COVID-19

CONSOLIDATED REGIONAL AND GLOBAL INFORMATION ON ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) AGAINST COVID-19 AND OTHER UPDATES

Twenty-eighth report

WASHINGTON, DC

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CONTENTS

CANADA

As of 15 October 2021, 39,897,633 doses of the Pfizer-BioNTech COVID-19 vaccine, 14,010,806 doses of the Moderna vaccine, and 2,792,104 doses of the AstraZeneca/Covishield vaccine (AstraZeneca vaccine manufactured by the Serum Institute of India) had been administered.

A total of 20,032 individual reports of one or more adverse events following immunization (AEFI) (0.026% of doses administered) were received. Of these reports, 5,161 involved serious adverse events (0.009% of doses administered).

In all, there were 53,709 reported AEFI, of which 20,032 involved one or more events. The most frequently reported adverse events were non-serious events such as paresthesia, injection-site pain, headache, pruritus, dyspnea, fatigue, urticaria, nausea, etc.

Number of reports and reporting rate of adverse events (per 100,000 doses administered), by vaccine, as of 15 October 2021

Vaccine	Number of reports of non-serious AEFI		Number of reports of serious AEFI		Total number of reports of AEFI	
	N	Rate/100,000 doses administered	N	Rate/100,000 doses administered	N	Rate/100,000 doses administered
Pfizer-BioNTech	7,843	19.66	3.,457	8.66	11,300	28.32
Moderna	5,051	36.05	912	6.51	5,963	42.56
Covishield/AstraZeneca	1,899	68.01	664	23.78	2,563	91.79
Unknown	33	-	173	-	206	
Total	14,826	25.89	5,206	9.09	20,032	34.98

Number of reports and reporting rate of the main serious AEFI (per 100,000 doses administered), by vaccine, as of 15 October 2021			
Vaccine	**Pfizer-BioNTech**	**Moderna**	**Covishield/AstraZeneca**
Anaphylaxis	314 (0.79/100,000)	89 (0.64/100,000)	16 (0.57/100,000)
Thrombosis with thrombocytopenia syndrome (TTS)	16 (0.04/100,000)	5 (0.04/100,000)	61 (2.18/100,000)
Guillain-Barré syndrome	34 (0.09/100,000)	19 (0.14/100,000)	32 (1.15/100,000)
Capillary leak syndrome	-	-	2 (0.07/100,000)
Myocarditis/pericarditis	573 (1.44/100,000)	357 (2.55/100,000)	21 (0.75/100,000)
Bell's palsy/facial paralysis	406 (1.02/100,000)	122 (0.87/100,000)	44 (1.58/100,000)
Fatal events	197* post-vaccination deaths		
** Following a medical review of the 197 deaths, it was determined that 75 were not linked to administration of the COVID-19 vaccine, while 39 are still under investigation; 6 (cases of TTS) are considered to be potentially attributable to the vaccination, and 77 could not be classified due to insufficient information.*			

An analysis of 951 of the 956 cases of myocarditis/pericarditis, with indication of the vaccine administered, is shown below:

Vaccine	Total number of cases (rate per 100,000 doses administered)	By sex (median age)		Number of reports, by dose administered		
		Number of women (median age)	Number of men (median age)	1st	2nd	Unknown
Pfizer-BioNTech*	573 (1.44)	205 (39 years)	358 (22 years)	231	258	84
Moderna**	357 (2.55)	90 (34 years)	261 (26 years)	77	241	39
Covishield/ AstraZeneca	21 (0.75)	Not available	Not available	Not available	Not available	Not available

** In seven cases, the sex of the individual was not specified, and in two cases the sex was indicated as "other."*

*** In five cases, the sex of the individual was not specified, and in one case the sex was indicated as "other."*

Source: Public Health Agency of Canada. Canadian COVID-19 vaccine safety report. Ottawa: Public Health Agency of Canada; October 22, 2021. https://health-infobase.canada.ca/covid-19/vaccine-safety/. Data reproduced by PAHO/WHO.

