REPORT N°11

ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH COVID-19 VACCINES IN LEBANON

COVID-19 Vaccines - Lebanon

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February 14, 2021 - June 30, 2022

INDEX

EXECUTIVE SUMMARY Page 3

BACKGROUND Page 4

HIGHLIGHTS Page 4

REPORTING OVERVIEW Page 6

a. Global Analysis
b. Demographics
c. Non-Serious Adverse Events Following Immunization
d. Serious Adverse Events Following Immunization
e. Adverse Events Following Immunization in Pregnant Women
f. Adverse Events Following Immunization in Adolescents
g. Safety Signals

DESCRIPTION OF SERIOUS ADVERSE EVENTS FOLLOWING IMMUNIZATION Page 20

COMPARISON OF AEFIS WITH COVID-19 VACCINES IN LEBANON WITH INTERNATIONAL DATA Page 21

CONCLUSION Page 23

TECHNICAL NOTES Page 23

CAVEAT Page 25

BIBLIOGRAPHY Page 25

EXECUTIVE SUMMARY

This executive summary provides an overview of Adverse Events Following Immunization (AEFIs) that were temporally associated (i.e., occurred after administration of the vaccine) to the five COVID-19 vaccines (Pfizer-BioNTech Vaccine, AstraZeneca Vaccine, Sputnik V Vaccine, Moderna Vaccine, and Sinopharm Vaccine) available in Lebanon during the mass campaign immunization between February 14th, 2021, and June 30th, 2022. According to the World Health Organization (WHO), an AEFI is any untoward medical occurrence that follows immunization and does not necessarily have a causal relationship with the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

The following information summarizes COVID-19 vaccines doses since their first deployment in Lebanon, from February 14th, 2021, until June 30th, 2022:

TOTAL NUMBER OF REGISTERED PERSONS 6,243,469	**TOTAL ADMINISTERED DOSES** 5,427,072 (86.9%)	**FIRST DOSE** 2,561,338 (47.2%)	**SECOND DOSE** 2,253,619 (41.52%)	**THIRD DOSE** 601,949 (11.1%)
TOTAL PFIZER-BIONTECH DOSES 4,500,089 (82.92%)	**TOTAL ASTRAZENECA DOSES** 720,793 (13.28%)	**TOTAL SPUTNIK V DOSES** 123,740 (2.28%)	**TOTAL MODERNA DOSES** 49,817 (0.91%)	**TOTAL SINOPHARM DOSES** 19,228 (0.35%)

As per the COVID-19 vaccination dashboard provided by IMPACT platform on June 30th, 2022

Data related to dose 4 is not reported

All percentages are calculated with respect to the total administered doses

BACKGROUND

Within the scope of the AEFI surveillance related to the available COVID-19 Vaccines in Lebanon, the Pharmacovigilance (PV) Program established a procedure for the management of reported AEFIs. Vaccine recipients experiencing any AEFI can report through one of the following means: 1214 Hotline Call Center, IMPACT Platform, Vaccination Sites/Hospital Sites through "Kobo toolbox: AEFIs Software for reporting" or by direct contact with the PV program, and other sources including Preventive Medicine, Epidemiology Surveillance Program, Health Education, other departments from the Ministry of Public Health (MoPH) and the Marketing Authorization Holder (MAH). A case report refers to a report received by the PV Program which pertains to one individual vaccine recipient who reported at least one adverse event after receiving the COVID-19 vaccine (i.e., temporally associated with the vaccine). All case reports are screened and validated for data completion. Incomplete or inconsistent case reports are followed-up directly with the initial reporter. The case reports are classified as serious or non-serious cases. The non-serious case reports are entered directly into the national web-based report management system, VigiFlow, while serious cases go through a follow–up/ investigation, causality assessment and validation by the Serious AEFI Special Committee before they are entered into VigiFlow. The surveillance aims to establish a rigorous safety profile regarding the COVID-19 vaccines administered in Lebanon.

HIGHLIGHTS

- A total of 7,029 case reports and 25,484 AEFIs were received following the administration of 5,427,072 doses of COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik V, Moderna, and Sinopharm) in Lebanon between the 14th of February 2021 and the 30th of June 2022:
  - This is equivalent to a reporting rate of 1.30 case reports and 4.70 AEFIs per 1,000 doses administered
  - This represents an increase of 111 case reports and 376 AEFIs in comparison with the previous report dated from February 14th, 2021 to April 15th, 2022
  - The age group of vaccine recipients who mostly reported AEFIs was between 18 and 44 years old (54.8%), with females reporting more than males (60.8% vs. 39.2%) (Table 5)
  - Most of the reporters were vaccine recipients (83.4%) (Table 6)

- The 7,029 case reports were received through one of the following means (Table 1):
  - IMPACT Platform: 3,845 case reports (54.7%)
  - 1214 Hotline Call Center: 2,087 case reports (29.7%)
  - Vaccination Sites/Hospital Sites through "Kobo toolbox: AEFIs Software for reporting" or by direct contact with the PV program: 946 case reports (13.5%)
  - Marketing Authorization Holder (MAH): 81 case reports (1.1%)
  - Other reporting sources which may include Preventive Medicine, Epidemiology Surveillance Program, Health Education, and other departments from the MoPH: 70 case reports (1.0%)

- Out of the 7,029 case reports (Table 2):
  - 5,285 case reports were associated with dose 1 of vaccination (75.20%)
  - 1,429 case reports were associated with dose 2 of vaccination (20.33%)
  - 266 case reports were associated with dose 3 of vaccination (3.78%)
  - 49 case reports were missing this information (0.69%)

- The 7,029 case reports were received from 8 governorates in Lebanon (Mount Lebanon, Beirut, North Lebanon, Bekaa, South Lebanon, Nabatiyeh, Akkar, and Baalbeck-Hermel). Out of the 7,029 case reports (Table 3):
  - 2,890 (41.12%) were from Mount Lebanon
  - 2,066 (29.39%) were from Beirut
  - 726 (10.32%) were from North Lebanon
  - 396 (5.63%) were from South Lebanon
  - 251 (3.57%) were from Bekaa
  - 210 (2.98%) were from Nabatiyeh
  - 141 (2.01%) were from Akkar
  - 96 (1.36%) were from Baalbeck-Hermel
  - 253 (3.59%) were missing this information

- Out of the 7,029 case reports (Figure 3, Table 4):
  - 6,515 case reports were non-serious (92.69% of total case reports)
  - 514 case reports included serious AEFIs (7.31% of total case reports) as per the WHO definition (refer to Technical Notes for serious cases definition as per WHO), out of which:
    - 371 case reports included serious AEFIs that did not require hospitalization nor lead to death. These were identified as other medically important events (5.28% of total case reports)
    - 143 case reports resulted in either hospital admission or death representing 2.03% of all case reports and a reporting rate of 0.026 per 1,000 doses of vaccines

- Of the total received AEFIs, the most reported AEFIs by System Organ Class (SOC) with the five COVID-19 vaccines available in Lebanon were (Table 13):
  - General Disorders and Administration Site Conditions (82.8% of total reported AEFIs per SOC)
  - Nervous System Disorders (44.7% of total reported AEFIs per SOC)
  - Gastrointestinal Disorders (26.2% of total reported AEFIs per SOC)

- Of the total received non serious AEFIs (6,515 case reports), the 5 most frequently reported AEFIs with the five COVID-19 vaccines available in Lebanon were (Table 7):
  - Injection site pain (42.1%)
  - Fatigue (40.6%)
  - General pain which may correspond to body pain or joint pain (40.0%)
  - Headache (36.4%)
  - Pyrexia (32.6%)

- The most frequently reported non-serious AEFIs per vaccine were (Table 8, 9, 10, 11 and 12):
  - Injection site pain following the Pfizer-BioNTech Vaccine (36.3% of total reported AEFIs).
  - Fatigue following the AstraZeneca Vaccine (56.2% of the total reported AEFIs), the Sputnik V Vaccine (66.2% of the total reported AEFIs), and the Sinopharm Vaccine (50.0% of the total reported AEFIs).
  - Pain following the Moderna Vaccine (38.6% of total reported AEFIs).

