nhra BAHRAIN
الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

مكتب الرئيس التنفيذي
Chief Executive Office

مملكة البحرين
Kingdom of Bahrain

Date: 20 April 2021

Circular No. (10) for year 2021

To All physicians and Healthcare facilities

NHRA would like to raise your attention to report any suspected case with unusual thrombotic events and thrombocytopenia in vaccinated patients with any of the approved vaccines in the kingdom of Bahrain.

Please refer to the attached National protocol for Vaccine- Induced thrombosis and thrombocytopenia.

You are to report to Public Health department to Immunization@health.gov.bh using the attached from.

Your cooperation is highly appreciated in improving health services in the Kingdom.

Dr. Mariam Athbi AlJalahma

Chief Executive Officer

Public Awareness Campaign to Combat Coronavirus (COVID-19)

الحملة الوطنية لمكافحة فيروس كورونا (COVID-19)

Vaccine-Induced Thrombosis and Thrombocytopenia

Symptoms that may indicate Vaccine-Induced Thrombosis and Thrombocytopenia

- Severe headache
- Visual changes
- Abdominal pain
- Nausea and vomiting
- Backache
- Shortness of breath
- Leg pain or swelling
- Petechiae, or easy bruising

Case definition of Vaccine-Induced Thrombosis and Thrombocytopenia

- ‘Diagnosis of exclusion’ as there is currently no validated confirmatory assay.
- Timing of vaccine (4 – 28 days prior to presentation).
- Unexplained platelet count less than 150x 109/L or <50% from baseline (BL)
- No LMWH/UFH exposure or history of HIT.
- Other causes of DIC or thrombocytopenia excluded.
- Demonstration of PF4-dependent antibodies essential.
- HIT ELISA is sensitive but nonspecific.
- Non-ELISA HIT assays are neither sensitive nor specific, and false positive rates are not yet known.
- Functional assay required to confirm presence of platelet-activating antibodies.

Case definition of Vaccine-Induced Thrombosis and Thrombocytopenia

Confirmed case:

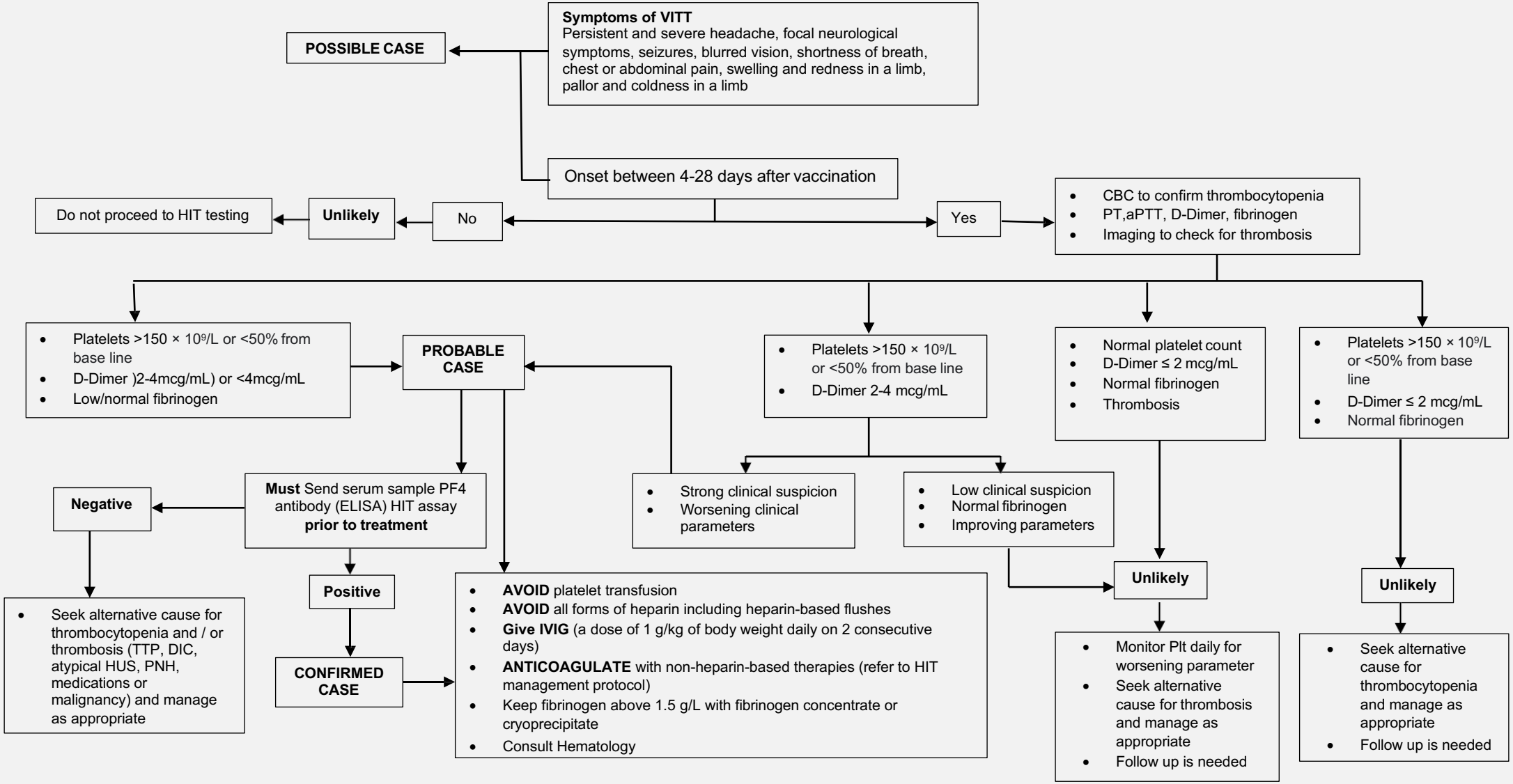
1. Onset of symptoms between 4-28 days after vaccination.
2. Platelet count <150 x109/L or <50% from baseline.
3. D-Dimers >4 mcg/mL or between (2-4 mcg/mL) +/- inappropriately low fibrinogen.
4. Confirmed cerebral venous thrombosis (CVT), splanchnic venous thrombosis or other sites of VTE as well as arterial ischemia may also occur.
5. Positive ELISA HIT assay.

