and neonatal outcomes, and mortality in groups prioritized for vaccination

Advise to notify all events with possible association to vaccines and vaccination through the AEFI notification system, over the phone, email and fax to the Epidemiology Unit.

Other logistic requirements

- 1 ml syringes with needles (23 G needle with 24 mm in length) to vaccinate as the number equal to number of doses estimated to vaccinate and 3 ml syringes with needs to dilute as the number equal to vaccine vials required to be diluted.
- Adequate cotton swabs
- Sharp disposal safety boxes (1 standard box =10 L, can hold 100 syringes with needles)
    - Estimated number of AD syringes /100 = required number of safety boxes
- Emergency tray and portable oxygen cylinders with essential items in the emergency tray (to attend immediate Adverse Events Following Immunization (AEFI) as with National guidelines should be available in all immunization clinic centres).

Implementation of the vaccination and Immunization clinic functioning

- The campaign mode vaccination for 1st round and 2nd round of vaccination as with the identified categories and dates informed by the Epidemiology Unit, Ministry of Health as with the evolving requirement of the country for the best impact.
- Vaccinate as one dose campaign for the 2nd dose for those who have received the 1st dose of Covishield and not received the 2nd dose due to supply constraints.
- The vaccination data should be updated on the same day to the National Immunization Programme, Epidemiology Unit, Ministry of Health.
- Vaccine stock request from the RMSD needs to be done by using the Monthly Stock Return of Vaccine and Injection Safety Devices (Annexure 1)
- Vaccine stocks received to the institution are required to be entered into the existing Vaccine/drugs stock ledger in the institution and into the existing MOH office-Vaccine Movement Register (Blue colour book) (format: Annexure 2)
- Vaccine stock request to the clinic, should be based on the existing Clinic-Vaccine Movement Register (Yellow colour book) (format :Annexure 3)
- At the end of the clinic session, if any remaining vials (freeze, unthawed) returned from the clinic, needs to be stored separately in the recommended freezing temperature. (vaccines will be sent in freezer trucks and required return to the same truck to return to freezer rooms)
- At the end of the clinic session, Vaccine Movement Registers need to be balanced, and Immunization Clinic Returns need to be completed and sent to the Regional Epidemiologist (Annexure 8)
- After the 2nd dose of the campaign the Monthly Stock Return of Vaccine and Injection Safety Devices Vaccine Stock Return need to be completed to request required stocks (Annexure 1)

- Vaccine stocks should not keep in any of the institutional refrigerators after the campaign and should return to the freezer truck to store at freezer rooms.
- All clinic centres vaccinating is advised to ready in attending AEFI emergencies and be ready with "emergency tray" to attend any AEFI emergencies.
- Conducting immunization clinics can be done adhering to National guidelines of vaccination under the guidance and supervision by the immunization supervisory health teams from the RDHS/PDHS/ Epidemiology Unit / teams from the Ministry of Health.
- Vaccination clinics should function with adequate human resource to ensure smooth functioning of the clinic.
- Volunteer support can be obtained for services outside the clinic for crowd control, guiding for information and targeted advices for the vaccination in improving the campaign efficiency.
- Take measures to prevent unnecessary gatherings of the crowd in and around the vaccination clinic.
- All precautionary measures need to be taken by the vaccination teams and supporting individuals to the clinic during the clinic sessions in prevention of possible COVID-19 transmission.
- Clinic setting should arrange as 1) waiting area 2) eligibility screening with consent to vaccinate 3) registration and issuing the vaccination card 4) marking of a tally sheet, vaccination and next appointment date 5) AEFI observation area
- Clinic station arrangement should be organized in a way that minimum time wasting at different stations to get the maximum efficiency in the clinic
- Immunization Clinic registration format (Annexure 4) is provided and photocopied sheets of the format can be used for the registration or the printed register provided to identify eligible population can be used for the registration of the vaccination during the session.
- In addition to this, ensure proper registration data is entered into the Electronic web-based person information registration system developed by the Ministry of Health.
- All registration formats / Vaccination Registers should be duly filed in the institution for future review requirements, next dose reminders and if any other official requirements.
- The same Register / Register format used can be utilized for the 2nd dose vaccination or a fresh Register format can be used for the 2nd dose for the convenience. But, ask about the initial dose (1st dose) from the history (H) or check from the "Vaccination card" (C) to ensure completeness of the vaccination.
    - Mark a tick at the appropriate column for the 1st dose, if information is gathered from the Immunization card as "✓ / C" or if information is gathered from the history as "✓ / H".
- It is not advisable to interchange vaccination with different COVID-19 vaccine types (as with existing evidence so far).
    - Take measures to follow up the 2nd dose of the vaccination using the same vaccine product (component II).
- Consent form given in 3 languages should be signed at the most comfortable language for the consent to vaccination (Annexure 5)
- Previous COVID-19 positive and recovered patients should be vaccinated irrespective of the previous COVID-19 disease condition and can vaccinate 2 weeks after the recovery.
- In any doubtful cases for the eligibility, should contact a Consultant/Medical Officer in the hospital/ MOH in the area/ Regional Epidemiologist/Medical Officers-MCH/Provincial or District CCP/ Epidemiology Unit for an advice.