REPORTING OVERVIEW

a. Global Analysis

All data presented below will include AEFIs of case reports related to the five COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik V, Moderna, and Sinopharm).

Table 1 summarizes the case reports by reporting means: 1214 Hotline Call Center, IMPACT Platform, Vaccination Sites/Hospital Sites through "Kobo toolbox: AEFIs Software for reporting", Marketing Authorization Holder (MAH) or direct contact with the PV program, and other sources including Preventive Medicine, Epidemiology Surveillance Program, Health Education, other departments from the MoPH.

Table 1: Summary of case reports by means of reporting

Means of Reporting	IMPACT Platform	1214 Hotline	Vaccination Sites/ Hospital Sites	MAH	Others§
Number of Case Reports	3,845	2,087	946	81	70
Percentage	54.7%	29.7%	13.5%	1.1%	1.0%

§MAH was included under others in report 10, due to the low number of received cases during that period.

Table 2 classifies the 7,029 reported cases according to their occurrence after the 1st, 2nd, and 3rd dose of COVID-19 vaccines. Out of these 7,029 case reports, 5,285 case reports (75.2%) were after the 1st dose, 1,429 case reports (20.33%) were after the 2nd dose, and 266 case reports (3.78%) were after the 3rd dose. The remaining 49 case reports (0.69%) were missing the dose number.

Table 2. Summary of case reports* and AEFIs according to received dose**

	Total Doses		Dose 1		Dose 2		Dose 3	
All Vaccines Combined	**Case Reports (%)**	**AEFIs (%)**	**Case Reports (%)**	**AEFIs (%)**	**Case Reports (%)**	**AEFIs (%)**	**Case Reports (%)**	**AEFIs (%)**
Pfizer-BioNTech	4,421 (63.0)	13,749 (53.95)	2,965 (67.1)	8,530 (44.5)	1,181 (26.71)	4,408 (82.34)	238 (5.38)	722 (88.4)
AstraZeneca	2,310 (32.8)	10,538 (41.35)	2,127 (92.1)	9,889 (51.6)	170 (7.36)	585 (10.9)	2 (0.08)	9 (1.1)
Sputnik V	235 (3.3)	986 (3.86)	175 (74.46)	684 (3.57)	60 (25.54)	302 (5.64)	0	0
Moderna	47 (0.67)	154 (0.6)	8 (17.02)	22 (0.11)	12 (25.53)	40 (0.75)	26 (55.32)	85 (10.42)
Sinopharm	16 (0.23)	57 (0.22)	10 (62.5)	39 (0.20)	6 (37.5)	18 (0.33)	0	0
Total	7,029 (100)	25,484 (100)	5,285 (75.2)	19,164 (75.2)	1,429 (20.33)	5,353 (21.0)	266 (3.78)	816 (3.2)

49 case reports were missing the dose number (0.69%)

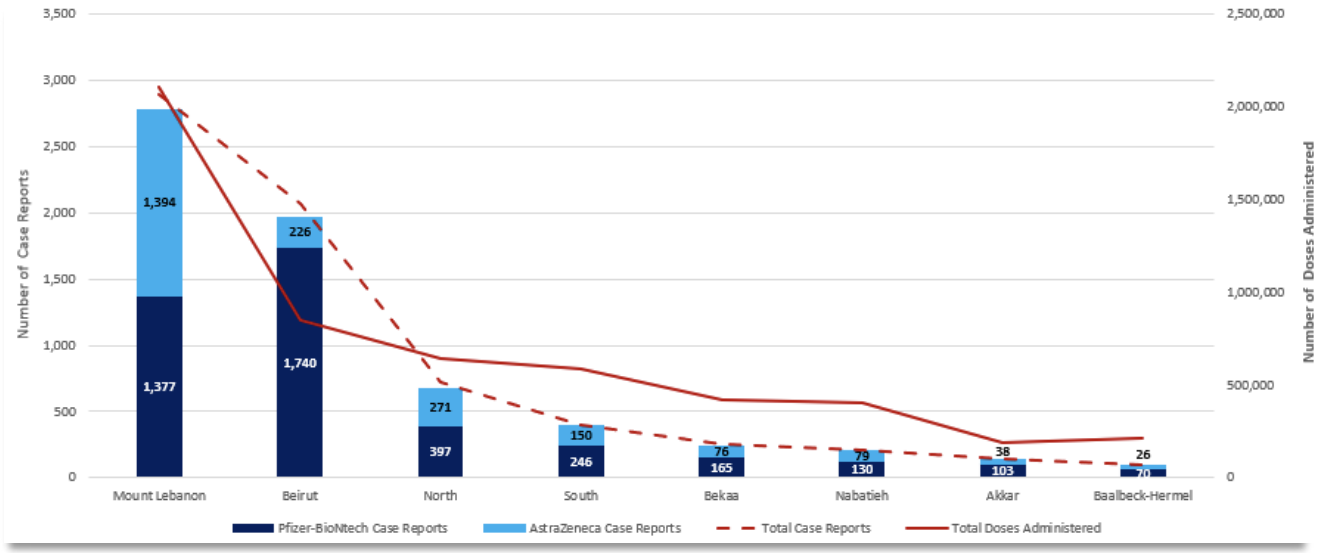
** 151 AEFIs were missing dose number (0.60%)*

Table 3 represents the distribution of the 7,029 reported cases and administered doses over the 8 governorates in Lebanon (Mount Lebanon, Beirut, North Lebanon, Bekaa, South Lebanon, Nabatiyeh, Akkar, and Baalbeck-Hermel) from February 14th, 2021, till June 30th, 2022. The geographical division of Lebanon and all the data pertaining to each governorate are retrieved from the IMPACT platform.

Table 3. Summary of administered doses and case reports^° per governorate

	Total Dose Administered		Total Case Reports	
Total	**5,427,072**		**7,029**	
Governorates	**Count**	**Percentage**	**Count**	**Percentage**
Mount Lebanon*	2,107,820	38.83%	2,890	41.12%
Beirut**	846,420	15.60%	2,066	29.39%
North Lebanon†	646,647	11.91%	726	10.32%
South Lebanon¶	590,065	10.9%	396	5.63%
Bekaa§	422,730	7.78%	251	3.57%
Nabatiyeh¶¶	403,435	7.43%	210	2.98%
Akkar‖	193,500	3.57%	141	2.01%
Baalbeck-Hermel ‡	216,455	3.98%	96	1.36%

^253 case reports had the governorate section missing (3.59%)
° A case report may include more than one AEFI
**Mount Lebanon governorate includes vaccination centers in Aley, Baabda, Chouf, Matn, Jbeil, Keserwan, and Baskinta*
***Beirut governorate includes vaccination centers in Beirut area*
†North Lebanon governorate includes vaccination centers in Batroun, Bcharreh, Koura, Minieh-Danniyeh, and Tripoli
§Bekaa governorate includes vaccination centers in Rashaya, West Bekaa, and Zahleh
¶South Lebanon governorate includes vaccination centers in Jezzine, Saida, and Tyre
¶¶Nabatiyeh governorate includes vaccination centers in Bint Jbeil, Hasbaya, and Marjeyoun
‖Akkar governorate includes vaccination centers in Akkar
‡Baalbeck-Hermel governorate includes vaccination centers in Baalbeck and Hermel



