

Guidelines for Covid-19 Vaccine
SARS-CoV-2 Vaccine (Vero Cell), Inactivated (BBIBP-CorV)
vaccination Campaign

Different types of COVID-19 vaccines which are scientifically proven to be effective and safe are introduced through the National Immunization Programme to get the maximum effect of preventing the COVID-19 transmission, severe morbidity and mortality in the country.

The Sinopharm, SARS-CoV-2 Vaccine (Vero Cell), BBIBP-CorV -COVID-19 vaccine is an inactivated vaccine made of virus particles grown in a culture and doesn't have disease-producing capability.

- This SARS-CoV-2 (Vero Cell), Inactivated vaccine is formulated with SARS-CoV-2 strain which is inoculated on the Vero cells for culturing. The virus is inactivated with β -proplotactone, concentration and purification were done and adsorbed with aluminium adjuvant to form the liquid vaccine.
- It is expected to develop antibodies against the SARS-CoV-2 after vaccination, to prevent the COVID-19 disease.
- The vaccine product is a semi-transparent turbid suspension with slight white colour. It can be layered due to precipitation, and the precipitation can be easily dispersed by shaking.
- The vaccine is stable in storage at 2^o-8^oC.

Target group:

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, morbidity and mortality.

This product can be used for people aged 18 years old and above, but the vaccination category and the age will be informed by the Epidemiology Unit, Ministry of Health considering the best impact of prevention of transmission, prevention of morbidity and mortality.

Vaccine stock requirement:

Number of vaccine doses and number vaccinated will be the same as the vaccine product available at present is the single dose vial presentation.

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

Active composition: vial contains 0.5mL of product for each administration by intramuscular Injection, in which each dose contains 6.5U of inactivated SARS-CoV-2 antigen.

Other excipients of the vaccine include, Disodium hydrogen phosphate, Sodium chloride, Sodium dihydrogen phosphate, Aluminium hydroxide.

Dosage schedule: recommend to vaccinate with 2 doses (each of 0.5 ml) into the deltoid muscle (left side), at 4 weeks interval with each dose of 0.5ml, intramuscular (consistent of 6.5U of inactivated SARS-CoV-2 antigen per dose).

If the administration of the second dose is delayed beyond the duration of 4 weeks, it should be administered at the earliest possible opportunity. (Requirement of any additional booster doses will be informed after the global recommendations with further evidence).

Storage

- SARS-CoV-2 Vaccine (Vero Cell), Inactivated (BBIBP-CorV) vaccine should be stored at +2⁰ C to +8⁰ C temperature at all levels at all the time.
- The vaccine is freeze sensitive and should not expose to freezing temperature at any time.
- The vaccine is heat sensitive and should protect from direct sunlight.
- During the clinic session, vaccine vials should be kept in the vaccine carrier until taking a vial out for the vaccination.

Adverse events that have been reported with the SARS-CoV-2 Vaccine (Vero Cell),

Inactivated include: [Very common (≥10%), common (1-10%), occasional (0.1-1%), rare (0.01-0.1%), very rare (<0.01%).]

1. Local reactions: at the injection site

Very common: Pain;

Occasional: Redness, swelling, induration, pruritus;

Rare: Erythema

2. Systemic reactions

Very common: Headache

Common: Fever, fatigue, myalgia, arthralgia, cough, dyspnea, nausea, diarrhea, pruritus;

Occasional: dizziness, anorexia, vomiting, oropharyngeal pain, dysphagia, running nose, constipation, hypersensitivity;

Rare: acute allergic reaction, lethargy, drowsiness, difficulty falling asleep, sneezing, nasopharyngitis, nasal congestion, dry throat, influenza, hypoesthesia, limb pain, palpitations, abdominal pain, rash, abnormal skin mucosa, acne, ophthalmodynia, ear discomfort, lymphadenopathy;

Very rare: Chills, taste dysfunction, loss of taste, paresthesia, tremor, attention disorder, epistaxis, asthma, throat irritation, tonsillitis, physical discomfort, neck pain, jaw pain, neck lump, mouth ulcers, toothache, esophagus disorders, gastritis, fecal discoloration, ophthalmodynia, blurred vision, eye irritation, earache, tension, hypertension, hypotension, urinary incontinence, delayed menstruation.

