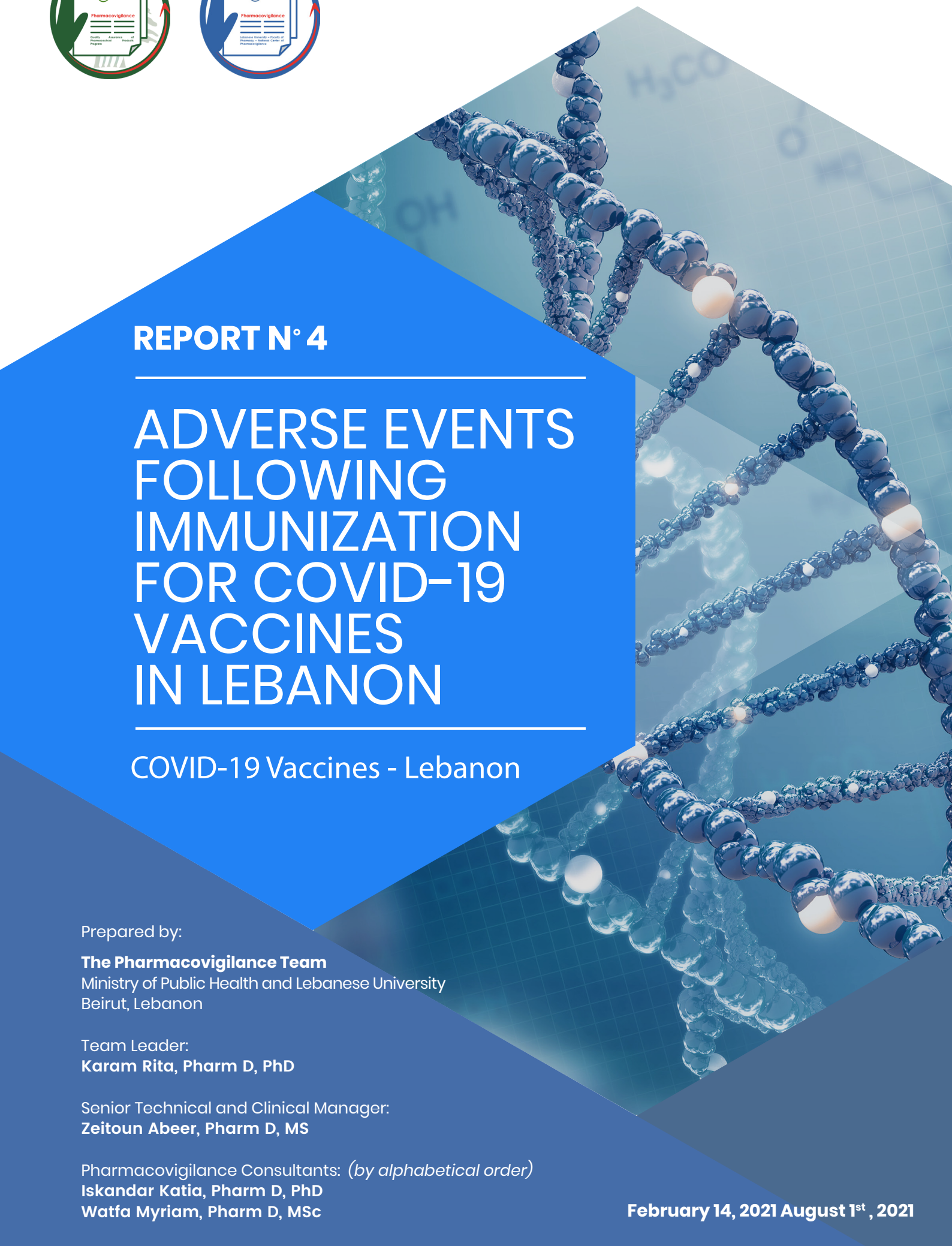

REPORT N° 4

ADVERSE EVENTS FOLLOWING IMMUNIZATION FOR COVID-19 VACCINES IN LEBANON

COVID-19 Vaccines - Lebanon

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February 14, 2021 August 1st , 2021

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EXECUTIVE SUMMARY

This executive summary provides an overview of Adverse Events Following Immunization (AEFI) that were temporally associated (i.e., occurred after administration of the vaccine) to the four vaccines available in Lebanon during the mass campaign immunization between February 14, 2021 and August 1st, 2021 (Pfizer-BioNTech Vaccine, AstraZeneca Vaccine, Sputnik V Vaccine and Sinopharm Vaccine). 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.

During the time period covered by this report (14 February, 2021 to 1 August, 2021), the total number of registered persons on the national platform for the mass immunization with COVID-19 vaccines was 2,319,763.