253 cases were missing the governorates

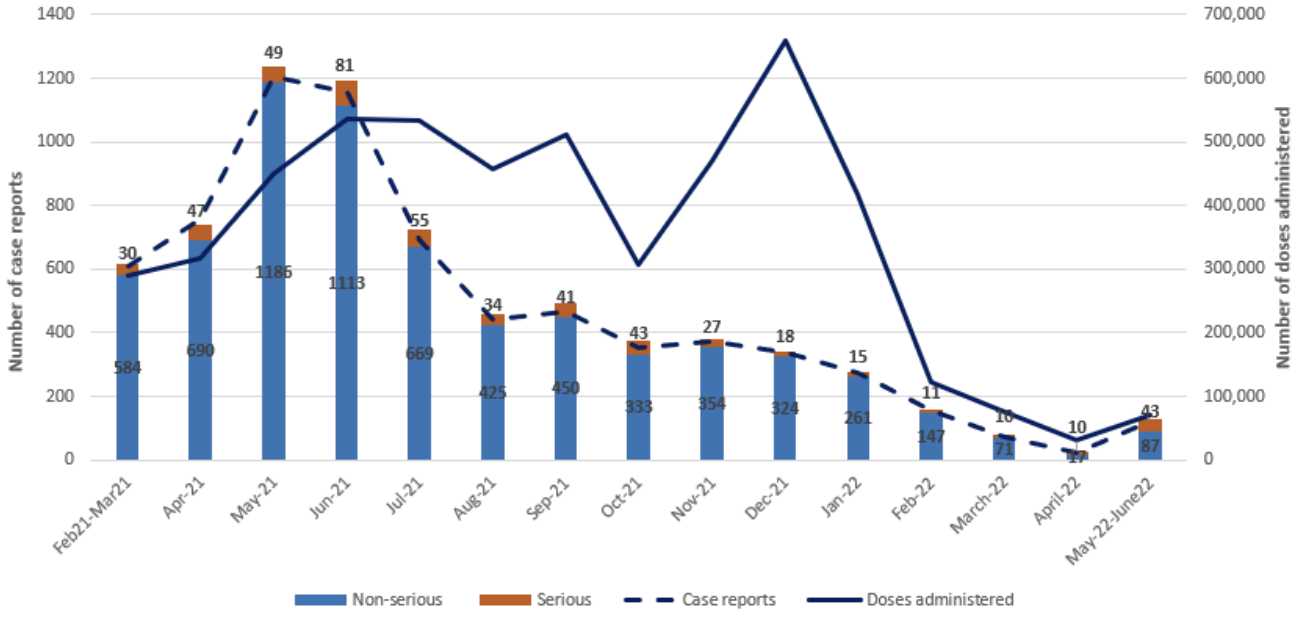
Figure 1. Summary of administered doses and case reports following Pfizer-BioNTech and AstraZeneca COVID-19 vaccines per governorate

This figure presents the total doses administered and total number of case reports per governorate. The number of case reports received per governorate decreases with the number of doses administered. The highest number of case reports were from Mount-Lebanon which was associated with the highest number of administered doses whereas in Nabatiyeh, for example, a lower number of case reports was received which may be attributed to the lower number of doses administered. As for the type of vaccine administered, it is worth to note that, in Mount-Lebanon, there is a similar count of case reports following both Pfizer-BioNTech and AstraZeneca COVID-19 vaccines (1,377 and 1,394 respectively), unlike Beirut where there are clearly more case reports with the Pfizer-BioNTech than the AstraZeneca COVID-19 vaccine (1,740 vs 226 respectively).

Table 4. Summary of all case reports related to COVID-19 vaccines available in Lebanon, from February 14th, 2021, to June 30th, 2022

	All Vaccines Combined	Pfizer-BioNTech	AstraZeneca	Sputnik V	Moderna	Sinopharm
Total Doses Administered	5,427,072	4,500,089	720,793	123,740	49,817	19,228
Total case reports (%)	7,029 (100)	4,421 (63.0)	2,310 (32.8)	235 (3.3)	47 (0.67)	16 (0.23)
Non serious case reports* (%)	6,515 (92.69)	4,066 (91.97)	2,168 (93.85)	225 (95.75)	44 (93.6)	12 (75.0)
Serious case reports** (%)	514 (7.31)	355 (8.03)	142 (6.15)	10 (4.25)	3 (6.4)	4 (25.0)
Total reporting rate per 1,000 doses administered	1.30	0.98	3.2	1.90	0.95	0.9
Serious reporting rate per 1,000 doses administered	0.09	0.08	0.20	0.08	0.06	0.22

Data Source: VigiLyze (Dataset date: 30/06/2022, MedDRA version: 24.1)
** Non serious cases include expected local and systemic AEFIs resolved without the need for further follow up or investigation*
*** Serious cases are those who meet the WHO seriousness criteria (refer to Technical Notes)*



**Numbers presented on the blue and red bars reflect the number of case reports reported by month*

Figure 2: Number of case reports*, doses administered, non-serious and serious cases by month of the five COVID-19 Vaccines' administration in Lebanon, from February 14th, 2021, to June 30th, 2022

Case reports are assessed based on the date of vaccine administration. The administration period ranges from February 14th, 2021, to June 30th ,2022. Accordingly, case reports were received as of February 14th, 2021, with an increase in both serious and non-serious case reports. The highest reporting rate was during the month of May, 2021 for the non-serious cases and June for the serious cases.

b. Demographics

Tables 5 and 6 present a summary of case reports related to the COVID-19 vaccines by age group, gender, and reporter qualification.

Table 5. Summary of all case reports by age group and gender related to the five COVID-19 vaccines available in Lebanon, from February 14th, 2021, to June 30th, 2022

Gender	COUNT	PERCENTAGE
Female	4,272	60.8
Male	2,757	39.2
Age		
2 - 11 years	1	0%
12- 17 years	256	3.6%
18 - 44 years	3,852	54.8%
45 - 64 years	2,057	29.3%
65 - 74 years	361	5.1%
≥ 75 years	426	6.1%
Unknown	76	1.1%

Data Source: VigiLyze (Dataset date: 30/06/2022, MedDRA version: 24.1)
Note: Age represents the age at time of vaccination. Some case reports may be missing the date of birth

Table 6. Summary of all case reports by reporter qualification related to the five COVID-19 vaccines available in Lebanon, from February 14th, 2021, to June 30th, 2022

Reporter Qualification	COUNT	PERCENTAGE
Physician	264	3.8%
Pharmacist	203	2.9%
Other Health Professional	693	9.9%
Consumer/Non-Health Professional	5,869	83.4%

Data Source: VigiLyze (Dataset date: 30/06/2022, MedDRA version: 24.1)

c. Non serious Adverse Events Following Immunization

A case report refers to a report received by the PV Program, which pertains to one individual vaccine recipient who has reported at least one adverse event after receiving one of the COVID-19 vaccines (i.e., temporally associated with the vaccine).

The tables below give an overview of the top reported non-serious AEFIs.

i. Most Reported Non-Serious AEFIs Related to COVID-19 Vaccines:

Table 7. Top 15 AEFIs by reported Preferred Terms (PTs)* related to the five COVID-19 vaccines available in Lebanon, from February 14th, 2021, to June 30th, 2022

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
Injection site pain	2,743	42.1%
Fatigue	2,643	40.6%
Pain	2,609	40.0%
Headache	2,373	36.4%
Pyrexia	2,121	32.6%
Chills	1,938	29.7%
Nausea	1,059	16.3%
Injection site swelling	621	9.5%
Dyspnea	515	7.9%
Abdominal pain	473	7.3%
Diarrhea	463	7.1%
Cough	414	6.4%
Injection site erythema	414	6.4%
Dizziness	388	6.0%
Vomiting	349	5.4%

Data Source: VigiLyze (Dataset date: 30/06/2022, MedDRA version: 24.1).
**Preferred Terms (PTs) are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*

ii. Non serious AEFIs per specific vaccine:

Table 8. Top 10 AEFIs by reported Preferred Terms (PTs)* related to the Pfizer-BioNTech COVID-19 vaccine available in Lebanon, from February 14th, 2021, to June 30th, 2022

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
Injection site pain	1,475	36.3%
Pain	1,370	33.7%
Fatigue	1,258	31.0%
Headache	1,169	28.8%
Pyrexia	1,002	24.7%
Chills	891	21.9%
Nausea	505	12.4%
Injection site swelling	396	9.7%
Dyspnea	300	7.4%
Dizziness	266	6.5%

