



## Report N° 12

Adverse Events Following  
Immunization with COVID-  
19 Vaccines in Lebanon

# SUPPLEMENT

## ADVERSE EVENTS OF SPECIAL INTEREST AFTER COVID-19 VACCINES

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## List of Abbreviations

<b>AEFI</b>	Adverse Event Following Immunization
<b>AESI</b>	Adverse Event of Special interest
<b>LNPVP</b>	Lebanese National Pharmacovigilance Program
<b>MoPH</b>	Ministry of Public Health
<b>NITAG</b>	National Immunization Technical Advisory Group
<b>SPEAC</b>	Safety Platform for Emergency vACcines
<b>VITT</b>	Vaccine-Induced Immune Thrombotic Thrombocytopenia
<b>WHO</b>	World Health Organization

## Background

The development of safe and effective vaccines was key in containing the SARS-CoV-2 pandemic. Despite rigorous safety evaluation during clinical development, they are, however, not completely free of risks, and occasional adverse events will occur following widespread vaccination. Following the authorization of novel COVID-19 vaccines, post-marketing surveillance has been conducted to monitor the safety of these new vaccines throughout the implementation of the immunization programs.

While reporting Adverse Events Following Immunization (AEFIs) to the Lebanese National Pharmacovigilance Program (LNPVP) has been an important component of post-marketing surveillance in Lebanon, reporting of Adverse Events of Special Interest (AESIs) for COVID-19 vaccines in the context of overall AEFI surveillance was essential to enable enhanced monitoring of pre-specified events which may otherwise not be captured or readily analyzed from a passive surveillance system.

As per the World Health Organization (WHO), an AESI is “a pre-specified medically-significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further special studies”<sup>1</sup>. In other words, AESIs are specific AEFIs that have been identified by regulatory authorities or public health organizations as important to monitor due to their potential seriousness or impact on public health.

## AESI Selection Criteria

A list of AESIs for COVID-19 vaccines was identified by the international health authorities based on a theoretical rationale for a possible association with COVID-19 vaccines<sup>2</sup>. Such events are shortlisted if there is a:

- Proven association with immunization that is true for most, if not all, vaccines;

- Proven association with a known vaccine platform or adjuvant that is being used in any COVID-19 vaccine;
- Theoretical concern based on immunopathogenesis of COVID-19 disease;
- Theoretical concern related to viral replication during COVID-19 infection; or
- Theoretical concern because it has been demonstrated in an animal model with one or more candidate vaccine platforms.

As such and in response to the pandemic, a set of AESIs for COVID-19 vaccines was established and prioritized by the Coalition for Epidemic Preparedness and Innovation (CEPI) in collaboration with the Brighton Collaboration through their Safety Platform for Emergency vACcines (SPEAC) project. Internationally agreed case definitions for each of the AESIs enable consistent assessment and diagnosis of AESIs across multiple healthcare networks and countries.

*Table 1: COVID-19 Priority AESI List, SPEAC Project (October, 2022)*

SPEAC Pre-Identified AESIs	
Acute respiratory distress syndrome	Acute pancreatitis
Multisystem inflammatory syndrome	Rhabdomyolysis
Myocarditis	Pericarditis
Thrombosis and Thromboembolism	Subacute thyroiditis
Hemorrhagic disorders including DIC	Anaphylaxis
Anosmia - Ageusia	Thrombocytopenia
Chilblain – like lesions	Generalized convulsion
Erythema multiforme	Acute disseminated encephalomyelitis
Single Organ Cutaneous Vasculitis	Guillain Barré Syndrome
Acute kidney injury	Acute aseptic arthritis
Acute liver injury	Aseptic meningitis
Delayed hypersensitivity reaction <sup>6</sup>	Encephalitis / Encephalomyelitis
Extensive limb swelling	Bell's Palsy
Dizziness and tinnitus	Vaccine associated enhanced disease
Facial swelling in individuals with dermal fillers	Thrombocytopenia and Thrombosis Syndrome
Capillary Leak Syndrome (Flare up in individuals with prior history of capillary leak syndrome)	Immune Thrombocytopenia (ITP)

## Identification of AESIs

Pre-specified AESIs are usually identified through an active surveillance process and then investigated and analyzed to identify signals, and to estimate the association between the use of the vaccine and the incidence of those AESIs<sup>1</sup>. Specifically, sentinel surveillance is a useful safety surveillance study design intended for AESI identification that can result in signal surveillance and detection.