2,052,456 doses of COVID-19 vaccines have been administered during the period of time covered by the report, out of which 1,142,267 persons received the first dose of COVID-19 vaccine (55.7%) and 909,188 persons received both doses of COVID-19 vaccine (44.3%). 1000 persons' doses were missing. As a result, 39.2% of the total registered people on the national platform are fully immunized.

The doses were administered as stated below:
1,648,032 doses of Pfizer-BioNTech Vaccine (80.3% of total doses of COVID-19 vaccines)
278,375 doses of AstraZeneca Vaccine (13.5% of total doses of COVID-19 vaccines)
107,775 doses of Sputnik V Vaccine (5.3% of total doses of COVID-19 vaccines)
12,362 doses of Sinopharm Vaccine (0.6% of total doses of COVID-19 vaccines)
5,912 doses were identified by IMPACT Platform as missing (0.3% of total doses of COVID-19 vaccines)

As per the COVID-19 vaccination dashboard provided by IMPACT platform on 1st of August, 2021

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 AEFI. 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 tool box: AEFIs Software for reporting", and other sources including Preventive Medicine, Epidemiology Surveillance Program, Health Education and other departments from the MoPH.

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. The surveillance aims to establish a rigorous safety profile in regards to the COVID-19 Vaccines administered in Lebanon.

HIGHLIGHTS

- A total of 4,508 case reports/16,709 AEFIs were received following the administration of 2,052,456 doses of COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik V and Sinopharm) in Lebanon between the 14th of February and the 1st of August 2021.
  - This is equivalent to a reporting rate of 2.2 case reports/8.12 AEFIs per 1,000 doses administered.
  - This represents an increase of 1,652 case reports/7,248 AEFIs in comparison with the previous report dated 14 February to 30 May, 2021.

- The 4,508 case reports were received through one of the following means (Table 1):
  - IMPACT Platform: 3,198 case reports (70.94%)
  - 1214 Hotline call center: 998 case reports (22.13%)
  - Vaccination Sites/Hospital Sites through "Kobo tool box: AEFIs Software for reporting": 270 case reports (6%)
  - Other reporting sources may include Preventive Medicine, Epidemiology Surveillance Program, Health Education and other departments from the MoPH: 42 case reports (0.93%)

- Out of the 4,508 case reports (Table 2):
  - 3,767 case reports were associated with dose 1 of vaccination (83.56%)
  - 732 case reports were associated with dose 2 of vaccination (16.24%)
  - 9 case reports were missing this information (0.2%)

- Out of the 4,508 case reports (Table 3):
  - 4,242 case reports were non-serious (94.1% of total case reports)
  - 266 case reports were classified as serious cases as per the WHO definition (5.9% of total case reports), out of which:
    - 177 case reports were serious cases that did not require hospitalization nor lead to death. These were identified as other medically important events (3.92% of total case reports)
    - 89 case reports were serious cases that were either admitted to the hospital or resulted in death (1.98% of total case reports) (refer to Technical Notes for serious cases definition per WHO)

- Among the 4,508 case reports, 114 case reports fit the Important Medical Event Terms definition by EMA (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.

- Of the total received AEFIs, the 5 most frequently reported AEFIs with the four vaccines were (Table 6):
  - Injection site pain (44.6 % of total reported AEFIs)
  - General pain (44% of total reported AEFIs). This may correspond to body pain or joint pain
  - Fatigue (43.1 % of total reported AEFIs)
  - Headache (37.5 % of total reported AEFIs)
  - Chills (32.8 % of total reported AEFIs)

- The most frequently reported AEFIs per vaccine were: (Tables 9,11, 13, 15)
  - General pain, reflecting body or joint pain, was the most frequently reported adverse event for the Pfizer-BioNTech Vaccine (38.6% of the total reported AEFIs related to Pfizer-BioNTech Vaccine)
  - Fatigue was the most common adverse event following all other vaccines: 57.8 % of the total reported AEFIs related to AstraZeneca Vaccine, 63.8 % of the total reported AEFIs related to Sputnik V, and 43.8 % of the total reported AEFIs related to Sinopharm Vaccine.

REPORTING OVERVIEW

a. Global Analysis

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).

Table 1 summarizes the case reports by reporting means: 1214 Hotline Call Center, IMPACT Platform, Vaccination Sites/Hospital Sites through "Kobo tool box: AEFIs Software for reporting", 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
Count of Case report	3,198	998	270	42
Percentage	70.94%	22.13%	6%	0.93%

Table 2 classifies the 4,508 reported cases according to their occurrence: after the first or second dose of COVID-19 vaccine. Out of these 4,508 case reports, 3,767 case reports were post dose 1 (83.56%), while 732 case reports were post dose 2 (16.24%). 9 case reports (0.2%) were missing the dose number.