Data Source: VigiLyze (Dataset date: 30/06/2022, MedDRA version: 24.1).
**Preferred Terms (PTs) are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*

Table 9. Top 10 AEFIs by reported Preferred Terms (PTs)* related to the AstraZeneca COVID-19 vaccine available in Lebanon, from February 14th, 2021, to June 30th, 2022

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
Fatigue	1,220	56.2%
Injection site pain	1,138	52.5%
Pain	1,101	50.8%
Headache	1,079	49.7%
Pyrexia	1,005	46.3%
Chills	926	42.7%
Nausea	495	22.8%
Abdominal pain	222	10.2%
Injection site swelling	203	9.4%
Dyspnea	196	9.0%

Data Source: VigiLyze (Dataset date: 30/06/2022, MedDRA version: 24.1).
**Preferred Terms (PTs) are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*

Table 10. Top 10 AEFIs by reported Preferred Terms (PTs)* related to the Sputnik V COVID-19 vaccine available in Lebanon, from February 14th, 2021, to June 30th, 2022

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
Fatigue	149	66.2%
Pain	118	52.4%
Injection site pain	112	49.8%
Chills	111	49.3%
Headache	110	48.9%
Pyrexia	98	43.6%
Nausea	52	23.1%
Diarrhea	20	8.9%
Injection site swelling	16	7.1%
Cough	15	6.7%

Data Source: VigiLyze (Dataset date: 30/06/2022, MedDRA version: 24.1).
**Preferred Terms (PTs) are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*

Table 11. Top 10 AEFIs by reported Preferred Terms (PTs)* related to the Moderna COVID-19 vaccine available in Lebanon, from February 14th, 2021, to June 30th, 2022

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
Pain	17	38.6%
Headache	13	29.5%
Injection site pain	13	29.5%
Pyrexia	13	29.5%
Chills	9	20.5%
Fatigue	9	20.5%
Injection site swelling	6	13.6%
Dyspnea	4	9.1%
Myalgia	4	9.1%
Nausea	4	9.1%

Data Source: VigiLyze (Dataset date: 30/06/2022, MedDRA version: 24.1).
**Preferred Terms (PTs) are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*

Table 12. Top 10 AEFIs by reported Preferred Terms (PTs)* related to the Sinopharm COVID-19 vaccine available in Lebanon, from February 14th, 2021, to June 30th, 2022

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
Fatigue	6	50.0%
Injection site pain	5	41.7%
Dyspnea	3	25.0%
Nausea	3	25.0%
Pain	3	25.0%
Pyrexia	3	25.0%
Chest pain	2	16.7%
Cough	2	16.7%
Dizziness	2	16.7%
Headache	2	16.7%

Data Source: VigiLyze (Dataset date: 30/06/2022, MedDRA version: 24.1).
**Preferred Terms (PTs) are distinct descriptors (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic.*

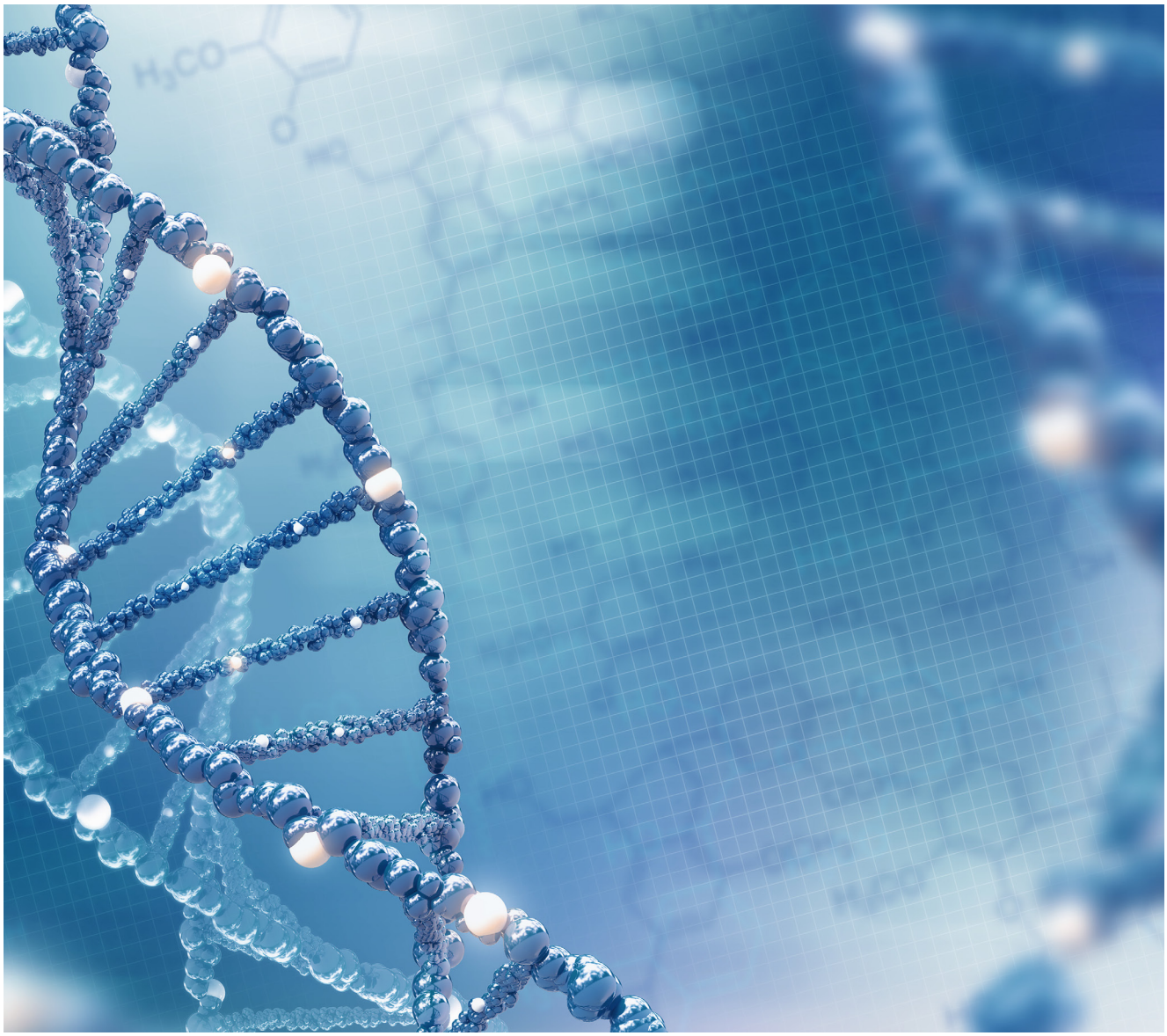


Table 13. Summary of number and percentage of reported non-serious AEFIs by System Organ Class (SOC)* related to the five COVID-19 vaccines available in Lebanon, from February 14th, 2021, to June 30th, 2022