CHILE

According to Chile's Ministry of Science, Technology, Knowledge, and Innovation, between 24 December 2020 and 14 August 2021, 26,735,775 doses of COVID-19 vaccines were administered in the country: 18,939,998 doses (70.8%) of the CoronaVac vaccine, 6,813,756 doses (25.5%) of the Pfizer-BioNTech vaccine, 472,202 doses (1.8%) of the AstraZeneca vaccine, and 509,819 doses (1.9%) of the Convidencia/CanSino Biologics Inc. vaccine.

During the same period, there were 11,150 reports of AEFI, as described below:

Vaccine	Number of reports of AEFI	AEFI reporting rate per 100,000 doses administered	Number of reports of serious AEFI	Reporting rate of serious AEFI per 100,000 doses administered
AstraZeneca	432	91.9	15	3.18
Convidencia/CanSino	188	37.1	9	1.77
CoronaVac	5,722	30.2	276	1.45
Pfizer-BioNTech	4,385	64.4	121	1.78
Not indicated	423	-	-	-
Total	11,150	41.7	422	1.58

Of the 10,727 reported cases for which the administered vaccine was known, 7,907 (73.7%) were in women and 2,724 (25.4%) in men; in 96 cases, the sex of the individual was unknown (0.9%).

The group registering the highest number of events consisted of adults between the ages of 16 and 39.

Among the most frequently reported clinical manifestations for the three vaccines were: pain at the injection site, headache, fever, malaise, and myalgia.

The following adverse events of special interest were reported for the vaccines indicated below:

	Vaccine/Rate of AESI per 1,000,000 doses administered			
Adverse Event of Special Interest (AESI)	**AstraZeneca**	**Convidencia/CanSino**	**CoronaVac**	**Pfizer-BioNTech**
Anaphylaxis	2.12	3.92	7.66	7.48
Seizures	12.71	3.92	1.95	2.94
Bell's palsy	-	-	1.74	1.91
Anosmia	-	3.92	1.48	1.17
Myocarditis	-	1.96	0.11	1.03
Guillain-Barré syndrome	-	3.92	0.26	0.59
Thromboembolism	10.59	-	0.69	0.44

Source: National Institute of Health of Chile; 15 October 2021. Available at: https://www.ispch.cl/wp-content/uploads/2021/10/20211015-Sexto-informe-estad%C3%ADstico-ESAVI-vacunas-COVID_VF.pdf. Data reproduced by PAHO/WHO.

UNITED STATES

- As of the date of this report, two cases of TTS had been reported to VAERS (for the Moderna vaccine) following the administration of more than 388 million doses of mRNA vaccines in the United States. Based on the available information, there does not appear to be an increased risk of TTS following vaccination with mRNA COVID-19 vaccines.
- As of 13 October, more than 15.2 million doses of the J&J/Janssen COVID-19 vaccine had been administered. The Centers for Disease Control and Prevention (CDC) and the Federal Drug Administration (FDA) have identified 47 confirmed reports of people who received this vaccine and subsequently developed TTS. Women under the age of 50 should be alerted to the increased risk of this

adverse event, though it is uncommon. This risk has not been observed in relation to the other available COVID-19 vaccines.

- Following administration of more than 15.2 million doses of the J&J/Janssen vaccine, there have been approximately 233 preliminary reports, as of 13 October 2021, of Guillain-Barré syndrome. These reported cases occurred two weeks after the vaccines had been administered, and were mostly in men, many of whom were 50 years old or older.
- As of 13 October, VAERS had received 1,638 reports of myocarditis or pericarditis in people 30 years old or younger who had received a COVID-19 vaccine. Most reported cases involved individuals who had received an mRNA-based vaccine (Pfizer-BioNTech or Moderna), and occurred particularly in male adolescents and young adults.
- Reports of deaths following vaccination with COVID-19 vaccines are rare. In the United States, more than 408 million doses of COVID-19 vaccine were administered between 14 December 2020 and 18 October 2021, during which time VAERS received 8,878 reports of deaths (0.0022%) among people who had received COVID-19 vaccines.