Contraindications:

1. Individuals who are allergic to any component of this product (including excipients- Disodium hydrogen phosphate, Sodium chloride, Sodium dihydrogen phosphate, Aluminium hydroxide).
2. Immediate or delayed onset allergic /anaphylactic reactions after a previous dose of the SARS-CoV-2 (Vero Cell), Inactivated Vaccine.
3. Patients with uncontrolled epilepsy or other progressive nervous system diseases, with a history of Guillain-Barre syndrome and any adverse nervous system reaction occurred after a previous dose of the same vaccine product.
4. Pregnant and lactating women lactation (lactation is considered only for the initial 6 months after delivery) [not done clinical trials so far for adequate evidence).
5. <18 years (not done clinical trials so far)

Special Warnings and Precautions for Use

1. Intravascular injection is strictly prohibited. There is no safety and efficacy data of the vaccine after subcutaneous and intradermal injection.
2. Use with caution in patients with acute diseases, acute onset of chronic diseases, severe chronic diseases, allergies and fever - advised to get clinician advise if necessary.
3. Use with caution in patients who have diabetes and those with a history or family history of convulsions, epilepsy, encephalopathy or mental illness.
4. Use with caution in patients who have decrease in platelets or clotting disorders (e.g. clotting factor deficiency, coagulopathy, platelet disorders) because of the risk of bleeding which may occur during intramuscular administration of the vaccine. Need to get specialized opinion if need of the disease condition.
5. Use with caution in patients with impaired immune function (such as malignant tumor, nephrotic syndrome, AIDS patients, etc.) because the safety and efficacy data are not available, and such population should be vaccinated on an individual basis.
6. People injected with immunoglobulin should be vaccinated with this product at least 1 month apart, so as not to affect the immune efficacy.
7. The concomitant clinical trials on this vaccine in combination with other vaccines have not yet been conducted. Consult a physician for advice if other vaccines have to be immunized at the same time.

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 (at least 1 month).

Following conditions are not contraindications for the 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)

Other logistic requirements

- 0.5ml AD syringes (number equal to number of doses estimated)
- 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
- Assess the adequacy of vaccine carriers to distribute vaccines to all hospital clinics and MOH central clinics.
- Assess the adequacy of ice packs for vaccine transport to all clinics (if inadequate need to re-distribute). Make sure adequate ice packs are in freeze and stored.
- Vaccines should store in RMSD-cold rooms and preferably in vaccine storing ILR, (Net capacity 200 L with standard capacity 90L) at hospitals and MOH settings adhering to National immunization vaccine storage guidelines. **It is strongly advised not to store vaccines with other pharmaceutical items other than with EPI vaccines.**
- Emergency tray with essential items to attend immediate Adverse Events Following Immunization (AEFI) as with National guidelines should be available in all immunization clinic centres.

Implementation of the vaccination

- The campaign mode vaccination for 1st round and 2nd round of vaccination needs to be conducted as with the identified categories and dates agreed with the Epidemiology Unit, Ministry of Health as with the evolving requirement of the country for the best impact.
- 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 returned from the clinic, needs to be stored separately (in returned unopened vial box) in the Ice Lined Refrigerator (ILR) and should be used as the priority in the next clinic session.
- 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)

- Remaining vaccine stocks at the end of the initial round of the campaign should store securely at 2⁰-8⁰C until the 2nd round of the campaign.
- These remaining vaccine stocks should mention in the monthly stock return to RMSD with a copy to the Regional Epidemiologist.
- After the 2nd dose of the campaign all remaining vaccine vials should return to RMSD by duly completing the Monthly Stock Return of Vaccine and Injection Safety Devices Vaccine Stock Return (Annexure 1)
- Vaccine stocks should not be kept in any of the institutional refrigerators after the 2nd dose of the campaign.
- Only selected institutions will allow to keep limited amount of vaccine stocks for the use of vaccination-postponed individuals.