- Tally sheet developed for age group should be used (Annexure 6), in that age category, sex and health status should be properly completed and the summary should enter into the "e-NIP" for national administrative data and should be provided to the Epidemiology Unit/Regional Epidemiologist at the end of the day with the clinic return as required.
- After registering the person (electronic web based system-Immunization tracker- and paper based - Annexure 4) and take measures to issue a "COVID-19 vaccination card" – Annexure 7 (important to mention the name of the vaccine)
- Advice to write the vaccination card in English language in case if required for international use.
- The correct name of the vaccine needs to be entered correctly as 1st or the 2nd dose at appropriate cage. (mention as "Sputnik V").
- Advise to use 0.5ml AD syringes at all possible instances and carefully withdraw all solution in the single dose ampule.
- The vaccine dose of 0.5 ml IM to be given to the upper arm preferably on left side.
- After vaccination, they should be observed for a minimum of 20 minutes in the clinic for immediate AEFI.
- All vaccination procedure and vaccine management in general should be in accordance with the National guidelines given in the Immunization Handbook (3rd Edition), Epidemiology Unit, Ministry of Health.
- Vaccine safety in Immunization clinics should be maintained and managed according to the circular "Initial Management of Anaphylaxis at Field level" (circular number 01-20/2001, dated 23/08/2011) and National guidelines given in the Immunization Handbook (3rd Edition), Epidemiology Unit, Ministry of Health.
- Any reported AEFI identified at the clinic need to be entered in the Clinic / Hospital AEFI Register and inform to the Epidemiology Unit, Regional Epidemiologist and MOH in the area using AEFI form I (available as carbonated 3 copies in a book: format - Annexure 9). If any significant AEFI needs to be informed to the Regional Epidemiologist and to the Epidemiology Unit immediately over the phone.
- At the end of the clinic, compile all the vaccination data and
    - complete the Immunization clinic return (Annexure 8) in two copies and send one copy to the Regional Epidemiologist and keep one copy at the institution.
    - Tally sheet summary should enter into the "eNIP" web based electronic National Immunization Programme database, together with the target number expected to be vaccinated at the end of the clinic.
- Disposal of sharps in safety boxes and waste bins should be done preferably as incineration and according to the standard accepted practices applied in the routine Immunization clinics.
- All used vaccine vials should be incinerated.
- All vaccine stocks related data, vaccine wastage information and vaccination related data should submit to the Regional Epidemiologist in the provided Immunization clinic return (Annexure 8).

Annexure II

කොවිඩ් 19 - ෆයිසර් එන්නත මාගේ දරුවාට ලබා දීමට කැමැත්ත ප්‍රකාශ කිරීම.

මාගේ දරුවාගේ ..... රෝගී තත්වය සලකා බැලීමේදී, කොවිඩ් 19 - ෆයිසර් එන්නත ලබා ගැනීමෙන් කොවිඩ් 19 රෝගයෙන් සැලකිය යුතු ආරක්ෂාවක් සැලසෙන බව දැනගතිමි.

එසේම ඉතාමත් ම කලාතුරකින් එම ඒන්නතෙහි අතුරු ආබාධ ලෙස උග්‍ර ආසාත්මිකතාද, හෘදයේ පටක ඉදිදිමීමේ හැකියාවක් ද ඇති බව දැනගතිමි.

ඉහත කරුණු සලකා බලා, කොවිඩ් 19 - ෆයිසර් එන්නත මාගේ දරුවාට ලබා දීමට කැමැත්ත ප්‍රකාශ කරමි.

දරුවාගේ නම : .....

ලිපිනය :

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මව/පියා/භාරකරු : .....

ජා.හැ.ප.අංකය : .....

දිනය : __ __ / __ __ /_ __ __ _ අත්සන : .....

Covid-19 பைசர் தடுப்பூசியை எனது பிள்ளைக்கு வழங்குவதற்கு சம்மதம் தெரிவித்தல்

எனது பிள்ளையின் ..... நோய் நிலைமையை கருத்தில் கொள்ளும்போது Covid-19 பைசர் தடுப்பூசி வழங்குவதன் மூலம் Covid-19 தொற்றிலிருந்து குறிப்பிட்டத்தக்களவு பாதுகாப்பினை பெற முடியும் என்பதனை நான் அறிந்து கொண்டேன்.

மேலும் தடுப்பூசியின் அரிதான பக்க விளைவுகளாக ஓவ்வாமை மற்றும் இதயத்தின் அழற்சி தன்மை என்பன ஏற்படக்கூடும் என்பதையும் அறிந்துகொண்டேன்.

மேற்குறிப்பிட்ட விடயங்களை கருத்தில் கொண்டு covid-19 பைசர் தடுப்பூசியை எனது பிள்ளைக்கு வழங்குவதற்கு சம்மதம் தெரிவிக்கின்றேன்.

பிள்ளையின் பெயர் .....

விலாசம் .....

தாய்/தந்தை /பாதுகாவலர் .....

அடையாள அட்டை இலக்கம் .....

திகதி _ _/_ _/_ _ _ _ கையொப்பம் .....