Source: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.

MEXICO

- On 6 October 2021, Mexico's Secretariat of Health published a report on AEFI that occurred after administration of COVID-19 vaccines. A total of 79,399,446 doses of vaccines were administered in Mexico between 24 December 2020 and 30 September 2021.
- As of 30 September 2021, 29,646 AEFI had been reported; these are disaggregated by vaccine in the following table:

Vaccine	Doses administered	Serious AEFI	Non-serious AEFI	Total AEFI	AEFI per 100,000 doses
Pfizer-BioNTech	25,416,970	275	17,594	17,869	70
AstraZeneca	29,157,558	258	6,987	7,245	25
SinoVac	13,906,520	106	1,611	1,717	12
Sputnik V	4,450,465	28	581	609	14
CanSino	5,122,301	57	1,291	1,348	26
Janssen	1,345,632	8	804	812	60
Unknown	-	4	18	22	-
Vaccinated abroad	-	2	22	24	-
TOTAL	79,399,446	738	28,908	29,646	37

- The highest proportion of serious (59.45%) and non-serious (73.12%) AEFI occurred in women. In terms of the distribution by age group, the non-serious AEFI occurred mostly in the 30- to 39-year-old age group, while serious AEFI occurred mostly in people over 60 years old (38.45%).
- The main signs and symptoms reported for non-serious AEFI were headache, 64.73% (18,784), injection-site pain or tenderness, 46.03% (13,357), and asthenia, 40.37% (11,717); while the most common serious AEFI reported were headache, 45.80% (349), asthenia, 37.80% (288), and dyspnea, 32.28% (246).

Source: https://www.gob.mx/cms/uploads/attachment/file/671870/REPORTE_ESAVI_2021_09.pdf.

Publications on potential safety signals identified with the use of COVID-19 vaccines

Cerebral venous sinus thrombosis and other thrombotic events following administration of viral vector-based COVID-19 vaccines: Systematic review and meta-analysis

On 5 October, a systematic review and meta-analysis of cerebral venous sinus thrombosis and other thrombotic events following administration of COVID-19 viral vector vaccines was published. The objective was to systematically evaluate the scientific literature on the proportion of cases of cerebral venous sinus thrombosis (CVST) among the cases of thrombosis with thrombocytopenia syndrome (TTS), and to evaluate its characteristics and outcomes. A systematic review and meta-analysis of clinical trials, cohort studies, case series, and registry-based studies was conducted, in order to assess (1) the pooled mortality rate of CVST, TTS-associated CVST, and TTS; and (2) the pooled proportion of patients with CVST among patients with any thrombotic event and TTS. Secondary outcomes comprised clinical characteristics of patients with post-vaccination thrombotic events. Sixty-nine studies were included in the qualitative analysis comprising 370

patients with CVST out of 4,182 patients with any thrombotic event associated with SARS-CoV-2 vector-based vaccine administration. Twenty-three studies were further included in the quantitative meta-analysis. Among TTS cases, the pooled proportion of CVST was 51% (95% CI: 36–66%; P = 61%). TTS was independently associated with a higher likelihood of CVST, when compared to non-TTS patients with thrombotic events after vaccination (OR: 13.8; 95% CI: 2.0-97.3; P = 78%). The pooled mortality rates of TTS and TTS-associated CVST were 28% (95% CI: 21–36%) and 38% (95% CI: 27–49%), respectively. Thrombotic complications developed within two weeks of exposure to vector-based SARS-CoV-2 vaccines (mean interval: 10 days; 95% CI: 8–12), and affected predominantly women under the age of 45 (69%, 95% CI: 60–77%), even in the absence of pro-thrombotic risk factors.