Immunization clinic functioning

- Immunization clinic centres should be established in hospitals, MOH offices and in field Immunization clinic centres to vaccinate relevant selected target groups as instructed by the Ministry of Health.
 - Other field level vaccination centres can be organized by assessing the resources, availability of health care staff, other support staff and facilities to conduct the clinic and attending emergency situations.
 - All clinic field level centres vaccinating is advised to communicate with areas MOH/ Regional Epidemiologist/District and Provincial Consultant Community Physicians, for the “emergency tray” preparation and arrangements to attend any AEFI emergencies.
- Implementation of the 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 organizing 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 (tracker) 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 evidence so far).
- Take measures to follow up the 2nd dose of the vaccination using the same vaccine product.
- All persons coming for the vaccination should screen adequately for the eligibility, contra-indications and high risk conditions should be asked before vaccination.
- 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 (Annexure 6), sex and health status should be properly completed and provided to the Regional Epidemiologist/Epidemiology Unit at the end of the day with the clinic return.
- Register the person (electronic web based (tracker) and paper based - Annexure 4) and issue “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.
- Shake the vaccine vial gently to mix the solution uniformly before withdraw the SARS-CoV-2 (Vero Cell), Inactivated Vaccine dose from the vial.

- Advise to use 0.5ml AD syringes at all possible instances and carefully withdraw the correct dose (0.5ml) by keeping the upper edge of the plunger at the 0.5ml mark in the syringe without any air bubbles.
- Vaccination should be given as IM injection (advise to withdraw and vaccinate by the same person adhering to minimum handling, in order to minimize the possible contamination).
- SARS-CoV-2 Vaccine (Vero Cell), Inactivated (BBIBP-CorV) vaccine 0.5 ml IM to be given to upper arm preferably on left side.
- After vaccination, they should be observed for a minimum of 20 minutes in the clinic for 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 needs 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)
- At the end of the clinic compile all the 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.
- 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, if any vaccine wastage information and vaccination related data should submit to the Regional Epidemiologist in the provided Immunization clinic return (Annexure 8).

MONTHLY STOCK RETURN OF VACCINE & INJECTION SAFETY DEVICES

Institution : D.P.D.H.S. Division : No. 05910
 Month : Year :

Annexure 1

[illegible]

[illegible]

Clinic Vaccine Movement Register Format

Annexure 3

Date :							
Type of vaccine/item	No. of doses /items issued to the clinic	Batch number	No. of vaccinations performed	No. of doses /items used	No. of doses /items returned	No. of doses /items required for the next clinic	Remarks
BCG							
PVV							
OPV							
LJEV							
MMR							
DPT							
DT							
TT							
aTd							
BCG diluents							
LJEV diluents							
MMR diluents							
0.05 ml syringes							
0.5 ml syringes							
2ml syringes							
5 ml syringes							
Safety boxes							
Signature of assigned person at MOH office.....			Signature of assigned PHM at clinic.....				

Date :							
Type of vaccine/item	No. of doses /items issued to the clinic	Batch number	No. of vaccinations performed	No. of doses /items used	No. of doses /items returned	No. of doses /items required for the next clinic	Remarks
BCG							
PVV							
OPV							
LJEV							
MMR							
DPT							
DT							
TT							
aTd							
BCG diluents							
LJEV diluents							
MMR diluents							
0.05 ml syringes							
0.5 ml syringes							
2ml syringes							
5 ml syringes							
Safety boxes							
Signature of assigned person at MOH office.....			Signature of assigned PHM at clinic.....				

