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சுகாதார அமைச்சு
Ministry of Health

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2021/05/04

Deputy Director General, NHSL
Provincial Director of Health Services
Regional Director of Health Services
Director, National Hospital Kandy
Directors/ Medical Superintendents
Heads of all Specialized Hospitals, Teaching Hospitals
Provincial and District General Hospitals, Base Hospitals and
Divisional Hospitals

**Guidance on Diagnosis and Management of Thrombosis with Thrombocytopenia
Syndrome (TTS) in persons who received COVID-19 vaccination**

Herewith I enclose the guideline developed by the Expert Technical Committee to investigate Severe Adverse Events Following COVID-19 Immunization on Diagnosis and Management of TTS.

You are kindly requested to bring this guideline to the attention of all Consultants and Medical officers of your hospital and to ensure the guidance is strictly followed.


Dr. Asela Gunawardena
Director General of Health Services

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

Copy: Secretary
Additional Secretary (PHS)/(MS)
All Deputy Director Generals
Director, Private Health Sector Development- Please inform all
private hospital authorities to follow the same guidance
Chief Epidemiologist
Provincial/ District Consultant Community Physicians

Guidance developed by the Expert Panel to investigate Severe Adverse Events Following COVID-19 Immunization, appointed by the Ministry of Health (EPMoH), Sri Lanka
Focussed on the Thrombosis and Thrombocytopenia syndrome (TTS)

Guidance on Management: TTS

A rare syndrome of thrombosis, often involving cerebral venous sinuses, and thrombocytopenia is being reported in several countries, after COVID-19 vaccination with Oxford AstraZeneca vaccine and is thought to affect people mainly below 60 years in both genders. There is no clear signal of what the risk factors are at present.

The Ministry of Health has established an Expert Technical Committee to investigate severe adverse events following COVID-19 immunization [Annex 1] and a Multi-Disciplinary Team (MDT)[Annex11] for the clinical management of similar cases if reported in Sri Lanka. Accordingly, all cases with similar manifestation and has a history of COVID-19 vaccination are expected to transfer to the National Hospital of Sri Lanka after initial management and once the patient is stabilized. Clinicians need to be on alert for this syndrome, to understand how to make the diagnosis and manage it. The EPMoH is available around the clock to offer MDT support for the management of these cases.

All suspected cases must be immediately reported to the Epidemiology Unit through the telephone No 0113415985 which is active round the clock [Annex 111].

The syndrome is characterised by thrombocytopenia, raised D Dimers and progressive thrombosis, with a high preponderance of cerebral venous sinus thrombosis (CVST). Other sites such as portal veins, renal vessels, pulmonary veins and arteries are also commonly affected by thromboembolic disease. Hyperfibrinolysis and bleeding can occur.

- Signs/symptoms of thromboembolism: New onset
 - Severe, persistent headache, +/- vision change, seizure like activity
 - Severe persistent abdominal pain
 - Leg pain or swelling
 - Chest pain and/or shortness of breath
- Typical laboratory features include a platelet count $<150 \times 10^9/L$, very raised D Dimer levels above the level expected for Venous Thromboembolism (VTE) and inappropriately low fibrinogen.
- Antibodies to Platelet Factor 4 (PF4) have been identified. Therefore, it has similarities to Heparin-Induced thrombocytopenia (HIT), but in the absence of the patient's exposure to heparin treatment. These PF4 antibodies are detected by ELISA HIT assay but not usually shown by other HIT assay methods.

While this is being further evaluated, we recommend to be vigilant and the following action to be taken:

POSSIBLE CASE OF TTS

Any patient presenting with both acute venous or arterial thrombosis AND new onset thrombocytopenia within 28 days of receiving COVID 19 vaccination and no known recent exposure to Heparin.

Symptoms of acute thrombosis include but are not restricted to severe headache persisting for more than 3 days post vaccination, any new neurological manifestations, unexplained abdominal pain, limb oedema, chest pain and difficulty in breathing. Bleeding manifestations such as skin ecchymosis, haematuria and ENT bleeds that a patient has hitherto not experienced also requires urgent attention.

Investigations

- FBC- specifically to confirm thrombocytopenia $<150 \times 10^9/L$
 - Coagulation screen, including Clauss fibrinogen and D Dimers
 - Blood film to confirm true thrombocytopenia and identify alternative causes
 - Appropriate imaging according to the site of suspected thrombosis.
- If CVST is suspected the patient should be transferred urgently to a centre with MRI/MRV/MRA facilities.***

Based on the above the patient will be categorized as A) Unlikely Case of TTS or B) Probable case of TTS

A) UNLIKELY CASE OF TTS:

1. Thrombocytopenia without thrombosis with D dimer at or near normal and normal fibrinogen.
2. Thrombosis with a normal platelet count and D dimer <2000 and normal fibrinogen

B) PROBABLE CASE OF TTS:

Any patient presenting with both acute venous or arterial thrombosis AND new onset thrombocytopenia within 28 days of receiving COVID 19 vaccination and no known recent exposure to Heparin.