Reaction (MedDRA)	All Vaccines Combined (%)	Pfizer-BioNTech (%)	Astra Zeneca (%)	Sputnik V (%)	Moderna (%)	Sinopharm (%)
General disorders and administration site conditions	5,394 (82.8)	3,183 (78.3)	1,958 (90.3)	210 (93.3)	31 (70.5)	83.3 (10)
Nervous system disorders	2,913 (44.7)	1,545 (38.0)	1,225 (56.5)	119 (52.9)	19 (43.2)	5 (41.7)
Gastrointestinal disorders	1,707 (26.2)	871 (21.4)	751 (34.6)	70 (31.1)	12 (27.3)	3 (25.0)
Respiratory, thoracic and mediastinal disorders	784 (12)	493 (12.1)	261 (12.0)	20 (8.9)	7 (16.7)	3 (25.0)
Musculoskeletal and connective tissue disorders	698 (10.7)	400 (8.8)	268 (12.4)	16 (7.1)	13 (29.5)	1 (8.3)
Skin and subcutaneous tissue disorders	529 (8.1)	317 (7.8)	190 (8.8)	17 (7.6)	4 (9.1)	1 (8.3)
Vascular disorders	260 (4.0)	196 (4.8)	63 (2.9)	0	1 (2.3)	0
Cardiac disorders	172 (2.6)	126 (3.1)	45 (2.1)	0	1 (2.3)	0
Investigations**	142 (2.2)	99 (2.4)	41 (1.9)	0	1 (2.3)	1 (8.3)
Eye disorders	135 (2.1)	78 (1.9)	53 (2.4)	2 (0.9)	1 (2.3)	1 (8.3)
Infections and infestations	93 (1.4)	66 (1.6)	22 (1.0)	3 (1.3)	0	1 (8.3)
Blood and lymphatic system disorders	89 (1.4)	77 (1.9)	9 (0.4)	2 (0.9)	1 (2.3)	0
Ear and labyrinth disorders	63 (1.0)	43 (1.1)	16 (0.7)	4 (1.8)	0	0
Reproductive system and breast disorders	45 (0.7)	24 (0.6)	20 (0.9)	1 (0.4)	0	0
Injury, poisoning and procedural complications	42 (0.6)	20 (0.5)	21 (1.0)	0	1 (2.3)	0
Psychiatric disorders	38 (0.6)	17 (0.4)	21 (1.0)	0	0	0
Immune system disorders	37 (0.6)	17 (0.4)	13 (0.6)	0	2 (4.5)	
Metabolism and nutrition disorders	37 (0.6)	14 (0.3)	22 (1.0)	0	1 (2.3)	0
Renal and urinary disorders	14 (0.2)	8 (0.2)	6 (0.3)	0	0	0
Surgical and medical procedures	3 (0)	3 (0.1)	0	0	0	0
Endocrine disorders	2 (0)	2 (0)	0	0	0	0

Data Source: VigiLyze (Dataset date: 30/06/2022, MedDRA version: 24.1)
**System Organ Classes (SOCs) are groupings by etiology (e.g., Infections and infestations), manifestation site (e.g., Gastrointestinal disorders) or purpose (e.g., surgical and medical procedures)*
*** Investigations include cases of abnormal blood pressure, increased blood pressure, decreased blood pressure, increased systolic blood pressure, increased heart rate, irregular heart rate, increased Fibrin D-Dimer, decreased weight, decreased oxygen saturation, increased blood glucose levels, decreased blood iron, increased blood pH, increased intraocular pressure, red blood cells in urine, decreased urine output, and cases who tested positive or negative for SARS-CoV-2.*

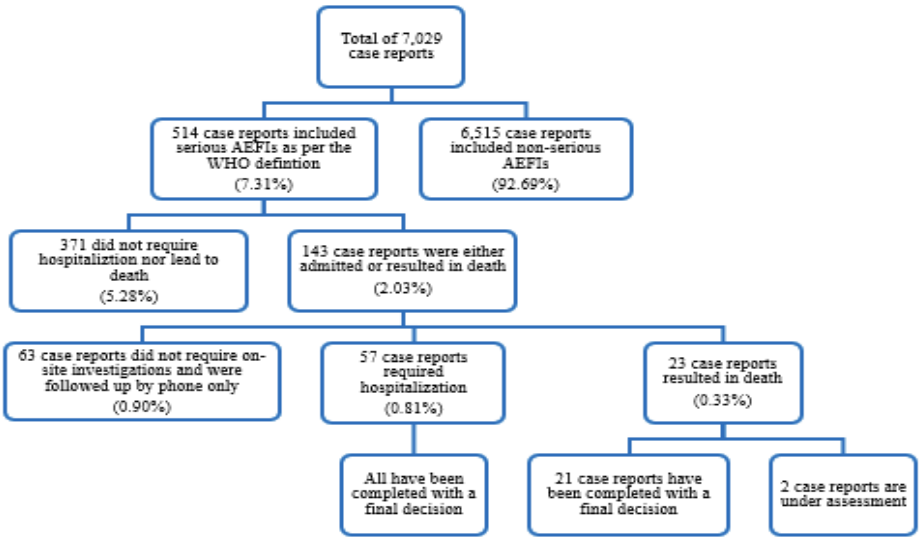
d. Serious Adverse Events Following Immunization

According to the WHO, a serious AEFI is an event that results in death, hospitalization, or prolongation of an existing hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth, defect or is life-threatening. The ICH E2A and E2D Guidelines (refer to Technical Notes) have also stated that other situations such as other medically important event or reaction which may jeopardize the patient or may require intervention to prevent one of the outcomes stated in the serious case definition, should also be considered serious after applying medical and scientific judgment. Those "other situations" are open to interpretation and could vary from jurisdiction to jurisdiction. In this report, serious case reports following immunization were classified as follows:

- **Other Medically Important Events :** This includes unexpected AEFIs, local or systemic, that may be serious in their nature but did not require hospitalization nor resulted in death. They may include ER visits and may or may not be resolved in the next 48 hours. These case reports are followed by the PV team over the phone without further investigation.
- **Serious Cases :** This includes cases that resulted in death, hospitalization, disability, congenital abnormalities, or were life threatening. These are investigated and evaluated for causality assessment.

514 case reports included serious AEFIs as per the WHO definition, out of which 371 case reports did not require hospitalization nor lead to death. These were identified as other medically important events. 143 case reports were serious cases that were either admitted to the hospital or resulted in death (Figure 3).

Out of the 143 cases mentioned above, 63 case reports fit the WHO definition of seriousness criteria, but they did not require on-site investigations and they were followed up by phone only; 80 cases were serious reports that required full investigation. Of the 80 serious cases, 78 reports have been completed with a final decision by the Serious AEFI Special Committee at the Ministry of Public Health. The remaining 2 case reports are still under assessment by the PV team. Tables 14, 15 and 16 show detailed description of the 80 serious case reports.



**As per the WHO definition (refer to Technical Notes for serious cases definition as per WHO)*

Figure 3. Classification of case reports by seriousness criteria* related to the five COVID-19 vaccines available in Lebanon, from February 14th, 2021, to June 30th, 2022

Table 14. Summary of the 78 serious case reports that have been completed with a final decision by the Serious AEFI Special Committee

i. Per Vaccine Type

	All Cases	Pfizer-BioNTech	AstraZeneca	Sinopharm
Number of case report (%)	78 (100)	63 (80.8)	14 (17.9)	1 (1.3)
Age (years)				
12 - 17 years	3	3	0	0
18 - 44 years	13	8	4	1
45 - 64 years	23	14	9	0
65 - 74 years	13	12	1	0
≥ 75 years	26	26	0	0
Median Age in years (range)	61.86 (12-95)	64.86 (12-95)	49.71 (29-65)	43
Gender (%)				
Male	39 (50.0)	32 (50.79)	7 (50.0)	0
Female	39 (50.0)	31 (49.2)	7 (50.0)	1 (100)
Dose number (%)				
1st	45 (50.70)	33 (52.38)	11 (78.57)	1 (100)
2nd	26 (33.33)	24 (38.10)	2 (14.29)	0
3rd	6 (7.69)	6 (9.52)	0	0
1st and 2nd *	1 (1.28)	0	1 (7.14)	0
Median TTO in days (range)**	5 (0-93)	4 (0-93)	7 (2-32)	20
Median TTO in days (range) per dose				
1st	5 (0-32)	5 (0-26)	7 (2-32)	20
2nd	3 (0-93)	3 (0-93)	3.5 (2-5)	0
3rd	4 (0-44)	4 (0-44)	0	0
1st and 2nd *	9	0	9	0
Mean TTO in days (SD) per dose***				
1st	8.55 (7.94)	7.39 (7.30)	11 (9.11)	20
2nd	10.19 (18.93)	10.75 (19.62)	3.5 (2.12)	0
3rd	12.17 (17.54)	12.17 (17.54)	0	0
1st and 2nd *	9	0	9	0
Seriousness Criteria (%)				
Fatal	21 (26.92)	16 (25.40)	4 (28.57)	1 (100)
Hospitalized	57 (73.08)	47 (74.60)	10 (71.43)	0
AEFI Committee Decision (%)				
Coincidental	40 (51.28)	34 (53.97)	5 (35.71)	1 (100)
Indeterminate	25 (32.05)	20 (31.75)	5 (35.71)	0
Consistent	13 (16.67)	9 (14.28)	4 (28.58)	0