උපන් වර්ෂය
பிறந்த ஆண்டு
Year of Birth

පිටු අංකය
பக்க இலக்கம்
Page Number

ලේඛන අංකය பதிவிலக்கம் Reg. Number	නම සහ ජා. හැ.ප. අංකය பெயர் மற்றும் தே.அ.அ இலக்கம் Name & NIC Number	වයස வயது / Age	ස්ත්‍රී/පුරුෂ භාවය பாலினம் / Sex	ලිපිනය முகவரி Address	දුරකථන අංකය தொடர்பிலக்கம் Contact number	එන්නත ලබා දුන් දිනය கொவிட்-19 தடுப்புகருந்தேற்றிய திகதி Date of Covid 19 Vaccination				වෙනත් කරුණු குறிப்புகள் Remarks
						1 වන මානුව முதலாவது தடவை 1st Dose	2 වන මානුව இரண்டாவது தடவை 2nd Dose			
						DD/MM	DD/MM	DD/MM	DD/MM	
						YYYY	YYYY	YYYY	YYYY	
						DD/MM	DD/MM	DD/MM	DD/MM	
						YYYY	YYYY	YYYY	YYYY	
						DD/MM	DD/MM	DD/MM	DD/MM	
						YYYY	YYYY	YYYY	YYYY	
						DD/MM	DD/MM	DD/MM	DD/MM	
						YYYY	YYYY	YYYY	YYYY	
						DD/MM	DD/MM	DD/MM	DD/MM	
						YYYY	YYYY	YYYY	YYYY	
						DD/MM	DD/MM	DD/MM	DD/MM	
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						DD/MM	DD/MM	DD/MM	DD/MM	
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						YYYY	YYYY	YYYY	YYYY	

கூடுதல் ப்ரகாஸ கிரீஸே பத்ருட / சம்மதப் படிவம் / Consent form

දිනය :

திகதி :

Date :

MINISTRY OF HEALTH

COVID-19 vaccination : Immunization Clinic Tally Sheet - Different age groups

EPID/CV/TS 04

Sheet No

Date	Institution name	District	MOH area	Clinic centre name	Vaccine Name	
					1 st Dose ☐	2 nd Dose ☐

Age groups	Male					Total	Male					Total	Female					Total	Female					Total
	known healthy						known comorbid conditions *						known healthy						known comorbid conditions *					
60 years and above	1	2	3	4	5		1	2	3	4	5		1	2	3	4	5		1	2	3	4	5	
	6	7	8	9	10		6	7	8	9	10		6	7	8	9	10		6	7	8	9	10	
	11	12	13	14	15		11	12	13	14	15		11	12	13	14	15		11	12	13	14	15	
	16	17	18	19	20		16	17	18	19	20		16	17	18	19	20		16	17	18	19	20	
	21	22	23	24	25		21	22	23	24	25		21	22	23	24	25		21	22	23	24	25	
50 – 59 years	1	2	3	4	5		1	2	3	4	5		1	2	3	4	5		1	2	3	4	5	
	6	7	8	9	10		6	7	8	9	10		6	7	8	9	10		6	7	8	9	10	
	11	12	13	14	15		11	12	13	14	15		11	12	13	14	15		11	12	13	14	15	
	16	17	18	19	20		16	17	18	19	20		16	17	18	19	20		16	17	18	19	20	
	21	22	23	24	25		21	22	23	24	25		21	22	23	24	25		21	22	23	24	25	
40 – 49 years	1	2	3	4	5		1	2	3	4	5		1	2	3	4	5		1	2	3	4	5	
	6	7	8	9	10		6	7	8	9	10		6	7	8	9	10		6	7	8	9	10	
	11	12	13	14	15		11	12	13	14	15		11	12	13	14	15		11	12	13	14	15	
	16	17	18	19	20		16	17	18	19	20		16	17	18	19	20		16	17	18	19	20	
	21	22	23	24	25		21	22	23	24	25		21	22	23	24	25		21	22	23	24	25	
30 – 39 years	1	2	3	4	5		1	2	3	4	5		1	2	3	4	5		1	2	3	4	5	
	6	7	8	9	10		6	7	8	9	10		6	7	8	9	10		6	7	8	9	10	
	11	12	13	14	15		11	12	13	14	15		11	12	13	14	15		11	12	13	14	15	
	16	17	18	19	20		16	17	18	19	20		16	17	18	19	20		16	17	18	19	20	
	21	22	23	24	25		21	22	23	24	25		21	22	23	24	25		21	22	23	24	25	
20 – 29 years	1	2	3	4	5		1	2	3	4	5		1	2	3	4	5		1	2	3	4	5	
	6	7	8	9	10		6	7	8	9	10		6	7	8	9	10		6	7	8	9	10	
	11	12	13	14	15		11	12	13	14	15		11	12	13	14	15		11	12	13	14	15	
	16	17	18	19	20		16	17	18	19	20		16	17	18	19	20		16	17	18	19	20	
	21	22	23	24	25		21	22	23	24	25		21	22	23	24	25		21	22	23	24	25	
Less than 20 years	1	2	3	4	5		1	2	3	4	5		1	2	3	4	5		1	2	3	4	5	
	6	7	8	9	10		6	7	8	9	10		6	7	8	9	10		6	7	8	9	10	
	11	12	13	14	15		11	12	13	14	15		11	12	13	14	15		11	12	13	14	15	
	16	17	18	19	20		16	17	18	19	20		16	17	18	19	20		16	17	18	19	20	
	21	22	23	24	25		21	22	23	24	25		21	22	23	24	25		21	22	23	24	25	