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

Dose received	All Vaccines		Pfizer-BioNTech		AstraZeneca		Sputnik V		Sinopharm	
	COUNT	%	COUNT	%	COUNT	%	COUNT	%	COUNT	%
Dose 1	3,767	83.56%	1,911	50.73%	1,679	44.57%	167	4.44%	10	0.26%
Dose 2	732	16.24%	599	81.83%	73	9.97%	54	7.38%	6	0.82%

*9 case reports had dose specification as blank or unknown (0.2%)of all 4,508 case reports

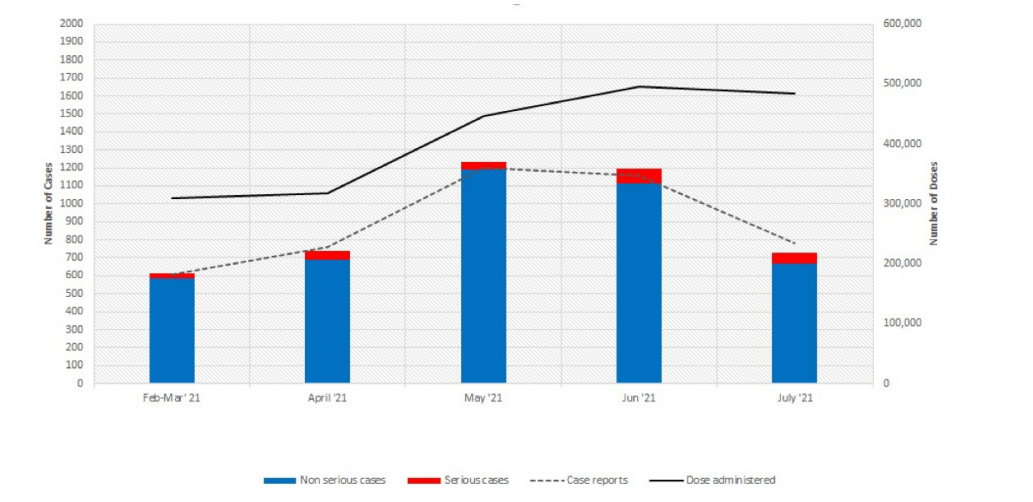
Table 3 represents a summary of 4,508 case reports that were received between the period of February 14, 2021 to August 1st, 2021

Table 3. Summary of all case reports related to COVID-19 vaccines in Lebanon, February 14, 2021 to August 1st, 2021

COVID-19 Vaccines	Pfizer-BioNTech		AstraZeneca		Sputnik V		Sinopharm		All combined	
	COUNT	%	COUNT	%	COUNT	%	COUNT	%	COUNT	%
Total case reports	2,517		1,754		221		16		4,508	
Non serious case reports*	2,353	93.5%	1,665	94.9%	212	95.9%	12	75%	4,242	94.1 %
Other medically important case reports**	115	4.6 %	50	2.9%	9	4.1%	3	18.8%	177	3.9%
Serious case reports***	49	1.9%	39	2.2%	0	0	1	6.3%	89	2%
Doses administered	1,648,032		278,375		107,775		12,362		2,052,456****	
Total reporting rate per 1,000 doses administered	1.53		6.3		2.1		1.3		2.2	
Serious reporting rate per 1,000 doses administered	0.03		0.14		0		0.08		0.044	

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24)
** Non serious cases include expected local and systemic AEFIs resolved with no need for further follow up or investigation*
*** Other medically important cases include unexpected AEFIs, local or systemic, that may be serious in their nature but did not require hospitalization nor resulted in death. They may be resolved or not in the next 48 hours*
**** Serious cases are those who meet the WHO seriousness criteria (refer to technical notes)*
***** Case reports with missing dose information are not included*

Figure 1: Number of Case reports, doses administered, non-serious and serious cases by month of the four COVID Vaccines administration in Lebanon between the period of February 14th to August 1st,2021



Note: Case reports are assessed based on date of vaccine administration. The administration month ranges from February 15, 2021 to August 1st, 2021. Accordingly, case reports were received as of February 14, 2021 with an incremental increase in both serious and non-serious case reports. The highest reporting rate was May for the non-serious and June for the serious cases. Despite the steady state achieved as of June, yet, the number of reported cases is dropping.

b. Demographics

Tables 4 and 5 present a summary of case reports related to the COVID-19 vaccines by age group, gender and reporter qualification.