## AESI Monitoring in Lebanon

A list of AESIs has been prepared by the Serious AEFI Special Committee<sup>3</sup> [National Immunization Technical Advisory Group (NITAG)] committee in Lebanon. The latter was mainly extracted from the WHO- Safety Platform for Emergency vACcines (SPEAC) Project list of AESIs (2) and adapted to the documented AEFIs passively-reported to the LNPVP following the deployed COVID-19 vaccines in Lebanon.

*Table 2: AESIs identified in Lebanon*

AESIs identified in Lebanon	
1	Coagulation Disorders
2	Acute Cardiovascular Injury
3	Guillain-Barré Syndrome
4	Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)
5	Bell's Palsy
6	Subacute Thyroiditis

The rationale behind the choice of AESIs is based on the following criteria:

- Previous incidence following the deployed COVID-19 vaccines in other countries: Canada (aggregated in the “Ontario Adverse Events Following COVID-19 Vaccines” report)<sup>4</sup> .
- Previous cases passively-reported to the Lebanese National Pharmacovigilance Program (LNPVP) following the deployed COVID-19 vaccines in Lebanon (aggregated in the Ministry of Public Health (MoPH)’s “Serious Adverse Events Following Immunization with COVID-19 Vaccines in Lebanon” internal report from February 14th, 2021, till June 30th, 2022) .

## Brighton Collaboration Case Definitions

### 1. Coagulation Disorders

A thrombus is a localized hemostatic plug or blood clot in a blood vessel. Thrombosis occurs when a thrombus causes blockage in the blood vessel. This blockage can result in partial or complete blood flow obstruction either in larger vessels such as arteries or veins, or smaller vessels collectively termed as microcirculation. Thrombosis can affect both veins (venous thrombosis) and arteries (arterial thrombosis), leading to serious health consequences such as deep vein thrombosis, pulmonary embolism, stroke, or heart attack<sup>5</sup>.

### 2. Acute Cardiovascular Injury

Myocarditis and/or pericarditis (also known as myopericarditis) are inflammatory diseases involving the myocardium (with non-ischemic myocyte necrosis) and/or the pericardial sac. They can be caused by various factors, including viral infections, bacterial or fungal infections, autoimmune diseases, certain medications, or exposure to toxins<sup>6</sup>.

### 3. Guillain-Barré Syndrome

Guillain–Barré syndrome constitutes an important proportion of acute flaccid paralysis cases world-wide. It is a condition characterized by various degrees of weakness, sensory abnormalities, and autonomic dysfunction due to damage to peripheral nerves and nerve roots. It is considered to be an immune-mediated disorder resulting from the generation of autoimmune antibodies and/or inflammatory cells which cross-react with epitopes on peripheral nerves and roots, leading to demyelination or axonal damage or both<sup>7</sup>.

### 4. Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)

Vaccine-Induced Immune Thrombotic Thrombocytopenia is characterized by the occurrence of blood clotting (thrombosis) combined with low platelet counts (thrombocytopenia), typically within a few days to a few weeks after vaccination. The condition is believed to involve an immune response triggered by the vaccine that leads to abnormal clotting in various parts of the body<sup>8</sup>.

### 5. Bell's Palsy

Bell's Palsy (idiopathic peripheral facial palsy) is a clinical diagnosis characterized by the sudden onset of unilateral facial weakness or paralysis of upper and lower muscles of one side of the face with no apparent cause. It can be observed in the context of many conditions, including infections, traumatic injury, malignancy, autoimmune disorders, and hormonal changes during pregnancy<sup>9</sup>.

### 6. Subacute Thyroiditis

Subacute Thyroiditis is an inflammatory disease of the thyroid caused by viral infection or autoimmune reactions, associated with signs and symptoms of either hyperthyroidism (thyrotoxicosis) or hypothyroidism. It is often associated with viral infections<sup>10</sup>.





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