* Diabetes mellitus, Hypertension, Cardio vascular diseases, Cerebro-vascular diseases, Kidney diseases, Liver diseases, Chronic lungs diseases, Malignancies, History of transplant, Immune compromised patients and any other chronic medical conditions

උපදෙස් / அறிவுறுத்தல்கள் / Instructions



සෞඛ්‍ය අමාත්‍යාංශය - ශ්‍රී ලංකාව
சுகாதார அமைச்சு
Ministry of Health, Sri Lanka

Annexure 7

මගේ COVID-19 එන්නත් කාඩ්පත සුරැකිව තබන්න.

இந்த கொவிட்-19 தடுப்பூசி அட்டையினை நீங்கள் பாதுகாப்பாக வைத்திருப்பதை உறுதிப்படுத்துங்கள்

Make sure you protect this COVID-19 vaccination card

සෞඛ්‍ය නිලධාරීන් ලබාදුන් නියමිත දිනයේදී සහ වේලාවේදී නියමිත උපදෙස් මත COVID-19 එන්නත් රේලා මාත්‍රාව ලබා ගැනීමට මතක තබා ගන්න.

சுகாதாரப் பணியாளர்களால் அறிவுறுத்தப்பட்டதற்கு அமைவாக, அடுத்த தடவை கொவிட்-19 தடுப்பூசியினை பெற்றுக் கொள்ள வேண்டிய நாளில், குறித்த நேரத்தில் சென்று அதனைப் பெற்றுக்கொள்ள மறவாதீர்கள்

Remember to get the next dose of the COVID-19 vaccine on due date and time as instructed by the Health staff

වැඩිදුර විස්තර සඳහා තම ප්‍රදේශයේ සෞඛ්‍ය වෛද්‍ය නිලධාරී හෝ සෞඛ්‍ය අමාත්‍යාංශයේ වසංගත රෝග විද්‍යා අංශය අමතන්න

மேலதிக தகவல்களுக்கு தொடர்பு கொள்ளுங்கள்: உங்கள் பகுதி சுகாதார வைத்திய அதிகாரி அல்லது தொற்றுநோய் விஞ்ஞானப் பிரிவு, சுகாதார அமைச்சு. தொ

For further information contact: Medical Officer of Health in your area or Epidemiology Unit, Ministry of Health.

දුරකථන/பே.எண்/Telephone. 0112695112

www.epid.gov.lk

COVID-19 එන්නත් කාඩ්පත கொவிட்-19 தடுப்பூசி அட்டை COVID-19 Vaccination card

නම பெயர் Name:			
ජා.නැ.අ./මගේ බලපත්‍ර අංකය தே.அ.அட்டை/கடவுச்சீட்டு இலக்கம் NIC number/Passport number			
වයස வயது Age		ස්ත්‍රී පුරුෂ භාවය பாலினம் Sex	
ලිපිනය முகவரி Address			
දුරකථන අංකය தொடர்பு இலக்கம் Contact number			
දිස්ත්‍රික්කය மாவட்டம் District			
සෞ. වෛ. නි. ප්‍රදේශය ச.வை.அ பிரிவு MOH area			
ග්‍රාම නිලධාරී වසම கிராம அலுவலர் பிரிவு Grama Niladhari area			
ලේඛනයේ අනුක්‍රමික අංකය பதிவேட்டில் உள்ள தொடரிலக்கம் Serial Number in the register			

COVID-19 vaccination details

COVID-19 vaccine	Name of the Vaccine	Place of vaccination	Date of Vaccination	Batch number	Remarks
1 st dose			DD/MM/YYYY		
2 nd dose			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		
			DD/MM/YYYY		

