REPORT N° 9

ADVERSE EVENTS FOLLOWING IMMUNIZATION WITH COVID-19 VACCINES IN LEBANON

COVID-19 Vaccines - Lebanon

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February 14, 2021 - February 19, 2022

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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, Sinopharm, and Moderna Vaccine) available in Lebanon during the mass campaign immunization between February 14th, 2021, and February 19th, 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 February 19th, 2022:

TOTAL NUMBER OF REGISTERED PERSONS 6,017,418	**TOTAL ADMINISTERED DOSES** 5,134,093 (85.32%)	**FIRST DOSE** 2,493,054 (48.55%)	**SECOND DOSE** 2,134,017 (41.60%)	**THIRD DOSE** 505,062 (9.85%)
TOTAL PFIZER-BIONTECH DOSES 4,259,387 (82.96%)	**TOTAL ASTRAZENECA DOSES** 717,370 (13.97%)	**TOTAL SPUTNIK V DOSES** 123,520 (2.41%)	**TOTAL SINOPHARM DOSES** 17,934 (0.35%)	**TOTAL MODERNA-DOSES** 2,189 (0.04%)

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

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, and other departments from the Ministry of Public Health (MoPH). 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 6,808 case reports and 24,837 AEFIs were received following the administration of 5,134,093 doses of COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik V, Sinopharm) in Lebanon between the 14th of February 2021 and the 19th of February 2022:
  - This is equivalent to a reporting rate of 1.33 case reports and 4.84 AEFIs per 1,000 doses administered
  - This represents an increase of 230 case reports and 600 AEFIs in comparison with the previous report dated from February 14th to January 19th, 2022
  - The age group of vaccine recipients who mostly reported AEFIs was between 18 and 44 years old (55.0%), with females reporting more than males (60.7% vs. 39.3%) (Table 5)
  - Most of the reporters were vaccine recipients (83.9%) (Table 5)

- The 6,808 case reports were received through one of the following means (Table 1):
  - IMPACT Platform: 3,829 case reports (56.3%)
  - 1214 Hotline Call Center: 1,979 case reports (29.0%)
  - Vaccination Sites/Hospital Sites through "Kobo toolbox: AEFIs Software for reporting" or by direct contact with the PV program: 924 case reports (13.6%)
  - Other reporting sources which may include Preventive Medicine, Epidemiology Surveillance Program, Health Education, and other departments from the MoPH: 76 case reports (1.1%)

- Out of the 6,808 case reports (Table 2):
  - 5,231 case reports were associated with dose 1 of vaccination (76.84%)
  - 1,369 case reports were associated with dose 2 of vaccination (20.10%)
  - 202 case reports were associated with dose 3 of vaccination (2.97%)
  - 6 case reports were missing this information (0.09%)

- The 6,808 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 6,808 case reports (Figure 1, Table 3):
  - 2,845 (41.80%) were from Mount Lebanon
  - 2,015 (29.60%) were from Beirut
  - 712 (10.46%) were from North Lebanon
  - 390 (5.72%) were from South Lebanon
  - 247 (3.62%) were from Bekaa
  - 207 (3.0%) were from Nabatiyeh
  - 140 (2.0%) were from Akkar
  - 86 (1.3%) were from Baalbeck-Hermel

- Out of the 6,808 case reports (Figure 3, Table 4):
  - 6,356 case reports were non-serious (93.4% of total case reports)
  - 452 case reports included serious AEFIs (6.6% of total case reports) as per the WHO definition (refer to Technical Notes for serious cases definition as per WHO), out of which:
    - 321 case reports included serious AEFIs that did not require hospitalization nor lead to death. These were identified as other medically important events (4.7% of total case reports)
    - 131 case reports resulted in either hospital admission or death representing 1.92% of all case reports and a reporting rate of 0.025 per 1,000 doses of vaccines

- Of the total received AEFIs, the 5 most frequently reported AEFIs with the four COVID-19 vaccines available in Lebanon were (Table 7):
  - Injection site pain (42.6% of total reported AEFIs)
  - Fatigue (41.1% of total reported AEFIs)
  - General pain which may correspond to body pain or joint pain (40.6% of total reported AEFIs)
  - Headache (36.8% of total reported AEFIs)
  - Pyrexia (32.7% of total reported AEFIs)

- Of the total received AEFIs, the most reported AEFIs by System Organ Class (SOC) with the four COVID-19 vaccines available in Lebanon were (Table 12):
  - General Disorders and Administration Site Conditions (83.2% of total reported AEFIs per SOC)
  - Nervous System Disorders (44.9% of total reported AEFIs per SOC)
  - Gastrointestinal Disorders (26.3% of total reported AEFIs per SOC)

- The most frequently reported AEFIs per vaccine were (Table 8, 9, 10, 11):
  - Injection site pain was the most frequently reported non-serious adverse event following the Pfizer-BioNTech Vaccine (36.7% of total reported AEFIs)
  - Fatigue was the most common adverse event following all other vaccines: 56.3% of the total reported AEFIs related to AstraZeneca Vaccine, 66.4% of the total reported AEFIs related to Sputnik V Vaccine, and 50.0% of the total reported AEFIs related to Sinopharm Vaccine.