The authors conclude that approximately half of TTS cases present with CVST, while nearly one-third of TTS patients do not survive. Further research is required to identify independent predictors of TTS following adenovirus vector-based vaccination. In addition, the authors urge caution regarding the findings presented, since there is a greater tendency to publish information on cases with severe clinical manifestations.

Source: Palaiodimou L, Stefanou MI, Katsanos AH, et al. Cerebral Venous Sinus Thrombosis and Thrombotic Events After Vector-Based COVID-19 Vaccines: A Systematic Review and Meta-analysis. Neurology. 2021 Oct 5:10.1212/WNL.0000000000012896. doi: 10.1212/WNL.0000000000012896. Preprint Epub. PMID: 34610990. Available at: https://n.neurology.org/content/early/2021/10/05/WNL.0000000000012896.long.

Real-world safety data for the Pfizer BNT162b2 SARS-CoV-2 vaccine: historical cohort study

On 27 September, a cohort study conducted in Israel, with a control group, was published, whose objective was to analyze the presence of Bell's palsy, shingles, Guillain-Barré syndrome (GBS), and other neurological conditions after vaccination against COVID-19 (Pfizer BNT162b2 vaccine). Rates were compared between vaccinated and unvaccinated individuals. Individuals ≥16 years vaccinated with at least one dose of BNT162b2 were eligible for this historical cohort study, in a health maintenance organization insuring 1.2 million Israeli citizens. Each vaccinated person was matched to a non-vaccinated control by sex, age, population sector (general Jewish, Arab, ultra-orthodox Jewish), and comorbidities. Diagnosis of Covid-19 before or after vaccination was an exclusion criterion. The outcome was a diagnosis of Bell's palsy, GBS, herpes zoster, or symptoms of numbness or tingling, coded in the visit diagnosis field using ICD-9 codes. Diagnoses of Bell's palsy and GBS were verified by individual file review. Of 406,148 individuals vaccinated during the study period, 394,609 (97.2%) were eligible (11,539 were excluded). A total of 233,159 (59.1%) were matched with unvaccinated controls. Mean follow-up was 43 ± 15.14 days. In vaccinated and

unvaccinated individuals there were 23 versus 24 cases of Bell's palsy (RR 0.96, CI: 0.54–1.70), one versus zero cases of GBS, 151 versus 141 cases of herpes zoster (RR 1.07, CI: 0.85–1.35), and 605 versus 497 cases of numbness or tingling (RR 1.22, CI: 1.08–1.37), respectively. The authors note that in this study no association was found between vaccination and the clinical presentation of Bell's palsy, herpes-zoster, or GBS. Symptoms of numbness or tingling were more common among vaccinated individuals.

Source: Shasha D, Bareket R, Sikron FH, et al. Real-world safety data for the Pfizer BNT162b2 SARS-CoV-2 vaccine: historical cohort study. Clin Microbiol Infect. 2021 Sep 27:S1198–743X(21)00538–3. doi: 10.1016/j.cmi.2021.09.018. Preprint Epub. PMID: 34592420; PMCID: PMC 8479307. Available at: https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X(21)00538-3/fulltext.

Inclusions in the WHO Emergency Use Listing (EUL)

WHO added another production site for AstraZeneca's COVID-19 Vaxzevria vaccine to the Emergency Use Listing (EUL), as indicated below:

COVID-19 vaccine (EUL)	Authorized site added to the WHO/EUL		
	EUL holder*	Finished product (Countries)	Responsible NRA
Vaxzevria ChAdOx1-S (recombinant) AstraZeneca	AstraZeneca AB Sweden	Germany Australia Italy United Kingdom Republic of Korea USA	Health Canada

* Authorization holder

Responsible NRA: The NRA that first authorized the vaccine and that is responsible for oversight of the vaccine.