*Note: If there is high index of clinical suspicion but PF4 antibodies (HIT ELISA assay) are negative, send serum and EDTA for HIPA testing for confirmation

Probable case:

1. Onset of symptoms between 4-28 days after vaccination.
2. Platelets <150x 109/L or <50% from baseline .
3. Low or normal fibrinogen.
4. Evidence of thrombosis and D-Dimer 2-4mcg/mL or D-Dimer >4mcg/mL

Case categorization pathway of Vaccine-Induced Thrombosis and Thrombocytopenia



MINISTRY OF HEALTH
PUBLIC HEALTH DIRECTORATE
DCS-IMMUNIZATION GROUP

Adverse Events Following Immunization:(AEFI) DCS/EPI Program No 18 form 1 of 5

Case Report

Facility Name: _____ **Date:** ____/____/_____

This form is to be completed by the vaccinator/school staff/ health care worker providing vaccination and forwarded to the Immunization Group in Disease Control Section at Public Health Directorate, Hotline: 38817484, P.O. Box 42, Fax No. 279290 E-mail : immunization@health.gov.bh

Name:		**CPR No:**		**Nationality:**	
Address : Flat: House: Road: Block: Area : Mobile:					
Sex: Male ( ) Female ( )			Date of Birth: / /		
Date of Immunization: / / Interval to Symptoms Days ……. Hours …….					
Type of AEFI					
i. Local					
Injection Site abscess			Yes	No	Unknown
BCG Lymphadenitis			Yes	No	Unknown
Local reaction			Yes	No	Unknown
Pain ,Redness, at injection site			Yes	No	Unknown
Redness and swelling at injection site			Yes	No	Unknown
Joint Pain			Yes	No	Unknown
Joint Swelling			Yes	No	Unknown
ii. CNS					
Acute flaccid paralysis			Yes	No	Unknown
Encephalopathy, Encephalitis, Meningitis			Yes	No	Unknown
Seizure			Yes	No	Unknown
iii. Other					
Anaphylaxis			Yes	No	Unknown
Fever			Yes	No	Unknown
Toxic shock			Yes	No	Unknown
Others (specify Below)			Yes	No	Unknown
Immediate symptoms: (please circle)					
▪ Tachycardia	Yes	No	▪ Fainting	Yes	No
▪ Cough	Yes	No	▪ Itching at injection Site	Yes	No
▪ Cold extremities	Yes	No	▪ Difficulty breathing	Yes	No
▪ Vomiting	Yes	No	▪ Abdominal cramps	Yes	No
Late symptoms: (please circle)					
▪ Headache	Yes	No	▪ Change in behavior	Yes	No
▪ Rash	Yes	No	▪ Pain & swelling of joints	Yes	No
If symptoms resulted in absenteeism, state period of absenteeism (in days):					

Vaccine(s) given within one month of AEFIs								
Name of vaccine	***Details of Vaccine***					***Details of diluents if used***		
	Dose No.	Lot batch No.	Man ufact urer	Exp. Data	Storage Temp.	Lot No.	Manufacturer	Exp. Data
Health worker who gave the vaccine(s)	***Previous history of same reaction to vaccine in the same patient***					***Site of vaccine***		
Name:						Thigh	Deltoid	Buttock
Examined: Y N								
Findings:								
Treatment required	Y	N	Unknown	If "Yes" specify				
Hospitalized	Y	N	Unknown	If "Yes" specify hospital				
Death	Y	N	Unknown					
Specimen collection and dispatch a. Specimen type …….. b. Date collected …….. c. Dispatched to ……... d. Date of Dispatch / /								

Please Note*: All vaccine recipients should be observed minimum for 30 minutes after administration of vaccine.*

Name and signature of Teacher/ **health care provider***:* _____

Name and signature of staff: _____