REPORTING OVERVIEW

a. Global Analysis

All data presented below will include AEFIs of case reports related to the four COVID-19 vaccines Pfizer-BioNTech, AstraZeneca, Sputnik V, Sinopharm) since no cases were reported with the Moderna COVID-19 vaccine so far.

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" or direct contact with the PV program, and other sources including Preventive Medicine, Epidemiology Surveillance Program, Health Education, and 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	Others
Number of Case Reports	3,829	1,979	924	76
Percentage	56.3%	29.0%	13.6%	1.1%

Table 2 classifies the 6,808 reported cases according to their occurrence after the 1st, 2nd and 3rd dose of COVID-19 vaccines. Out of these 6,808 case reports, 5,231 case reports (76.84%) were after the 1st dose, 1,369 case reports (20.10%) were after the 2nd dose and 202 case reports (2.97%) were after the 3rd dose (booster dose). The remaining 6 case reports (0.09%) were missing the dose number. Of the total registered persons, 35.46% have completed their primary COVID-19 vaccination series (dose 1 and 2).

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

	All Vaccines Combined	Pfizer-BioNTech	AstraZeneca	Sputnik V	Sinopharm
Total Case Reports (%)	6,808 (100)	4,255 (62.5)	2,302 (33.81)	235 (3.45)	16 (0.24)
Dose 1 (%)	5,231 (76.84)	2,919 (68.60)	2,127 (92.39)	175 (74.46)	10 (62.50)
Dose 2 (%)	1,369 (20.10)	1,133 (26.63)	170 (7.38)	60 (25.54)	6 (37.50)
Dose 3 (%)	202 (2.97)	200 (4.70)	2 (0.1)	0	0

**Six case reports were missing the dose number (0.09%).*

Table 3 represents the distribution of the 6,808 reported cases and administered doses over 8 governorates in Lebanon (Mount Lebanon, Beirut, North Lebanon, Bekaa, South Lebanon, Nabatiyeh, Akkar, and Baalbeck-Hermel) from February 14th, 2021, till February 19th, 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	**5,134,093**		**6,642**	
Governorates	**Count**	**Percentage**	**Count**	**Percentage**
Mount Lebanon*	2,026,508	39.50%	2,845	41.80%
Beirut**	796,278	15.50%	2,015	29.60%
North Lebanon†	600,796	11.70%	712	10.46%
South Lebanon¶	553,234	10.77%	390	5.72%
Bekaa§	390,638	7.60%	247	3.62%
Nabatiyeh¶¶	386,362	7.50%	207	3%
Akkar‖	181,364	3.54%	140	2%
Baalbeck-Hermel ‡	198,913	3.90%	86	1.30%

^166 case reports had the governorate section missing (2.5%)
° A case report may include more than one AEFI
**Mount Lebanon governorate includes vaccination centers in: Aley, Baabda, Chouf, Matn, Jbeil, Keserwan, Baskinta*
***Beirut governorate includes vaccination centers in: Beirut area*
†North Lebanon governorate includes vaccination centers in: Batroun, Bcharreh, Koura, Minieh-Danniyeh, Tripoli
§Bekaa governorate includes vaccination centers in: Rashaya, West Bekaa, Zahleh
¶South Lebanon governorate includes vaccination centers in: Jezzine, Saida, Tyre
¶¶Nabatiyeh governorate includes vaccination centers in: Bint Jbeil, Hasbaya, Marjeyoun
‖Akkar governorate includes vaccination centers in: Akkar
‡Baalbeck-Hermel governorate includes vaccination centers in: Baalbeck and Hermel