Source: WHO recommendation COVID-19 Vaccine (ChAdOx1-S ([recombinant]). Available at: https://extranet.who.int/pqweb/vaccines/who-recommendation-covid-19-vaccine-chadox1-s-recombinant_cnd.

U.S. Food and Drug Administration authorizes a booster dose of the COVID-19 vaccines of Moderna, Janssen, and Pfizer-BioNTech for certain at-risk populations

On 20 October 2021, the U.S. Food and Drug Administration (FDA), reported that it was authorizing a booster dose of COVID-19 vaccines in eligible populations, and that emergency use authorizations will be amended as follows:

- The use of a single booster dose of the Moderna COVID-19 vaccine may be administered at least 6 months after completion of the primary series to individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.
- The use of a single booster dose of the Janssen (Johnson and Johnson) COVID-19 vaccine may be administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older.

- The authorization of the Pfizer-BioNTech COVID-19 vaccine will be amended to indicate that a single booster dose of the vaccine may be administered at least 6 months after completion of the primary series to individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.

In addition, the FDA is authorizing the use of each of the available COVID-19 vaccines as a heterologous ("mix and match") booster dose in eligible individuals following completion of primary vaccination with a different available COVID-19 vaccine.

Source: FDA. Coronavirus (COVID-19) Update: FDA takes additional actions on the use of a booster dose for COVID-19 vaccines. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines

EMA ends rolling review of CVnCoV COVID-19 vaccine following withdrawal by CureVac AG

The European Medicines Agency (EMA) has ended the review of CVnCoV, CureVac AG's COVID-19 vaccine, after the company informed the Agency that it was withdrawing from the process. The CVnCoV vaccine contains a messenger RNA (mRNA) molecule that has instructions for making the spike protein. The mRNA is contained in tiny particles of fats (lipids) that prevent it from being broken down too quickly.

Since February 2021, EMA's Committee for Medicinal Products for Human Use (CHMP) has been reviewing data on CVnCoV as part of a rolling review, whereby the company submits data as they become available in order to speed up the evaluation of an eventual marketing authorization application. At the time of the company's withdrawal, EMA had received non-clinical (laboratory) data, data from ongoing clinical studies, data on the quality and manufacturing process of the vaccine, and the risk management plan.

Although EMA was speeding up its review of the data, some questions about the vaccine's quality, impacting the benefit-risk balance of the vaccine, and the fact that results of the main study showed only a modest vaccine efficacy in adults still remained to be satisfactorily addressed.

The company stated that it withdrew because it decided to focus its efforts on a different COVID-19 vaccine development program. The withdrawal means that EMA is no longer reviewing data on the vaccine and will not conclude this review.

People who have taken part in clinical trials with CVnCoV and have questions about their vaccination status, the EU digital COVID certificate, or travel restrictions associated with vaccination should contact the relevant authorities in their country of residence.

Source: EMA ends rolling review of CVnCoV COVID-19 vaccine following withdrawal by CureVac AG. Available at: https://www.ema.europa.eu/en/news/ema-ends-rolling-review-cvncov-covid-19-vaccine-following-withdrawal-curevac-ag.

CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS

Recommendations of the WHO Strategic Advisory Group of Experts (SAGE) on Immunization regarding WHO/EUL COVID-19 vaccines

From 4 to 7 October 2021, a meeting of the WHO Strategic Advisory Group of Experts (SAGE) on Immunization was held. For booster doses of COVID-19 vaccines included in the WHO Emergency Use Listing (EUL), they recommended the following:

- Moderately and severely immunocompromised individuals should be offered an additional dose of all WHO/EUL COVID-19 vaccines as part of an extended series since these individuals are less likely to respond adequately to vaccination following a primary vaccine series, and are at high risk of severe COVID-19.

- For the Sinovac and Sinopharm inactivated vaccines, an additional (third) dose of the homologous vaccine should be offered to persons age 60 and above as part of an extended primary series. The use of a heterologous platform vaccine for the additional dose may also be considered based on vaccine supply and access considerations. When implementing this recommendation, countries should initially aim at maximizing two-dose coverage in that population, and thereafter administer the third dose, starting in the oldest age groups.