- D Dimers > 4000 mcg/L (D Dimers 2000-4000 mcg/L may need to be treated as a probable case)
- Low fibrinogen levels

Management of a Probable Case – Treat first while Awaiting Confirmatory Diagnosis:

1. GIVE intravenous immunoglobulin (ivlg) urgently as this is the treatment most likely to influence the disease process. Give 1g/Kg (0.5g/Kg daily on two days if needed), irrespective of the degree of thrombocytopenia, and review clinical course. Further ivlg may be required to balance bleeding and thrombotic risks.
2. AVOID platelet transfusions. If an intervention is required in the midst of thrombocytopenia contact EPMoH or haematologist in local hospital.
3. Correction of fibrinogen should be done when there is active bleeding to ensure the level above 1.5 g/L with fibrinogen concentrate or cryoprecipitate.
4. When there is no active bleeding, anti-coagulate the patient in spite of low fibrinogen and thrombocytopenia. If anticoagulation is needed before, then it should be considered with close monitoring.
5. It is unknown whether heparin exacerbates the condition.
6. ANTICOAGULATE with non-heparin-based therapies fondaparinux or Direct Oral Anticoagulants (DOACs). However, if these products are not available, the EPMoH recommends anticoagulation with Low Molecular Weight Heparin (LMWH) ie **enoxaparin** over NO anticoagulation, based on local experience.
7. Give steroids: Methyl prednisolone 1gram infusion daily for 3 days if platelet count $< 50 \times 10^9/L$ and no absolute contraindication. Oral steroids 1mg/Kg/ day may be considered as an alternative and if the thrombocytopenia is $> 50 \times 10^9/L$.
8. Plasma exchange may also be considered if platelets are persistently $< 30 \times 10^9/L$ even after ivlg and steroids.
9. Avoid thrombopoietin receptor agonists.
10. Antiplatelet agents are not recommended based on current experience.
11. If no overt thrombosis, but thrombocytopenia with raised D Dimer, thromboprophylaxis with non-heparin-based anticoagulants should be considered – balancing bleeding and thrombotic risk. DOAC, or fondaparinux can be used. In the event that these drugs are not available LMWH (**enoxaparin**) can be considered.

CONFIRMED CASE

Discharge:

Continue anticoagulation for at least 3 months. If the thrombosis was purely arterial, the patient can be switched to an antiplatelet agent after D Dimers, platelet count and fibrinogen have returned to normal. Antiplatelet therapy should be continued for 3 months. The platelet count should be monitored to observe for relapse.

Further Vaccination:

Patients either affected by, or under investigation for this complication should **not** receive their second vaccine until further notice.

Notification:

Please notify all the cases of adverse events following COVID-19 vaccination through routine notification form for Adverse Events Following Immunization (Annex 1V). For severe cases immediately notify to Epidemiology unit through the telephone (No 0113415985) in addition to the routine notification form.

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 சுகாதார அமைச்சு
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22.03.2021

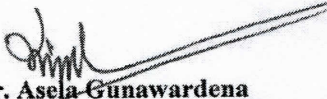
Dr. Sudath Samaraweera, Chief Epidemiologist, Epidemiology Unit [Chairperson]
 Dr. Samitha Ginige, Deputy Chief Epidemiologist, Epidemiology Unit [Member]
 Dr. Deepa Gamage, Consultant Epidemiologist, Epidemiology Unit [Member]
 Dr. Ananda Wijewickrama, Consultant Physician, NIID [Member]
 Dr. Upul Dissanayake, Consultant Physician, NHSL [Member]
 Dr. Sunethra Senanayake, Consultant Neurologist, NHSL [Member]
 Dr. Kanthi Nanayakkara, Consultant Virologist, MRI [Member]
 Dr. Rajiva de Silva, Consultant Immunologist, MRI [Member]
 Dr. Dhanushka Dassanayake, Consultant Immunologist, MRI [Member]
 Prof. Neelika Malavige, Professor and Head, Department of Immunology and Molecular Medicine, Faculty of Medical Sciences, University of Sri Jayewardenepura [Member]
 Dr. Lalindra Goonaratne, Consultant Haematologist, Senior Lecturer and Head, Department of Pathology, Faculty of Medicine, University of Colombo [Member]
 Dr. Ajith Thennakoon, Chief JMO, Colombo [Member]
 Dr. Ruwan Nanayakkara, Consultant JMO, TH Karapitiya [Member]
 Prof. Shalini Sri Ranganathan, Professor in Pharmacology, Department of Pharmacology, Faculty of Medicine, University of Colombo [Member]

Expert Technical Committee to Investigate Severe Adverse Events Following COVID-19 Immunization

I am pleased to inform you that you are appointed as Chairperson/Member of the Expert Technical Committee to Investigate Severe Adverse Events Following COVID-19 Immunization.

You are expected to:

- Conduct regular meetings and emergency meetings virtually or in person as and when necessary.
- Review in-depth all reported cases with severe forms of adverse events following COVID-19 immunization.
- Provide expert opinion and support the clinicians treating those patients in the case management.
- Recommend the Ministry of Health on any required modifications of the COVID-19 immunization programme.