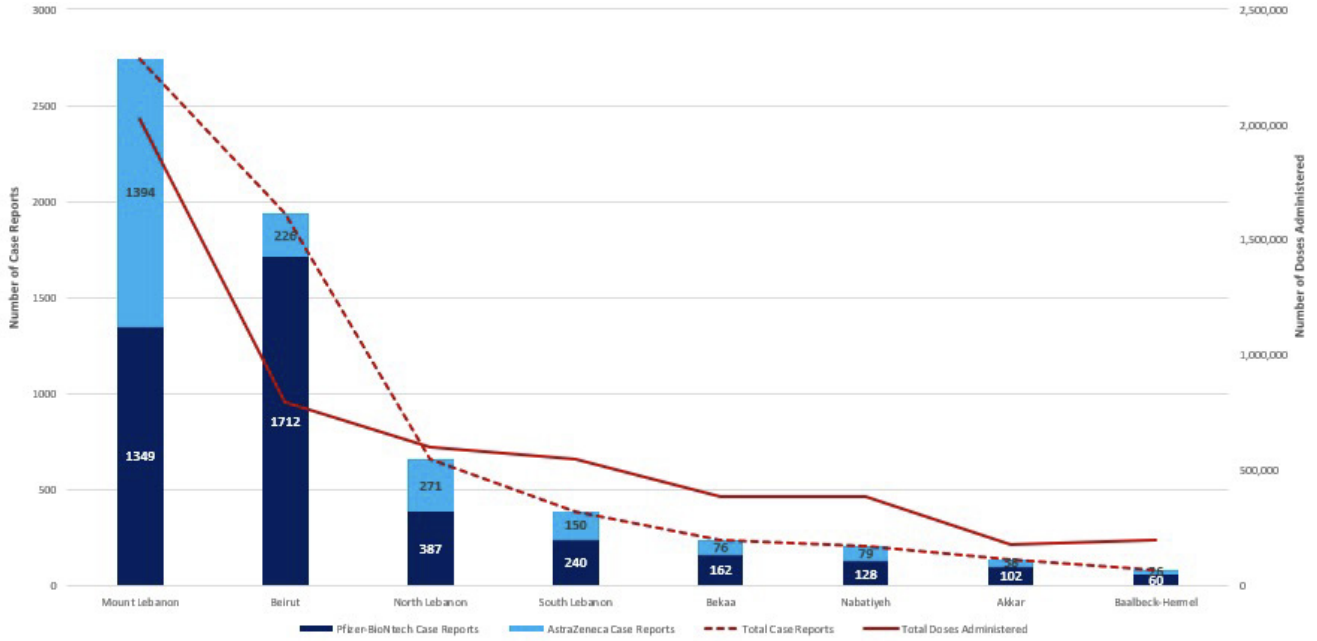


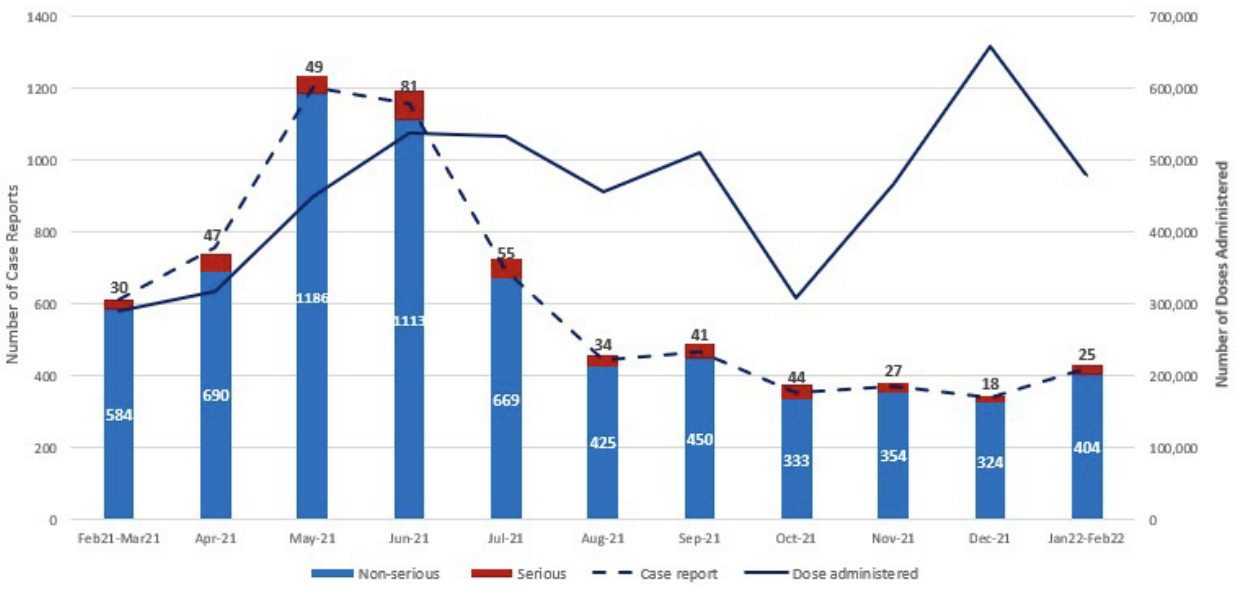
Figure 1. Summary of administered doses and case reports following Pfizer-BioNTech and AstraZeneca COVID-19 vaccines per governorate

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 (1349 and 1394 respectively), unlike Beirut where there are clearly more case reports with the Pfizer-BioNTech than the AstraZeneca COVID-19 vaccine (1712 vs 226 respectively).

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

	All Vaccines Combined	Pfizer-BioNTech	AstraZeneca	Sputnik V	Sinopharm
Total Doses Administered	5,134,093	4,259,387	717,370	123,520	17,934
Total case reports (%)	6,808 (100)	4,255 (62.5)	2,302 (33.81)	235 (3.45)	16 (0.24)
Non serious case reports* (%)	6,356 (93.36)	3,955 (93.0)	2,164 (94.0)	225 (95.75)	12 (75.0)
Serious case reports** (%)	452 (6.64)	300 (7.0)	138 (6.0)	10 (4.25)	4 (25.0)
Total reporting rate per 1,000 doses administered	1.33	0.99	3.2	1.90	0.9
Serious reporting rate per 1,000 doses administered	0.09	0.07	0.19	0.08	0.22