- In relation to the global COVID-19 vaccination strategy, drawing on SAGE's June 2021 recommendation, and given the progression of the pandemic, the strategy prioritizes vaccination of high-risk populations and all adults, and fully commits to ensure that by mid-2022 70% of the world's population is fully vaccinated.

Source: https://cdn.who.int/media/docs/default-source/immunization/sage/2021/october/sage_oct2021_meetinghighlights.pdf?sfvrsn=3dcae610_15.

Mix-ups between the influenza (flu) vaccine and COVID-19 vaccines

On 15 October 2021, the U.S. Institute for Safe Medication Practices (ISMP) indicated that since the influenza vaccine (2021-2022 season) became available in September 2021, it has received reports of 16 cases of accidental influenza and COVID-19 vaccines mix-ups. Most cases involved patients who consented to a flu vaccine but received one of the COVID-19 vaccines instead. In three cases, patients received the flu vaccine instead of the intended COVID-19 vaccine. All cases occurred in community/ambulatory care pharmacies, and most were reported by the vaccinated individuals.

Among the possible causal factors, the Institute cites the following:

- Increased demand for and co-administration of the vaccines: Flu season is already a busy vaccination time for community pharmacies, and given the approval of COVID-19 vaccinations, pharmacies have had a hard time meeting the demand for vaccinations. In addition, the ISMP notes that the ability to administer the flu and COVID-19 vaccines during the same visit may be a contributing factor.
- Syringes near each other: Two vaccine providers indicated that they had picked up the wrong syringe. Bringing both vaccines into a patient vaccination area, when they are not needed, can lead to confusion at the time of administration.
- Unlabeled syringes: While some flu vaccines come in manufacturer-prefilled syringes, which are identified with their respective labels, COVID-19 vaccines are available in multiple-dose vials, and must be prepared in a syringe for administration to patients. It is possible that these prepared COVID-19 syringes were not labeled. Also, the identity of the vaccine may not have been verified at the time of administration.
- Distractions at the time of administration: In one case, the vaccine provider told the patient that he had been distracted by their conversation. Interruptions and other distractions can lead to confusion at the time of vaccination.
- Staffing shortages and increased demand for vaccination.

In this regard, the ISMP recommends that the factors indicated above be considered, in order to avoid possible errors and confusion when administering influenza and COVID-19 vaccines. Further information available at the following link.

Source: https://www.ismp.org/alerts/mix-ups-between-influenza-flu-vaccine-and-covid-19-vaccines.

Adverse Events of Special Interest (AESI) and Related Risks: Thrombocytopenia

Definition (1): Thrombocytopenia (TP) is an abnormally low platelet count. Pathogenic mechanisms include insufficient production, abnormal distribution, or excessive destruction of platelets. A platelet count below $150\times10^{9}/L^{-1}$ is the most commonly used reference value in the hematological literature. In vaccine safety studies, the threshold criteria for thrombocytopenia ranged from 100 to $150\times10^{9}/L^{-1}$, and use of this value is supported by platelet count reference interval studies in different populations, representing approximately two standard deviations below average in a normal population. TP it is also known as immune thrombocytopenia (ITP), recognizing underlying immunological pathogenic causes. In primary IPT, no etiology is identified and is a reason for exclusion. Secondary IPT is recognized as an autoimmune thrombocytopenia that occurs in the course of another disease, or that follows an exogenous immune stimulus such as an infection, drug, or vaccine.