** This is an immunization-error case in which the patient received both doses during the same vaccination session*
*** TTO: Time to onset*
**** SD: Standard deviation*

ii. Per Seriousness Criteria

Completed Serious Cases	Total (N=78)	Hospitalized Case Reports (N=57)	Fatal Case Reports (N=21)
Gender (%)			
Males	39 (50.0)	28 (49.12)	11 (52.38)
Females	39 (50.0)	29 (50.88)	10 (47.62)
Age Range (years)	12 - 95	12 - 95	29 – 92
Dose Received (%)			
Dose 1	45 (50.70)	34 (59.65)	11 (52.38)
Dose 2	26 (33.33)	17 (29.83)	9 (42.86)
Dose 3	6 (7.69)	5 (8.77)	1 (4.76)
Dose 1 and 2	1 (1.28)	1 (1.75)	0
Time to Onset (days)	0 - 93	0 - 44	0 - 93
AEFI Committee Decision (%)*			
Coincidental	40 (51.28)	29 (50.88)	11 (52.38)
Indeterminate	25 (32.05)	17 (29.82)	8 (38.10)
Consistent	13 (16.67)	11 (19.30)	2 (9.52)

Three cases had new data supplements provided leading to a change in the final decision

Table 15. Summary of reported AEFIs for the 75 completed serious cases by System Organ Class (SOC)

Vaccine Brand / SOC	Total (N=78)	Pfizer-BioNTech (N=63)	AstraZeneca (N=14)	Sinopharm (N=1)
Cardiovascular disorders*	49	40	9	0
Nervous system disorders**	11	9	2	0
Infections and infestations***	8	7	1	0
Immune system disorders¶	5	5	0	0
Respiratory, thoracic, and mediastinal disorders^	3	2	0	1
Blood and lymphatic system disorders°	1	0	1	0
Surgical and medical procedures§	1	0	1	0

** Includes case reports of ischemic heart disease, cardiac arrest, cerebrovascular accidents, myocardial infarction, myocarditis, pericarditis, atrial fibrillation, extensive portal vein thrombosis, unstable angina, Kounis Syndrome, and thrombotic disorders*
*** Includes case reports of Guillain-Barré Syndrome, acute disseminated encephalomyelitis, Amyotrophic Lateral Sclerosis, cerebral hemorrhage, functional neurological dysfunction, epilepsy, and optic neuritis*
**** Includes case reports of pneumonia, acute bronchitis, and sepsis*
¶ Includes case reports of acute severe urticaria, anaphylactic shock, psoriasis exacerbation, autoimmune hemolytic anemia, and hyperstimulation of the immune system
^ Includes case reports of dyspnea, polypnea, and pulmonary edema
° Includes case reports febrile neutropenia and Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT)
§ Includes case reports of post-surgical bleeding

Table 16. Summary of the 2 serious case reports that are under assessment by the PV team

N°	Gender	Age (years)	AEFI	Vaccine Type	Dose Number	TTO* (days)	Seriousness Criteria
1	M	75	Ischemic CVA	Pfizer-BioNTech	1	8	Death
2	F	60	Thrombotic Thrombocytopenia	Pfizer-BioNTech	3	3	Death

**TTO: Time to onset*

e. Adverse Events Following Immunization in Pregnant Women

Between February 14th, 2021, and June 30th, 2022, 7 case reports were reported among pregnant women in Lebanon. Out of these 7 case reports, 5 were following Pfizer-BioNTech vaccine and the remaining 2 were following the AstraZeneca vaccine. All 7 case reports included non-serious AEFIs such as injection site pain, fever, and chills. Table 17 summarizes these 7 case reports.

Table 17. Summary of case reports following COVID-19 vaccines reported in pregnant women in Lebanon from February 14th, 2021, to June 30th, 2022

Pregnant Women	All Cases	Pfizer-BioNTech	AstraZeneca
Number of case report (%)	7 (100)	5 (71.4)	2 (28.6)
Age (Mean ± SD)*	33.57 ± 4.72	32 ± 4.42	37.5 ± 3.54
Dose number (%)			
1st	4 (57.15)	2 (40)	2 (100)
2nd	2 (28.57)	2 (40)	0
3rd	1 (14.28)	1 (40)	0
TTO in days per dose (Mean ± SD)**			
1st	2.71 ± 5.9	8 ± 11.3	0
2nd	1.5 ± 0.7	1.5 ± 0.7	--
3rd	0	0	--

** SD: Standard deviation*
*** TTO: Time to onset*

f. Adverse Events Following Immunization in Adolescents

Between February 14th, 2021, and June 30th, 2022, 1 non-serious case of dizziness was reported by an 11-year-old male with Pfizer-BioNTech vaccine. In addition, 256 cases were reported by adolescents aging between 12 and 17 years old divided into 237 non-serious (Table 18) and 19 serious cases as per the WHO definition. Out of these 19 serious cases, 16 did not require on-site investigation and were followed up by phone only, and the remaining 3 cases that were admitted to the hospital required investigation and causality assessment (Table 19).

Table 18. Summary of non-serious case reports following COVID-19 vaccines reported in adolescents in Lebanon from February 14th, 2021, to June 30th, 2022

		All vaccines combined	Pfizer-BioNTech	Moderna	Sinopharm
Gender	Male	131 (51.2)	130 (99.2)	0	1 (0.8)
	Female	125 (48.8)	122 (96.8)	3 (3.2)	0
Total doses administered (%)		353,910	353,591	227	92
Number of case reports (%)		256 (100)	252 (98.4)	3 (1.2)	1 (0.4)
Number of non-serious case reports (%)		237 (92.58)	233 (98.3)	3 (1.3)	1 (0.4)
Number of non-serious AEFIs		701	691	9	1
Top 10 non-serious AEFIs N (%)					
Pyrexia		67 (28.3)			
Injection site pain		64 (27)			
Fatigue		58 (24.5)			
Headache		58 (24.5)			
Dizziness		40 (16.9)			
Pain		40 (16.9)			
Hypotension		36 (15.2)			
Chills		31 (13.1)			
Nausea		28 (11.8)			
Abdominal pain		18 (7.6)			

Table 19. Summary of serious case reports following COVID-19 vaccines reported in adolescents in Lebanon from February 14th, 2021, to June 30th, 2022

N°	AEFI	Gender	Age (years)	Vaccine Type	Dose	TTO° (days)	Seriousness	Outcome	Final Decision
1	Epilepsy	M	16	Pfizer-BioNTech	1st	4	Hospitalization	Recovered	Indeterminate
2	Psoriasis Exacerbation	F	13	Pfizer-BioNTech	2nd	1	Hospitalization	Recovered	Consistent
3	Functional Neurological Disorder	M	12	Pfizer-BioNTech	1st	Same Day	Hospitalization	Recovered	Consistent

°TTO: Time to onset

f. Safety Signals

The PV team has adopted two sources for identifying signals (refer to Technical Notes) associated with AEFIs with Pfizer-BioNTech and AstraZeneca COVID-19 Vaccine: The French National Security Agency of Medicines and Health Products (ANSM) and the World Health Organization-Uppsala Monitoring Center (WHO-UMC) Classification.

Tables 20 and 21 summarize the reported AEFIs in Lebanon during the time of this report which may be either potential or confirmed signals for Pfizer-BioNTech and AstraZeneca COVID-19 vaccines according to the ANSM reports and/or the WHO-UMC Vigibase.