Data Source: VigiLyze (Dataset date: 19/02/2022, 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 four COVID-19 Vaccines' administration in Lebanon, from February 14th, 2021, to February 19th, 2022

Case reports are assessed based on the date of vaccine administration. The administration period ranges from February 14th, 2021, to February 19th, 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 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 four COVID-19 vaccines available in Lebanon, from February 14th, 2021, to February 19th, 2022

Gender	COUNT	PERCENTAGE
Female	4,135	60.7%
Male	2,673	39.3%
Age		
12- 17 years	248	3.6%
18 - 44 years	3,741	55.0%
45 - 64 years	1,999	29.4%
65 - 74 years	350	5.1%
≥ 75 years	423	6.2%
Unknown	47	0.7%

Data Source: VigiLyze (Dataset date: 19/02/2022, 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 four COVID-19 vaccines available in Lebanon, from February 14th, 2021, to February 19th, 2022

Reporter Qualification	COUNT	PERCENTAGE
Physician	234	3.4%
Pharmacist	191	2.8%
Other Health Professional	670	9.9%
Consumer/Non-Health Professional	5,713	83.9%

Data Source: VigiLyze (Dataset date: 19/02/2022, 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.

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

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

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
Injection site pain	2,707	42.6%
Fatigue	2,611	41.1%
Pain	2,578	40.6%
Headache	2,340	36.8%
Pyrexia	2,078	32.7%
Chills	1,908	30.0%
Nausea	1,047	16.5%
Injection site swelling	612	9.6%
Dyspnea	505	7.9%
Abdominal pain	468	7.4%
Diarrhea	455	7.2%
Injection site erythema	409	6.4%
Cough	406	6.4%
Dizziness	373	5.9%
Vomiting	341	5.4%

Data Source: VigiLyze (Dataset date: 19/02/2022, 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.*

c.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 February 19th, 2022

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
Injection site pain	1,451	36.7%
Pain	1,357	34.3%
Fatigue	1,236	31.3%
Headache	1,151	29.1%
Pyrexia	974	24.6%
Chills	870	22.0%
Nausea	497	12.6%
Injection site swelling	393	9.9%
Dyspnea	294	7.4%
Dizziness	254	6.4%

Data Source: VigiLyze (Dataset date: 19/02/2022, 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 February 19th, 2022

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
Fatigue	1,219	56.3%
Injection site pain	1,139	52.6%
Pain	1,100	50.8%
Headache	1,077	49.8%
Pyrexia	1,003	46.3%
Chills	925	42.7%
Nausea	495	22.9%
Abdominal pain	221	10.2%
Injection site swelling	203	9.4%
Dyspnea	196	9.1%

Data Source: VigiLyze (Dataset date: 19/02/2022, 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 February 19th, 2022

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
Fatigue	150	66.4%
Pain	118	52.2%
Chills	112	49.6%
Injection site pain	112	49.6%
Headache	110	48.7%
Pyrexia	98	43.4%
Nausea	52	23.0%
Diarrhea	20	8.8%
Injection site swelling	16	7.1%
Cough	15	6.6%

Data Source: VigiLyze (Dataset date: 19/02/2022, 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 Sinopharm COVID-19 vaccine available in Lebanon, from February 14th, 2021, to February 19th, 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: 19/02/2022, 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. Summary of number and percentage of reported non-serious AEFIs by System Organ Class (SOC)* related to the four COVID-19 vaccines available in Lebanon, from February 14th, 2021, to February 19th, 2022

Reaction (MedDRA)	All Vaccines Combined (%)	Pfizer-BioNTech (%)	AstraZeneca (%)	Sputnik V (%)	Sinopharm (%)
General disorders and administration site conditions	5,289 (83.2)	3,112 (78.7)	1,956 (90.4)	211 (93.4)	83.3 (10)
Nervous system disorders	2,855 (44.9)	1,508 (38.1)	1,223 (56.5)	119 (52.7)	5 (41.7)
Gastrointestinal disorders	1,674 (26.3)	851 (21.5)	750 (34.7)	70 (31.0)	3 (25.0)
Respiratory, thoracic and mediastinal disorders	766 (12.1)	482 (12.2)	261 (12.1)	20 (8.8)	3 (25.0)
Musculoskeletal and connective tissue disorders	677 (10.7)	391 (9.9)	269 (12.4)	16 (7.1)	1 (8.3)
Skin and subcutaneous tissue disorders	511 (8.0)	304 (7.7)	189 (8.7)	17 (7.5)	1 (8.3)
Vascular disorders	259 (4.1)	196 (5.0)	63 (2.9)	0	0
Cardiac disorders	169 (2.7)	124 (3.1)	45 (2.1)	0	0
Investigations**	136 (2.1)	94 (2.4)	41 (1.9)	0	1 (8.3)
Eye disorders	132 (2.1)	76 (1.9)	53 (2.4)	0	1 (8.3)
Infections and infestations	89 (1.4)	64 (1.6)	21 (1.0)	3 (1.3)	1 (8.3)
Blood and lymphatic system disorders	83 (1.3)	71 (1.8)	9 (0.4)	3 (1.3)	0
Ear and labyrinth disorders	63 (1.0)	43 (1.1)	16 (0.7)	4 (1.8)	0
Reproductive system and breast disorders	42 (0.7)	21 (0.5)	20 (0.9)	1 (0.4)	0
Psychiatric disorders	38 (0.6)	17 (0.4)	21 (1.0)	0	0
Injury, poisoning and procedural complications	37 (0.6)	16 (0.4)	21 (1.0)	0	0
Metabolism and nutrition disorders	36 (0.6)	14 (0.4)	22 (1.0)	0	0
Immune system disorders	31 (0.5)	18 (0.5)	13 (0.6)	0	0
Renal and urinary disorders	14 (0.2)	8 (0.2)	6 (0.3)	0	0
Surgical and medical procedures	2 (0.0)	2 (0.1)	0	0	0
Endocrine Disorders	1 (0.0)	1 (0.0)	0	0	0