Risk factors and diseases: Age, gender, genetics, seasonal, geographic. For secondary IPT or autoimmune disease, factors may include hematological malignancy, immunodeficiency, or vitamin B9 or B12 deficiency. For non-immune mediated thrombocytopenia or decreased platelet production: bone marrow replacement, bone marrow failure, certain neoplasms, inheritance or transmission from parents to children (rare), alcohol consumption and alcoholism, autoimmune disease, bone marrow diseases, chemotherapy and radiotherapy, splenomegaly caused by cirrhosis of the liver or Gaucher disease, exposure to toxic chemicals, protozoan infections, dengue, malaria, scrub typhus, rickettsial infections, meningococcus, leptospira, and certain viral infections that present with fever and thrombocytopenia.

Medications: Certain medications that occasionally induce TP include: heparin, quinine, trimethoprim/sulfamethoxazole, glycoprotein IIb/IIIa inhibitors, hydrochlorothiazide, carbamazepine, chlorpropamide, ranmpinidine, antibiotics, and drugs used to treat epilepsy, heart problems, hepatitis C, cytomegalovirus (CMV), Epstein-Barr virus (EBV), and human immunodeficiency virus (HIV).

Vaccines: Clinically apparent TP following vaccination is rare. A transient but sometimes sharp drop in platelet count has been reported after vaccination against hepatitis B, hepatitis A, influenza, diphtheria-tetanus-pertussis (DTwP), diphtheria/tetanus/acellular pertussis (DTaP), haemophilus influenzae type b (Hib), measles, mumps, and rubella (MMR), and measles, mumps, rubella, varicella (MMRV). The median interval between immunization with MMR vaccine and symptom onset is 12 to 25 days (range one to 83 days), with most post-immunization TP episodes resolving within three months, although low platelet counts rarely persist for more than six months.

Sources:

1. Barbara Law SO2- D2.5.2.1 - AESI Case Definition Companion Guide for 1st Tier AESI, Thrombocytopenia, Work Package: WP2 Standards and tools V1.0 – February 8th, 2021, Nature: Report | Diss. level: Public. https://brightoncollaboration.us/wp-content/uploads/2021/03/SPEAC_D2.5.2.1-Thrombocytopenia-Case-Definition-Companion-Guide_V1.0_format12065-1.pdf.
2. Robert Wise, Jan Bonhoeffer, Judy Beeler, Hugo Donato, Peter Downie, Dana Matthews, et al. Thrombocytopenia: Case definition and guidelines for collection, analysis, and presentation of immunization safety data, Vaccine, Volume 25, Issue 31, 2007, Pages 5717–5724, ISSN 0264–410X. https://pubmed.ncbi.nlm.nih.gov/17493712/.
3. Cleveland Clinic, thrombocytopenia. Last reviewed by a Cleveland Clinic medical professional on 11/23/2020. Thrombocytopenia: Causes, Symptoms & Treatment (clevelandclinic.org).
4. Wolfgang Miesbach W, Makris M. COVID-19: Coagulopathy, Risk of Thrombosis, and the Rationale for Anticoagulation. Clin Appl Thromb Hemost. 2020 Jan-Dec; 26:1076029620938149. doi:10.1177/1076029620938149. PMID: 32677459; PMCID: PMC7370334.
5. David J. Kuter. Thrombocytopenia: Other Causes. Last full review/revision Jun 2020 | Content last modified Jun 2020. MSD Professional Version.
6. Pan American Health Organization (PAHO). Handbook for the Surveillance of Events Allegedly Attributable to Vaccination or Immunization (ESAVI) in the Region of the Americas.
7. Brazil. Ministry of Health, Brazil Manual de vigilância epidemiológica de eventos adversos pós-vacinação, – 4. ed. – Brasília: Ministério da Saúde, 2014. 340 p.: il. https://bvsms.saude.gov.br/bvs/publicacoes/manual_vigilancia_epidemiologica_eventos_adversos_pos_vacinacao.pdf.
8. Veronica Hackethal, Vaccines and Rare Clotting Disorders: What is the Link? Causal relation appears possible, but evidence still indicates it is extremely rare, Enterprise & Investigative Writer, MedPage Today March 25, 2021.