නැවත එන්නත ලැබිය යුතු දිනය / அடுத்த வருகைக்கான திகதி / Next appointment date

DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY
DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY

EPIDEMIOLOGY UNIT

Epid/CV/CR/21/1

COVID-19 vaccination campaign: Immunization Clinic Return

Vaccine name:

(to be completed in 2 copies by the responsible officer in the hospital /MOH office/ field clinic /other institutional clinic and return one copy to Regional Epidemiologist at the end of the clinic session and keep one as a clinic copy)

District:, Institution name: MOH area:

Clinic name: Date:

Date	Total estimated/actual number to be vaccinated (Target) <i>(Number to be vaccinated from the institution / GN area/PHM area/expected number for the clinic session)</i>	Number of vaccine doses received	Total number vaccinated (per day)	Number of vaccine doses returned	Number of doses discarded	Coverage %	Wastage %	Number of AEFI reported
	A	B	C	D	$F = B - (C + D)$	$C / A \times 100 \%$	$F / (B - D) \times 100 \%$	G

Name: Designation: Signature:

Date:

Notification Form for Adverse Events Following Immunization (AEFI)

Patient Information						
Name:			MOH Division:			
Age: ☐ ☐ months/years		Sex: Male ☐ Female ☐		Telephone:		
Name & address of the Parent/Guardian:						
Information on the vaccine (primary suspected and other)						
Vaccine (Generic Name)	Vaccine (Trade name)*	Route	Dose (1 st 2 nd 3 rd 4 th)	Batch/Lot Number	Expiry date	VVM Status (I, II, III, IV)
Diluent used: Yes ☐ No ☐ If "yes", Diluent batch/lot number : Expiry date of Diluent :						
*Trade name is necessary only in private sector immunization						
Place vaccine administered:					Date:	
Person vaccine administered: Doctor ☐ PHNS/Nurse ☐ PHM ☐ PHI ☐					Time: am/pm	
Adverse Events						
Local Adverse Events Requiring investigation	Injection site abscess ☐ BCG Lymphadenitis ☐ Severe local reaction ☐					
CNS Adverse Events Requiring Investigation	Vaccine associated paralytic poliomyelitis ☐ GBS ☐ Encephalopathy ☐ Encephalitis ☐ Meningitis ☐ Seizures Febrile ☐ Seizures Afebrile ☐					
Other Adverse Events Requiring Investigation	Anaphylaxis ☐ Persistent screaming ☐ Osteitis / Osteomyelitis ☐ Hypotonic Hyporesponsive Episode ☐ Toxic Shock Syndrome ☐					
Adverse Events Not Requiring Investigation	Allergic reaction ☐ Arthralgia ☐ High fever (>39°C / 102°F) ☐ Nodule at the injection site ☐					
Other Adverse Events	a) b)					
Instruction: Before reporting an AEFI, please refer to the definition for the relevant AEFI given in overleaf and make sure that reporting event agrees with the criteria stipulated in the definition						
Date & Time onset of adverse event:						
Date & Time referring to medical care :						
Medical History/Other		Outcome				
		Hospitalized: Yes No If "Yes": Hospital:				
		BHT: Still in the hospital ☐ Discharged ☐				
		Outcome: Recovered completely ☐ Partially recovered ☐ Death ☐				
Reporting source						
Date of the notification:		Institution & Designation:			Telephone:	
Name & Signature of the notifying officer/General Practitioner:						

(Medical Officers who attend any patient suffering from Adverse Effects Following Immunization shall notify in this form to the Medical Officer of Health the area of the patients residence)

Definitions of Adverse Events Following Immunization

All of the following adverse events should be reported if temporally related to immunization. Unless otherwise specified this includes all such events occurring within four weeks of a vaccine administration.

1. Local Adverse Events

a. Injection – Site Abscesses

Occurrence of a fluctuant or draining fluid – filled lesion at the site of injection with or without fever.

Bacterial :- Existence of purulence, inflammatory signs, fever, positive Gram stain, positive culture, or finding of neutrophils. Predominance of content will support a bacterial site abscess, but the absence of some of these signs will not rule it out.

Sterile :- There is no evidence of bacterial infection following investigation.

b. Lymphadenitis (includes Suppurative Lymphadenitis)

Occurrence of either

At least one lymph node, 1.5 cm in size (one adult finger width) or larger or a draining sinus over a lymph node.