Table 20. Confirmed signals identified in Lebanon

Pfizer-BioNTech COVID-19 vaccine		AstraZeneca COVID-19 vaccine	
Safety Signal	**Count**	**Safety Signal**	**Count**
Arterial Hypertension†	132	Flu-Like Syndrome	33
Tinnitus	12	Tinnitus	8
Trigeminal Neuralgia§	4	Photophobia	3
Pericarditis	3	Thrombosis Associated with Thrombocytopenia	2
Myocarditis	2	Trigeminal Neuralgia§	1
Photophobia	1	Deafness	1
Deafness	1		
Corneal Transplant Rejection	1		
Subacute Thyroiditis	2		

Data Source: VigiLyze (Dataset date: 30/06/2022, MedDRA version: 24.1).
Data Source: ANSM (16/06/2022)
Data Source: World Health Organization-Uppsala Monitoring Center (WHO-UMC)
†Cases of arterial hypertension included the terms: blood pressure abnormal, blood pressure systolic increase, blood pressure increased, hypertension, hypertensive crisis, and hypertensive emergency.
§Cases of trigeminal neuralgia included the term: facial paralysis

Table 21. Potential signals identified in Lebanon

Pfizer-BioNTech		AstraZeneca	
Safety Signal	**Count**	**Safety Signal**	**Count**
Cardiac Rhythm Disorders§	188	Erythema nodosum#	170
Menstrual Irregularities‖	17	Arrhythmias§	71
Cerebral Vein Thrombosis‡	18	Elevated Blood Pressure¶	56
Shingles†	11	Mucocutaneous Bleeding¶¶	45
Vaccination Failure††	14	Venous and arterial thromboembolic event^	13
Pancreatitis	1	Pancreatitis	2
Rheumatoid arthritis	1	Myocardial Infarction	1

Data Source: VigiLyze (Dataset date: 30/06/2022, MedDRA version: 24.1).
Data Source: ANSM (16/06/2022)
§Cases of cardiac rhythm disorders and arrhythmias included the terms: tachycardia, palpitations, bradycardia, cardiac arrest, increased heart rate, arrhythmia, sinus bradycardia, Atrial fibrillation, and irregular heart rate
‖Cases of menstrual irregularities included the terms: menstruation irregular, menstruation delayed, menstrual disorder, and vaginal hemorrhage
‡Cases of cerebral vein thrombosis included the terms: ischemic stroke, ischemic cerebral infarction, cerebral ischemia, and transient ischemic attack
†Cases of shingles included the terms: herpes zoster
††Cases of vaccination failure included the terms: vaccination failure, drug ineffective
#Cases of erythema nodosum included the terms: rash erythematous, injection site erythema, and erythema
¶¶Cases of mucocutaneous bleeding included the terms: contusion, injection site bruising, epistaxis, and oral contusion
¶Cases of elevated blood pressure included the terms: blood pressure abnormal, blood pressure systolic increase, blood pressure increased, hypertension, hypertensive crisis, and hypertensive emergency
^Cases of venous and arterial thromboembolic event the terms: deep vein thrombosis, thrombosis, axillary vein thrombosis, portal vein thrombosis

DESCRIPTION OF SERIOUS ADVERSE EVENTS FOLLOWING IMMUNIZATION

AEFIs requiring Hospitalization or with Fatal Outcome (Tables 14, 15, and 16)

AEFIs are classified as serious according to the seriousness criteria of WHO (refer to the Technical Notes). These cases either require a phone call only or an investigation followed by a causality assessment to evaluate the potential relationship between the AEFI and the vaccine and to implement the appropriate follow-up actions. The investigation is carried out by the PV team members. It includes an extensive and rigorous scientific evaluation based on available information about the vaccination site, the patient's medical records, laboratory results, and information retrieved from the recipient or his/her relatives. After collecting all the available information, the investigation report is filled, and a causality assessment is performed by a group of experts to review the potential causal association between the AEFI and the vaccine. WHO forms and tools are used to carry out both the investigation and the causality assessment. Findings are discussed with the Serious AEFI Special Committee at the Ministry of Public Health. In the period of time covered by this report, there were 143 case reports classified as serious per the WHO-UMC definition that resulted in either hospitalization or death, representing 2.0% of all case reports and a reporting rate 0.026 per 1,000 doses of vaccines.

Overview of completed serious case reports (Tables 14 and 15)

Out of the 78 serious case reports that were completed with a final decision by the Serious AEFI Special Committee, there are 57 cases of hospitalization and 21 cases of death temporally associated with the receipt of the COVID-19 vaccine.

For the 57 suspected hospitalization cases post vaccination (28 Males, 29 Females), the vaccine recipients' age range was between 12 and 95 years old. 45 hospitalizations occurred after the first dose, 26 hospitalizations occurred after the second dose, while the remaining 6 hospitalizations occurred after the third dose. There is one case of immunization error where the patient received both doses during the same vaccination session. The 57 vaccine recipients experienced AEFIs within few minutes to 44 days' post-vaccination. The Serious AEFI Special Committee at the Ministry of Public Health confirmed the coincidental causality assessment in 29 case reports. 17 were considered as indeterminate, and 11 case reports were classified as consistent: 1 case of MI, 1 case of anaphylactic shock, 2 cases of Guillain-Barré Syndrome, 1 case of myocarditis, 1 case of pericarditis, 2 cases of ischemic CVA, 1 case of psoriasis exacerbation, 1 case of autoimmune hemolytic anemia, and 1 case of functional neurological disorder.

In the 21 suspected cases of death post vaccination (11 Males, 10 Females), the vaccine recipients' age range was between 29 and 92 years old. 11 death cases were after the first dose, 9 were after the second dose, and the remaining case was after the third dose. The 21 vaccine recipients experienced AEFIs within 30 minutes to 93 days' post-vaccination. The Serious AEFI Special Committee at the MoPH confirmed the coincidental classification in 11 case reports, 8 case reports were considered as indeterminate, and 2 case reports showed a consistent association due to the lack of other clearly attributing factors.

Overview of serious case reports under assessment (Table 16)

Two serious case reports are still under assessment by the PV team. Both cases are suspected deaths temporally associated with the Pfizer-BioNTech COVID-19 vaccine. The AEFIs occurred 3 days and 8 days after the receipt of the vaccine. The first case is a 75-year-old male who received his first dose, and the second case is about a 60-year-old female who received her 3rd dose of COVID-19 vaccine.

COMPARISON OF AEFIS WITH COVID-19 VACCINES IN LEBANON WITH INTERNATIONAL DATA

a. Ontario, Canada Based on the Public Health Ontario

Based on the weekly surveillance summary published by Public Health Ontario (PHO) regarding AEFI for COVID-19 in Ontario, covering the period between December 13th, 2020, to June 19th, 2022, 1,171 case reports have been classified as serious, representing 5.6% of the total AEFI reports and a serious AEFI reporting rate of 0.04 per 1,000 doses administered for all vaccine products combined. Of the 1,171 reports, 1,144 reports required hospital admission related to the adverse event and 27 were reports of death. To note, 659 serious cases were reported following Pfizer-BioNTech COVID-19 vaccine, which represented a reporting rate of 0.03 per 1,000 doses administered, and 131 serious cases were reported following AstraZeneca COVID-19 vaccine, which represents a reporting rate of 0.12 per 1,000 doses administered (Tables 22, 23, and 24).