Data Source: VigiLyze (Dataset date: 19/02/2022, 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

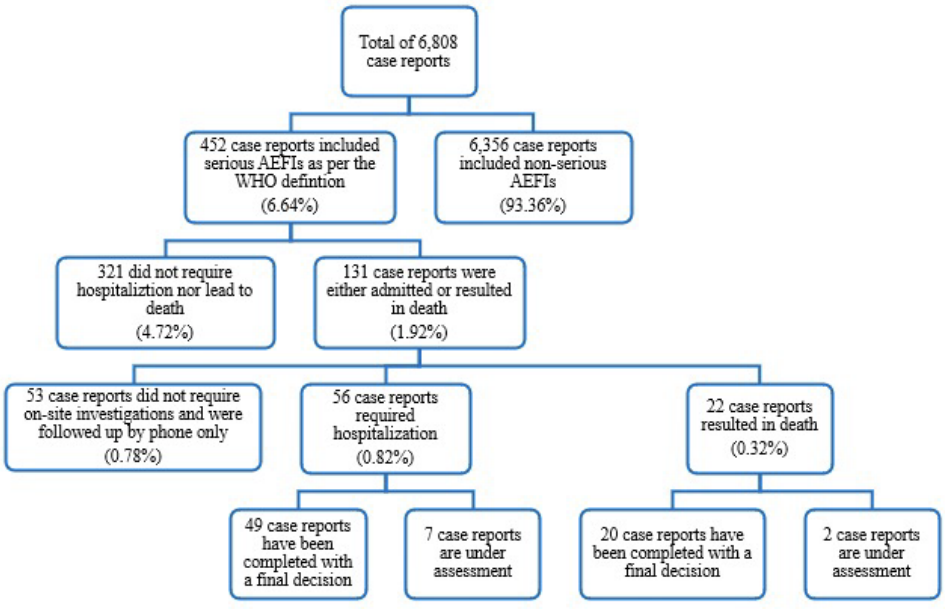
According to the WHO, a serious AEFI is an event that results in death, hospitalization, or prolongation of an existing hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth, defect or is life-threatening. The ICH E2A and E2D Guidelines (refer to Technical Notes) 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.

452 case reports included serious AEFIs as per the WHO definition, out of which 321 case reports did not require hospitalization nor lead to death. These were identified as other medically important events. 131 case reports were serious cases that were either admitted to the hospital or resulted in death (Figure 3).

Serious Cases:

Out of the 131 cases mentioned above, 53 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; 78 cases were serious reports that required full investigation. Of the 78 serious cases, 69 reports have been completed with a final decision by the Serious AEFI Special Committee at the Ministry of Public Health. The remaining 9 case reports are still under assessment by the PV team. Tables 13, 14 and 15 show detailed description of the 78 serious cases.



**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 four COVID-19 vaccines available in Lebanon, from February 14th , 2021, to February 19th, 2022

Table 13. Summary of 69 serious case reports that have been completed with a final decision by the Serious AEFI Special Committee

a. Per Vaccine Type

	All Cases	Pfizer-BioNTech	AstraZeneca	Sinopharm
Number of case report (%)	69 (100)	55 (79.71)	13 (18.84)	1 (1.45)
Age (years)				
12 - 17 years	1	1	0	0
18 - 44 years	12	7	4	1
45 - 64 years	20	12	8	0
65 - 74 years	12	11	1	0
≥ 75 years	24	24	0	0
Median Age in years (range)	66 (16-95)	72 (16-95)	52 (29-65)	43
Gender (%)				
Male	36 (52.17)	30 (54.55)	6 (76.15)	0
Female	33 (47.83)	25 (45.45)	7 (53.85)	1 (100)
Dose number (%)				
1st	41 (59.42)	30 (54.55)	10 (76.93)	1 (100)
2nd	24 (34.78)	22 (40)	2 (15.38)	0
3rd	3 (4.35)	3 (5.45)	0	0
1st and 2nd *	1 (1.45)	0	1 (7.69)	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)	10.5 (2-32)	20
2nd	3 (0-93)	3 (0-93)	3.5 (2-5)	0
3rd	1 (0-21)	1 (0-21)	0	0
1st and 2nd *	9	0	9	0
Mean TTO in days (SD) per dose***				
1st	8.83 (8.06)	7.6 (7.31)	11.4 (9.5)	20
2nd	10.62 (19.63)	11.33 (20.91)	3.5 (2.12)	0
3rd	7.33 (11.85)	7.33 (11.85)	0	0
1st and 2nd *	9	0	9	0
Seriousness Criteria (%)				
Fatal	20 (28.99)	15 (27.27)	4 (30.77)	1 (100)
Hospitalized	49 (71.01)	40 (72.73)	9 (69.23)	0
AEFI Committee Decision (%)				
Coincidental	37 (53.62)	31 (56.36)	5 (38.46)	1 (100)
Indeterminate	24 (34.78)	19 (34.55)	5 (38.46)	0
Consistent	8 (11.6)	5 (9.09)	3 (23.08)	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*

