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<mark>සෞඛ්ඵ අමාතඵාංශය</mark> சுகாதார அமைச்சு Ministry of Health

Deputy Director General – NHSL Deputy Director General – NH Kandy Provincial Directors of Health Services Regional Directors of Health Services

Directors and Superintendents of Teaching, Provincial General, District General and Base hospitals

<u>Provision of a second booster dose (fourth dose) of COMIRNATY - Covid 19 mRNA</u> Vaccine (Nucleoside modified -Pfizer BNT) in pregnancy

All pregnant women in Sri Lanka are recommended to receive a primary course of two doses of a locally approved COVID -19 vaccine followed by a booster dose of COMIRNATY Covid 19 mRNA (Nucleoside modified-Pfizer BNT) vaccine. It is further recommended that women with high-risk pregnancies receive an additional booster dose (fourth dose) of the COMIRNATY Covid 19 mRNA (Nucleoside modified-Pfizer BNT) vaccine as per the recommendations of the Sri Lanka College of Obstetricians and Gynaecologists.

Pregnant women with the conditions listed below are to be considered as high risk and offered a second booster dose.

- · Receiving active cancer treatment for tumors or cancers of the blood
- Recipient of an organ transplant and taking medicine to suppress the immune system
- Received chimeric antigen receptor (CAR) T-cell therapy (a treatment to help the immune system attach to and kill cancer cells) or received a stem cell transplant within the last two years
- Moderate or severe primary immuno-deficiency (e.g. DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high dose corticosteroid or other drugs that may suppress the immune response
- Diabetes mellitus requiring medication
- Hypertension
- Chronic cardiac disease ischaemic heart disease, valvular heart disease, congestive cardiac
 failure, cardiomyopathies, poorly controlled hypertension, pulmonary hypertension,
 complex congenital heart disease
- Chronic kidney disease
- Chronic liver disease cirrhosis, autoimmune hepatitis, non-alcoholic fatty liver disease

- Chronic neurological disease stroke, neurodegenerative disease (e.g. dementia, motor neuron disease, Parkinson's disease), myasthenia gravis, multiple sclerosis, cerebral palsy, myopathies, paralytic syndromes, epilepsy
- Chronic lung disease chronic obstructive pulmonary disease, cystic fibrosis, interstitial lung disease, and asthma
- Chronic inflammatory conditions requiring medical treatment with disease-modifying antirheumatic drugs (DMARDs) or immune-suppressive or immune-modulatory therapies – systemic lupus erythematosus, rheumatoid arthritis, Crohn's disease, ulcerative colitis, and similar conditions
- Obesity
- Underweight, BMI < 16.5 kg/m²

The following procedures should be adhered to in arranging for the second booster dose:

- > The hospital director should assign a Consultant Obstetrician and Gynaecologist to be in charge of the vaccination center to endorse the eligibility of vaccination and closely monitor the vaccination process of pregnant women.
- > Pregnant women with the aforementioned high-risk conditions should be identified, and a specialist Obstetrician and Gynaecologist should verify and advise on the eligibility and timing of the second booster dose.
- > The recommended time since the first booster dose is at least 12 weeks.
- ➤ Regional Epidemiologists, MO/MCH, MOOH, and all field level public health staff are advised to refer pregnant women with specified conditions mentioned above to hospitals where vaccination centers are functioning.
- All hospitals at the level of Base hospitals and above, where Consultant Obstetricians and Gynaecologists are available, will be considered to conduct vaccination centers for pregnant women.
- These recommendations are given based on the risks of developing severe COVID-19 complications in pregnant women with high-risk pregnancies that clearly outweigh the potential adverse events of the vaccine (AEFI).
- > Directors in hospitals are advised to make vaccine estimates in advance based on the recommendations of relevant Consultants in the hospital.
- It is advised to request the necessary minimum vaccine stock with plans to obtain any additional stocks as will be required.
- The vaccines taken out from the Ultra-Low Temperature (ULT) freezer (from -70°C) cannot be re-frozen in a ULT freezer.
- Vaccines supplied to the hospital should be stored only in the Ice Lined Refrigerator (ILR) at 2°-8°C, adhering to the national vaccine storage guidelines issued by the Epidemiology Unit. Even if the hospital has a ULT freezer (-70°C), the COMIRNATY Pfizer vaccine should not be stored in the ULT freezer as it is transported at a temperature of 2°-8°C.
- It is advised to strictly follow the COMIRNATY, Covid 19 mRNA (Nucleoside modified -Pfizer BNT) vaccination guidelines issued on 05/07/2021 by the Epidemiology Unit, Ministry of Health, for vaccine storage, vial preparation, administration, follow-up, and surveillance of Adverse Events Following Immunization (AEFI). This can be accessed at www.epid.gov.lk.
- Maintain regular communications with the Consultant Epidemiologists at the Epidemiology Unit and Regional Epidemiologists in respective districts on the vaccination process to receive the required vaccine supply and necessary technical guidance.
- ➤ Directors of hospitals are responsible for organizing the vaccination clinics with Consultant Obstetricians and Gynaecologists and other relevant specialties.
 - o Adhere to infection prevention and control measures.
 - o More than one registration desk should be arranged for the registration procedure to reduce waiting time

- Identify a focal point for vaccination in the hospital, preferably a Consultant Obstetrician and Gynaecologist, to endorse the eligibility of vaccination, offer necessary advice, and closely monitor the vaccination process
- o Deploy adequately trained and competent staff for vaccination (vaccine vial preparation and vaccination)
- o Identify suitable human resources for vaccination data entry in the hospital to enter data into the vaccine tracker.
- ➤ Individual vaccination data should be entered into the web-based "vaccine tracker" system.
- At the end of each day, the total number vaccinated should be provided to the Epidemiology Unit, and copy to the Regional Epidemiologist in respective districts.

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

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- v. Deputy Director General (PHS) -1
- vi. Deputy Director General (MS)
- vii. Chief Epidemiologist
- viii. Director/MCH Family Health Bureau
- ix. President/ Sri Lanka College of Obstetricians and Gynaecologists
- x. Provincial and district CCPs
- xi. Regional Epidemiologists
- xii. MOO/MCH