 Dr. Asela Gunawardena
 Director General of Health Services

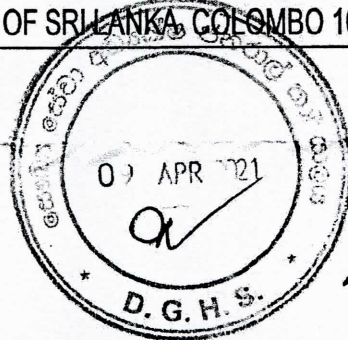
Dr. ASELA GUNAWARDENA
 Director General of Health Services
 Ministry of Health
 "Suwasiripaya"
 385 Rev. Baddegama Wimalawansa Thero Maw.,
 Colombo 10.

Copy: Secretary
 Additional Secretary (Public Health Services)
 Deputy Director General (Public Health Services) - 1

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THE NATIONAL HOSPITAL OF SRI LANKA, COLOMBO 10.

Director General of Health Services
Ministry of Health
Colombo 10.



06.04.2021

Establishment of multi - disciplinary team for the management of patients with neurological complications with a history of recent COVID – 19 vaccination.

As per the request made by the letter dated 26.03.2021 and No EPID/400/n-Cov/vaccine. Below mention team of Consultants are appointed for above purpose.

- | | |
|------------------------------|---------------------------------|
| 01.Dr.Upul Dissanayake | - Consultant Physician |
| 02.Dr.Harendra Karunathilake | - Consultant Physician |
| 03.Dr.Saman Wadanamby | - Consultant Neuro Surgeon |
| 04.Dr.Sanjeewa Garusinghe | - Consultant Neuro Surgeon |
| 05.Dr.Sunethra Senanayake | - Consultant Neurologist |
| 06.Dr.Gamini Pathirama | - Consultant Neurologist |
| 07.Dr.Prasad De Silva | - Consultant Radiologist |
| 08.Dr.Manjula Kularathne | - Consultant Neuro Anaesthetist |
| 09.Dr.B.P.K.Petangoda | - Consultant Neuro Anaesthetist |
| 10.Dr.Baddrika Jayaratne | - Consultant Haematologist |
| 11.Dr.Visaka Rathnamalala | - Consultant Haematologist |

Deputy Director General

National Hospital of Sri Lanka

Dr. W. K. Wickremasinghe,
MD, MSc (Medical Admin), MD (Med. Admin), MBA
Deputy Director General of Health Services.
National Hospital of Sri Lanka.

Copy : To Relevant Consultants

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 சுகாதார அமைச்சு
 Ministry of Health

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 திகதி) 19. 03. 2021
 Date)

Deputy Director General, NHSL
 Director, National Hospital Kandy
 Directors/ Medical Superintendents and Heads of all Specialized Hospitals, Teaching Hospitals,
 Provincial and District General Hospitals, Base Hospitals and Divisional Hospitals

Covishield COVID-19 Vaccination Campaign in Sri Lanka: Reporting of Hospital Admissions after Vaccination

As you may aware the COVID-19 National Vaccination Campaign was commenced on 29th January 2021. By now more than 800,000 people were vaccinated with the first dose of Covishield vaccine. In parallel with the vaccination programme, the reporting of adverse events following immunization (AEFI) has been implemented.

In order to strengthen AEFI reporting mechanism and also not to miss severe forms of adverse events following Covishield immunization, if any, all hospital admissions for any medical reason within the first three weeks after Covishield vaccination should be promptly notified to the Epidemiology Unit by calling Dr Nadeeja or Dr Nishani. The contact telephone number is 0113415985. Please note that the routine AEFI notification should continue as usual.

You are kindly requested to bring the contents of this letter to the attention of all Consultants and Medical Officers of your hospital and to ensure that the guidance is strictly followed.


Dr. Asela Gunawardena
 Director General of Health Services

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

Copy: Secretary
 Additional Secretary (PHS)/(MS)
 Deputy Director General (PHS) – 1/ (MS) – 1/ (MS) – 2
 Director, Private Health Sector Development – Please inform all private hospital authorities to follow the same guidance
 Chief Epidemiologist
 Provincial Directors of Health Services
 Regional Directors of Health Services
 Provincial/ District Consultant Community Physicians
 Regional Epidemiologists

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		Injection site abscess ☐ BCG Lymphadenitis ☐				
Requiring investigation		Severe local reaction ☐				
CNS Adverse Events		Vaccine associated paralytic poliomyelitis ☐ GBS ☐				
Requiring Investigation		Encephalopathy ☐ Encephalitis ☐ Meningitis ☐				
		Seizures Febrile ☐ Seizures Afebrile ☐				
Other Adverse Events		Anaphylaxis ☐ Persistent screaming ☐ Osteitis / Osteomyelitis ☐				
Requiring Investigation		Hypotonic Hyporesponsive Episode ☐ Toxic Shock Syndrome ☐				
Adverse Events Not		Allergic reaction ☐ Arthralgia ☐				
Requiring Investigation		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)