b. Per Seriousness Criteria

Completed Serious Cases	Total (N=69)	Hospitalized Case Reports (N=49)	Fatal Case Reports (N=20)
Gender (%)			
Males	36 (52.17)	25 (51.0)	11 (55.0)
Females	33 (47.83)	24 (28.9)	9 (45.0)
Age Range (years)	16 - 95	16 - 95	29 – 92
Dose Received (%)			
Dose 1	41 (59.42)	30 (61.2)	11 (55.0)
Dose 2	24 (34.78)	15 (30.6)	9 (45.0)
Dose 3	3 (4.35)	3 (6.1)	0
Dose 1 and 2	1 (1.45)	1 (2.1)	0
Time to Onset (days)	0 - 93	0 - 39	0 - 93
AEFI Committee Decision (%)			
Coincidental	37 (53.62)	27 (55.1)	10 (50.0)
Indeterminate	24 (34.78)	16 (32.7)	8 (40.0)
Consistent	8 (11.6)	6 (12.2)	2 (10.0)

Table 14. Summary of reported AEFIs for the 69 completed serious cases by System Organ Class (SOC)

Vaccine Brand / SOC	Total (N=69)	Pfizer-BioNTech (N=55)	AstraZeneca (N=13)	Sinopharm (N=1)
Cardiovascular disorders*	46	38	8	0
Nervous system disorders**	8	6	2	0
Infections and infestations***	7	6	1	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
Immune system disorders¶	3	3	0	0

** Includes case reports of cardiac arrest, cerebrovascular accident, 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, and epilepsy*
**** Includes case reports of pneumonia, acute bronchitis, and sepsis*
^ 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
¶ Includes case reports of acute severe urticaria, anaphylactic shock, and hyperstimulation of the immune system

Table 15. Summary of the 9 serious case reports that are still under assessment by the PV team

	Pfizer-BioNTech
Number of case report (%)	9 (100)
Age (years)	
12 - 17 years	2
18 - 44 years	1
45 - 64 years	2
65 - 74 years	1
≥ 75 years	3
Median Age in years (range)	60 (12-86)
Gender (%)	
Male	2 (22.22)
Female	7 (77.78)
Dose number (%)	
1st	4 (44.44)
2nd	1 (11.12)
3rd	4 (44.44)
Median TTO in days (range)*	3 (0-44)
Median TTO in days (range) per dose	
1st	4.5 (0-15)
2nd	1
3rd	7 (0-44)
Mean TTO in days (SD) per dose**	
1st	6 (6.98)
2nd	1
3rd	12.4 (17.95)
Seriousness Criteria (%)	
Fatal	2 (22.22)
Hospitalized	7 (77.78)

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

e. 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 16 and 17 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 16. Confirmed signals identified in Lebanon

Pfizer-BioNTech COVID-19 vaccine		AstraZeneca COVID-19 vaccine	
Safety Signal	**Count**	**Safety Signal**	**Count**
Arterial Hypertension†	125	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		

Data Source: VigiLyze (Dataset date: 19/02/2022, MedDRA version: 24.1).
Data Source: ANSM (10/02/2022)
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 17. Potential signals identified in Lebanon

Pfizer-BioNTech COVID-19 vaccine		AstraZeneca COVID-19 vaccine	
Safety Signal	**Count**	**Safety Signal**	**Count**
Cardiac Rhythm Disorders§	180	Erythema nodosum#	169
Menstrual Irregularities‖	17	Arrhythmias§	71
Cerebral Vein Thrombosis‡	17	Elevated Blood Pressure¶	56
Shingles†	11	Mucocutaneous Bleeding¶¶	45
		Venous and arterial thromboembolic event^	12
		Pancreatitis	2
		Myocardial Infarction	1

Data Source: VigiLyze (Dataset date: 19/02/2022, MedDRA version: 24.1). Data Source: ANSM (10/02/2022)
§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 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 13, 14, and 15)

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 131 case reports classified as serious per the WHO-UMC definition that resulted in either hospitalization or death, representing 1.92% of all case reports and a reporting rate 0.025 per 1,000 doses of vaccines.