Almost exclusively caused by BCG and occurring within 2 to 6 months after receipt of BCG and on the same side as inoculation (mostly axillary).

c. Severe Local Reaction : Redness and/or swelling centered at the site of injection and one or more of the following:

1. swelling beyond the nearest joint;
2. pain, redness and swelling for more than 3 days duration; or
3. Requires hospitalization.

2. Central Nervous System Adverse Events

a. Vaccine Associated Paralytic Poliomyelitis

Acute onset of flaccid paralysis within 4-30 days of receipt of oral poliovirus vaccine (OPV), or within 4-75 days after contact with a vaccine recipient, with neurological deficits remaining 60 days after onset, or death.

b. Guillan-Barre Syndrome (GBS)

Acute onset of rapidly progressive, ascending, symmetrical flaccid paralysis, without fever at onset of paralysis and with sensory loss. Cases are diagnosed by cerebrospinal fluid (CSF) investigation showing dissociation between cellular count and protein content. GBS occurring with 30 days after immunization should be reported.

c. Encephalopathy:

Cases occurring within 72 hours after vaccination should be reported. Encephalopathy is an acute onset of major illness temporally linked with immunization and characterized by any two of the following three conditions: Seizures; Severe alteration in level of consciousness lasting for one day or more; and distinct change in behaviour lasting one day or more.

d. Encephalitis:

(Any encephalitis occurring within 1 – 4 weeks following immunization should be reported). Encephalitis is characterized by the above mentioned symptoms and signs of cerebral inflammation and, in many cases, CSF pleocytosis and/or virus isolation.

e. Meningitis:

Acute onset of major illness with fever, neck stiffness/positive meningeal signs (Kernig, Brudzinski). Symptoms may be subtle or similar to those of encephalitis, CSF examination is the most important diagnostic measure: CSF pleocytosis and/or detection of microorganism (Gram stain or isolation).

f. Seizures:

Seizures lasting for several minutes to more than 15 minutes and not accompanied by focal neurological signs or symptoms. Seizures may be Febrile Seizures or Afebrile.

3. Other Adverse Events requiring investigation

a. Anaphylactic shock:

Circulatory failure (e.g. alteration of the level of consciousness, low arterial blood pressure, weakness or absence of peripheral pulses, cold extremities secondary to reduced peripheral circulation, flushed face and increased perspiration) with or without bronchospasm and/or laryngospasm/ laryngeal edema leading to respiratory distress occurring immediately after immunization.

b. Persistent Screaming:

Inconsolable continuous crying lasting at least 3 hours accompanied by high-pitched screaming

c. Hypotonic-Hypo responsive Episode (HHE) (shock collapse):-

Sudden onset of pallor or cyanosis, decreased level or loss of responsiveness, decreased level of muscle tone (occurring within 48 hours of vaccination). The episode is transient and self limiting

d. Osteitis/ Osteomyelitis:

Inflammation of the bone either due to BCG immunization (occurring within 8 to 16 months after immunization) or caused by other bacterial infection

e. Toxic-Shock Syndrome:

Abrupt onset of fever, vomiting and watery diarrhea within a few hours of immunization, often leading to death within 24-48 hours.

4. Other adverse events not requiring investigation

a. Allergic Reaction :

Characterized by one or more of the following:

1. skin manifestations (e.g. hives, eczema);
2. wheezing;
3. facial or generalized oedema

b. Arthralgia: Persistent joint pain lasting longer than 10 days. Transient: Joint pain lasting up to approximately 10 days.

c. High Fever:

The Endogenous elevation of at least one measured body temperature >39°C

d. Nodule at the injection site:

Presence of a discrete or well demarcated firm soft tissue mass or lump at the injection site that is sometimes referred to as a subcutaneous nodule, antigen cyst or granuloma, in the absence of abscess formation, erythema and warmth.

5. Other severe and unusual events occurring within 4 weeks after immunization and not covered under categories 1-4.

Any unexplained sudden death of a vaccine recipient temporally linked (within 4 weeks) to immunization, where no other clear cause of death can be established, should be reported. In addition, any unusual events should be reported.