Table 22. Case reports following COVID-19 vaccines in Lebanon in comparison with Ontario

	Lebanon Feb 14, 2021 – June 30, 2022	Ontario Dec 30, 2021 – June 19, 2022
	All Vaccines Combined*	All Vaccines Combined**
Total Doses Administered	5,427,072	32,882,531
Total Case Reports	7,029	20,867
Non-serious Case Reports (%)	6,515 (92.69)	19,696 (94.39)
Serious Case Reports (%)	514 (7.31)	1,171 (5.61)
Total Reporting Rate per 1,000 Doses Administered	1.30	0.63
Serious Reporting Rate per 1,000 Doses Administered	0.09	0.04

**Pfizer-BioNTech, AstraZeneca, Sputnik V, Sinopharm, and Moderna*
***Pfizer-BioNTech, Moderna, AstraZeneca, and Johnson & Johnson*

Table 23. Case reports following Pfizer-BioNTech COVID-19 vaccine in Lebanon in comparison with Ontario

	Lebanon Feb 14, 2021 – June 30, 2022	Ontario Dec 30, 2021 – June 19, 2022
	Pfizer-BioNTech	Pfizer-BioNTech
Total Doses Administered	4,500,089	21,483,221
Total Case Reports	4,421	12,377
Non-serious Case Reports (%)	4,066 (91.87)	11,718 (94.68)
Serious Case Reports (%)	355 (8.03)	659 (5.32)
Total Reporting Rate per 1,000 Doses Administered	0.98	0.58
Serious Reporting Rate per 1,000 Doses Administered	0.08	0.03

Table 24. Case reports following AstraZeneca COVID-19 vaccine in Lebanon in comparison with Ontario

	Lebanon Feb 14, 2021 – June 30, 2022	Ontario Dec 30, 2021 –June 19, 2022
	AstraZeneca	AstraZeneca
Total Doses Administered	720,793	1,087,570
Total Case Reports	2,310	1,664
Non-serious Case Reports (%)	2,168 (93.85)	1,533 (92.13)
Serious Case Reports (%)	142 (6.15)	131 (7.87)
Total Reporting Rate per 1,000 Doses Administered	3.20	1.53
Serious Reporting Rate per 1,000 Doses Administered	0.20	0.12

b. United-States of America based on the Centers for Disease Control and Prevention

According to the CDC, death reports after COVID-19 vaccination are rare. From December 14th, 2020, to June 30th, 2022, more than 596 million doses of COVID-19 vaccines were administered in the United States. Vaccine Adverse Event Reporting System (VAERS) received 15,205 preliminary death reports among people who received a COVID-19 vaccine (Table 25).

Table 25. Reports of death following COVID-19 vaccines in comparison with the United States according to the Centers for Disease Control and Prevention (CDC)

	Lebanon Feb 14, 2021 – June 30, 2022	United States of America Dec 14, 2020 – July 7, 2022
	All Vaccines Combined*	All Vaccines Combined**
Total Doses Administered	5,427,072	596,233,489
Preliminary Reports of Death^	21	15,205
Death Reporting Rate per 1000 doses	0.004	0.025

** Pfizer-BioNTech, AstraZeneca, Sputnik V, Sinopharm, and Moderna*
*** Pfizer-BioNTech, Moderna, Johnson & Johnson*
^ Reports of death do not necessarily mean that they are caused by the vaccine

CONCLUSION

In Lebanon, from January 3rd, 2020, to June 30th, 2022, there have been approximately 1.12 million of confirmed SARS-CoV-2 cases with 10,470 deaths declared to the MoPH. Vaccination is the single and most effective way to reduce deaths and hospitalizations from COVID-19. The national immunization campaign was first deployed on February 14th, 2021. Pfizer-BioNTech is the only COVID-19 vaccine available currently. AstraZeneca, Sputnik V, Sinopharm, and Moderna are no longer available which explains the stability in the number of their case reports.

In this report, 92.7% of the cases reported were classified as non-serious, and 7.3% were classified as serious. It is important to note that reports of adverse events following vaccination, including hospitalizations and deaths, do not necessarily mean that they are related to the vaccine.

The PV Program at the Ministry of Public Health continues to conduct constant monitoring for the safety of COVID-19 vaccines in collaboration with its partners, including individual case review, daily analysis of surveillance data for vaccine safety signals, and regular reporting.

TECHNICAL NOTES

- Important Medical Event Terms List: The EudraVigilance Expert Working Group (EV-EWG) has coordinated the development of an Important Medical Event Terms (IME, MedDRA version: 24.0) list. This IME list aims to facilitate the classification of suspected adverse reactions as well as aggregated data analysis and case assessment in the frame of the day-to-day PV activities of stakeholders. The IME list is intended for guidance purposes only.

- EudraVigilance is the system for managing and analyzing information on suspected adverse reactions to medicines which have been authorized or being studied in clinical trials in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the European Union (EU) medicines regulatory network.

- MedDRA (Medical Dictionary for Regulatory Activities) is a standardized medical terminology, published by the International Council for Harmonization, used for coding cases of adverse effects in clinical study reports and pharmacovigilance databases, and to facilitate searches in these databases.

- PIDM: The WHO Program for International Drug Monitoring (PIDM), established in 1968, provides a forum for WHO Member States to collaborate in the monitoring of drug safety, and notably, the identification and analysis of new adverse reaction signals from data submitted to the WHO global individual case safety report (ICSR) database by member countries.

- Seriousness Criteria: According to the WHO, a serious AEFI is an event that results in death, hospitalization, or prolongation of an existing hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth, defect or is life-threatening.

- ICH E2A Guidelines: Aims to develop standard definitions and terminology for key aspects of clinical safety reporting. It also provides guidance on the appropriate mechanism for handling expedited (rapid) reporting, in the investigational (i.e., pre-approval) phase.

- Safety Signal: According to the World Health Organization (WHO), a "signal" is a reported information on a possible causal relationship between an AE and a drug, the relationship being unknown or incompletely documented previously. Usually more than one report is required to generate a signal, depending on the seriousness of the event and the quality of the information.

- Trigeminal Neuralgia: is a neuropathic pain condition affecting the fifth cranial nerve and causing one of the most severe pains to be experienced. Symptoms include extreme, sporadic, sudden burning or shock like pain lasting from seconds up to two minutes and is usually unilateral.

- Myocarditis: An inflammation of the heart muscle (myocardium). Common myocarditis signs and symptoms include chest pain, rapid or abnormal heartbeat (arrhythmias), shortness of breath, or fluid buildup with leg swelling.

- Photophobia: Abnormal light sensitivity. It can occur as a symptom of various condition such as migraine headache or ophthalmic inflammation.

- Subacute thyroiditis: is a typically painful inflammatory condition of the thyroid, potentially causing hypothyroidism-like symptoms such as tachycardia, agitation, tremor, and hyperhidrosis.

- Corneal graft rejection: may occur at any time after transplant and can be caused by illness or injury of unknown cause. Typical symptoms include loss of vision, eye pain, red eyes and sensitivity to light with clinical signs including corneal edema, vascularization and precipitates.

- VigiFlow is a web-based individual case safety report (ICSR) management system that is available for use by national PV centers of the WHO Program for International Drug Monitoring.

- VigiBase is the WHO global ICSR database that contains ICSRs submitted by the participating member states enrolled under WHO's international drug monitoring program. It is the single largest drug safety data repository in the world.

- VigiLyze supports the collection, processing, and sharing of data of case reports to facilitate effective data analysis. VigiLyze is a signal detection and management system that can use national, regional, or global data as the starting point for quantitative signal detection.

DATA CAVEATS

- Each case report refers to a reporter who reported an AEFI after receiving a dose of COVID-19 vaccine. A case report may contain multiple AEFIs. Therefore, the total number of AEFIs can exceed the number of individual case reports reported in a given time frame. Case reports that did not contain an AEFI at the time of data extraction or was missing the Vaccine name have been excluded.

- AEFI reporting rates were calculated using the number of vaccines' specific AEFIs reported in the specified time period in Lebanon divided by the doses of vaccines administered in the same time period in Lebanon.

- The information available in this report does not represent Uppsala Monitoring Center (UMC) nor WHO's opinions.

DISCLAIMER:

CITATION:

Ministry of Public Health - Quality Assurance of Pharmaceutical Products - Pharmacovigilance Program (2022). Adverse Events Following Immunization for COVID-19 Vaccines in Lebanon: February 14th, 2021 to June 30th, 2022; Beirut, Lebanon.

FOR FURTHER INFORMATION:

For further information, contact us via email: pv@moph.gov.lb

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