Overview of completed serious case reports (Table 13, 14)

Out of the 69 serious case reports that were completed with a final decision by the Serious AEFI Special Committee, there are 49 cases of hospitalization and 20 cases of death temporally associated with the receipt of the COVID-19 vaccine.

For the 49 suspected hospitalization cases post vaccination (25 Males, 24 Females), the vaccine recipients' age range was between 16 and 95 years old. 30 hospitalizations occurred after the first dose, 15 hospitalizations occurred after the second dose, while the remaining 3 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 49 vaccine recipients experienced AEFIs within few minutes to 39 days' post-vaccination. The Serious AEFI Special Committee at the Ministry of Public Health confirmed the coincidental causality assessment in 27 case reports. 16 were considered as indeterminate, and 6 case reports were classified as consistent (one case of immunization error, one case of anaphylactic shock, two cases of Guillain-Barré, one case of Myocarditis, and one case of pericarditis).

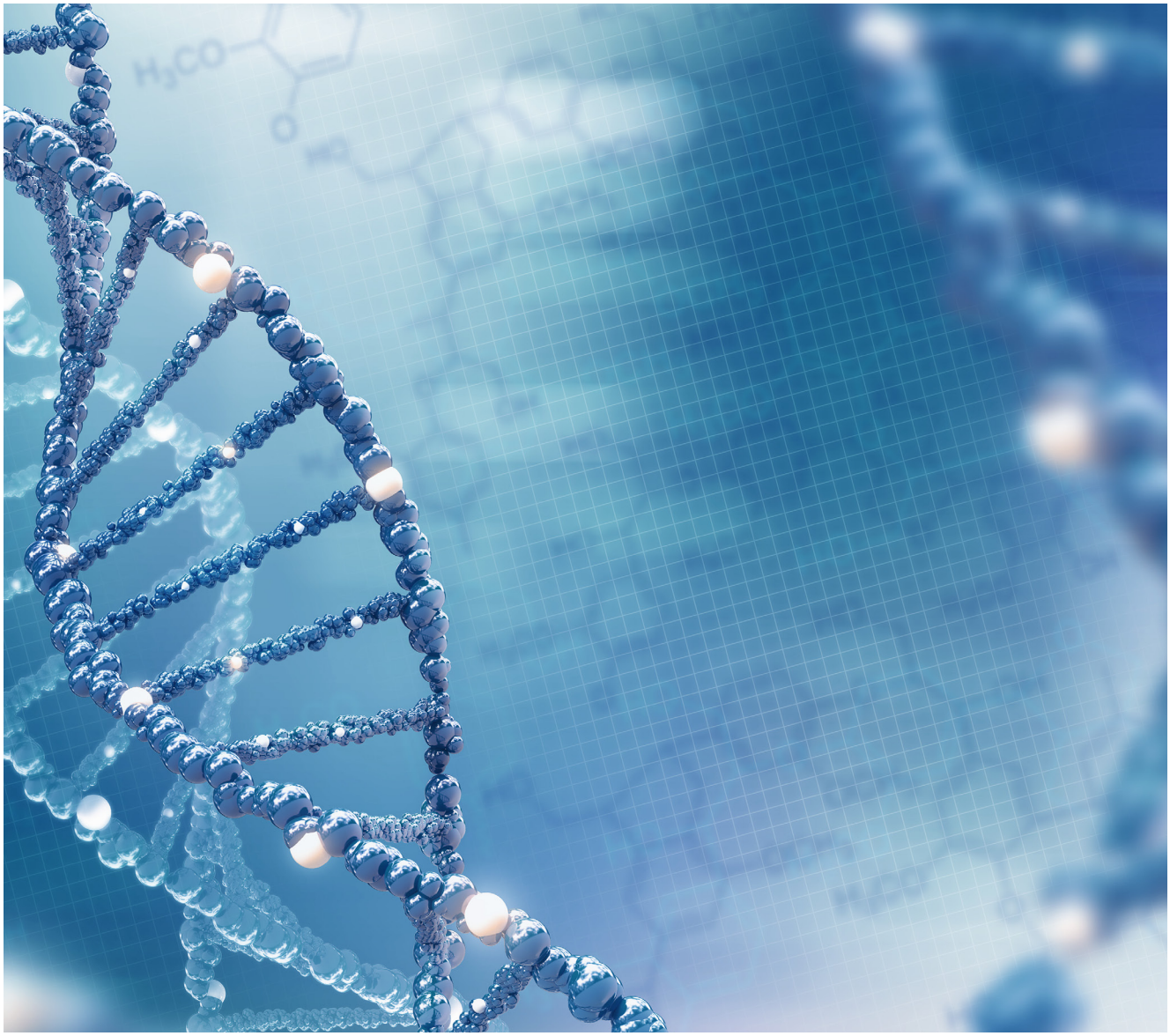
In the 20 suspected cases of death post vaccination (11 Males, 9 Females), the vaccine recipients' age range was between 29 and 92 years old. 11 death cases were after the first dose while the remaining 9 cases were after the second dose. The 20 vaccine recipients experienced AEFIs within 30 minutes to 93 days' post-vaccination. The Serious AEFI Special Committee at the MoPH confirmed the coincidental classification in 10 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 15)

Out of the 9 serious case reports that are still under assessment by the PV team, there are 7 cases of hospitalization and 2 cases of death temporally associated with the receipt of the COVID-19 vaccine.

For the 7 suspected hospitalization cases post vaccination (1 Males, 6 Females) the vaccine recipients' age range was between 12 and 86 years old. 3 hospitalizations occurred after the first dose, 1 hospitalization occurred after the second dose, and 3 hospitalizations occurred after the third dose. The 7 vaccine recipients experienced AEFIs within 20 minutes to 44 days' post-vaccination.

In the 2 suspected case of death post-vaccination (1 Male, 1 Female), the vaccine recipient's age was 75 and 84 years old respectively. Death occurred after the first dose in the first case while it was after the third dose in the second case. The vaccine recipients experienced AEFIs 8 days in the first case and 7 days' post-vaccination for the second case.



COMPARISON WITH INTERNATIONAL DATA RELATED TO AEFI WITH COVID-19 VACCINES

a. Ontario, Canada Based on the Public Health Ontario (Table 18, 19, and 20)

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 February 13th, 2022, 1,041 AEFI reports have been classified as serious, representing 5.5% of the total AEFI reports and a serious AEFI reporting rate of 0.03 per 1,000 doses administered for all vaccine products combined. 576 serious cases were reported following Pfizer-BioNTech COVID-19 vaccine, which represented a reporting rate of 0.03 per 1,000 doses administered, and 124 serious cases were reported following AstraZeneca COVID-19 vaccine, which represents a reporting rate of 0.11 per 1,000 doses administered. Of the 1,041 reports, 1,027 reports required hospital admission related to the adverse event and 14 were reports of death.

Table 18. Case reports following COVID-19 vaccines in Lebanon in comparison with Ontario

	Lebanon Feb 14, 2021 – Feb 19, 2022	Ontario Dec 30, 2021 – Feb 13, 2022
	All Vaccines Combined*	All Vaccines Combined**
Total Doses Administered	5,134,093	30,747,250
Total Case Reports	6,808	18,771
Non-serious Case Reports (%)	6,356 (93.36)	17,730 (94.45)
Serious Case Reports (%)	452 (6.64)	1,041 (5.55)
Total Reporting Rate per 1,000 Doses Administered	1.33	0.61
Serious Reporting Rate per 1,000 Doses Administered	0.09	0.03

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

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

	Lebanon Feb 14, 2021 – Feb 19, 2022	Ontario Dec 30, 2021 – Feb 13, 2022
	Pfizer-BioNTech	Pfizer-BioNTech
Total Doses Administered	4,259,387	20,052,546
Total Case Reports	4,254	11,165
Non-serious Case Reports (%)	3,955 (93.0)	10,589 (94.8)
Serious Case Reports (%)	300 (7.0)	576 (5.2)
Total Reporting Rate per 1,000 Doses Administered	0.99	0.56
Serious Reporting Rate per 1,000 Doses Administered	0.07	0.03

Table 20. Case reports following AstraZeneca COVID-19 vaccine in Lebanon in comparison with Ontario

	Lebanon Feb 14, 2021 – Feb 19, 2022	Ontario Dec 30, 2021 – Feb 13, 2022
	AstraZeneca	AstraZeneca
Total Doses Administered	717,370	1,088,547
Total Case Reports	2,302	1,620
Non-serious Case Reports (%)	2,164 (94.0)	1,496 (92.3)
Serious Case Reports (%)	138 (6.0)	124 (7.7)
Total Reporting Rate per 1,000 Doses Administered	3.2	1.48
Serious Reporting Rate per 1,000 Doses Administered	0.19	0.11

b. United-States of America based on the Centers for Disease Control and Prevention (Table 21)

According to the CDC, death reports after COVID-19 vaccination are rare. From December 14th, 2020, through February 14th, 2022, more than 547 million doses of COVID-19 vaccines were administered in the United States. Vaccine Adverse Event Reporting System (VAERS) received 12,304 preliminary death reports among people who received a COVID-19 vaccine.

Table 21. 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 – Feb 19, 2022	United-States of America Dec 14, 2020 – Feb 14, 2022
	All Vaccines Combined*	All Vaccines Combined**
Total Doses Administered	5,134,093	547,000,000
Preliminary Reports of Death^	20	12,304
Death Reporting Rate per 1000 doses	0.004	0.022

** Pfizer-BioNTech, AstraZeneca, Sputnik V, Sinopharm*
*** 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 February 18th, 2022, there have been 1,029,998 confirmed cases of SARS-CoV-2 with 9,890 deaths reported to the WHO. 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, AstraZeneca, Sputnik V, Sinopharm, and Moderna are the COVID-19 vaccines currently available in Lebanon. Most COVID-19 vaccines administered are Pfizer-BioNTech and AstraZeneca.

In this report, 93.4% were classified as non-serious case reports, and only 6.6% 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.

- 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 February 19th, 2022; Beirut, Lebanon.

FOR FURTHER INFORMATION:

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

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