Table 4. Summary of all case reports related to the four COVID-19 vaccines by age group and gender in Lebanon, February 14, 2021 to August 1st , 2021

PATIENT	COUNT	PERCENTAGE
Female	2,837	62.9 %
Male	1,671	37.1 %
12- 17 years	6	0.1%
18 - 44 years	2,179	48.3%
45 - 64 years	1,597	35.4 %
65 - 74 years	282	6.3 %
≥ 75 years	391	8.7%
Unknown Age	53	1.2 %

Note: Age represents the age at time of vaccination. Some case reports records may be missing date of birth
Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24)

Table 5. Summary of all case reports related to the four COVID-19 vaccines by reporter qualification in Lebanon, February 14, 2021 to August 1st , 2021

REPORTER QUALIFICATION	COUNT	PERCENTAGE
Physician	154	3.5 %
Pharmacist	179	4 %
Other Health Professional	330	7.4 %
Lawyer	6	0.1%
Consumer/Non Health Professional	3,839	85 %

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24)

c. Non serious Adverse Events Following Immunization

An AEFI 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 AEFIs.

c.i. Most reported AEFIs related to COVID-19 vaccines:

Table 6. Number and percentage of reported AEFIs (top 30) by symptom Preferred Terms (PT)* related to the four COVID-19 vaccines in Lebanon, February 14, 2021 to August 1st, 2021

Reported Preferred Terms* (MedDRA)	COUNT	PERCENTAGE
PT: Injection site pain	2,006	44.6%
PT: Pain	1,980	44.0%
PT: Fatigue	1,938	43.1%
PT: Headache	1,689	37.5%
PT: Chills	1,478	32.8%
PT: Pyrexia	1,400	31.1%
PT: Nausea	763	17.0%
PT: Injection site swelling	416	9.2%
PT: Abdominal pain	328	7.3%
PT: Diarrhoea	322	7.2%
PT: Injection site erythema	311	6.9%
PT: Dyspnoea	299	6.6%
PT: Cough	238	5.3%
PT: Vomiting	205	4.6%
PT: Rash	194	4.3%
PT: Respiratory symptom	172	3.8%
PT: Dizziness	167	3.7%
PT: Hypoaesthesia	146	3.2%
PT: Arthralgia	118	2.6%
PT: Pain in extremity	113	2.5%
PT: Chest pain	93	2.1%
PT: Myalgia	91	2.0%
PT: Oropharyngeal pain	87	1.9%
PT: Back pain	85	1.9%
PT: Hypertension	75	1.7%
PT: Tachycardia	70	1.6%
PT: Hyperhidrosis	63	1.4%
PT: Influenza like illness	49	1.1%
PT: Hypoaesthesia oral	43	1.0%
PT: Bone pain	42	0.9%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0).
**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 7. Number and percentage of reported AEFIs by System Organ Class (SOC)* related to the four COVID-19 vaccines in Lebanon, February 14, 2021 to August 1st, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Blood and lymphatic system disorders	37	0.8%
SOC: Cardiac disorders	127	2.8%
SOC: Ear and labyrinth disorders	53	1.2%
SOC: Endocrine disorders	1	0.0%
SOC: Eye disorders	83	1.8%
SOC: Gastrointestinal disorders	1,185	26.3%
SOC: General disorders and administration site conditions	3,847	85.5%
SOC: Immune system disorders	23	0.5%
SOC: Infections and infestations	61	1.4%
SOC: Injury, poisoning and procedural complications	39	0.9%
SOC: Investigations	105	2.3%
SOC: Metabolism and nutrition disorders	28	0.6%
SOC: Musculoskeletal and connective tissue disorders	458	10.2%
SOC: Nervous system disorders	1,963	43.6%
SOC: Psychiatric disorders	30	0.7%
SOC: Renal and urinary disorders	7	0.2%
SOC: Reproductive system and breast disorders	29	0.6%
SOC: Respiratory, thoracic and mediastinal disorders	470	10.4%
SOC: Skin and subcutaneous tissue disorders	338	7.5%
SOC: Surgical and medical procedures	1	0.0%
SOC: Vascular disorders	158	3.5%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0)
**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)*

c.ii. Non serious AEFIs per specific vaccine:

Table 8. Number and percentage of reported AEFIs (top 10) by symptom Preferred Term (PT)* related to Pfizer BioNTech COVID-19 vaccine in Lebanon, February 14, 2021 to August 1st , 2021

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
PT: Pain	968	38.6%
PT: Injection site pain	950	37.8%
PT: Fatigue	777	30.9%
PT: Headache	712	28.4%
PT: Chills	599	23.9%
PT: Pyrexia	544	21.7%
PT: Nausea	305	12.1%
PT: Injection site swelling	240	9.6%
PT: Injection site erythema	174	6.9%
PT: Diarrhoea	152	6.1%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0)
**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. Number and percentage of reported non-serious AEFIs by System Organ Class (SOC)* related to Pfizer BioNTech Vaccine in Lebanon, February 14, 2021 to August 1st , 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Blood and lymphatic system disorders	27	1.1%
SOC: Cardiac disorders	85	3.4%
SOC: Ear and labyrinth disorders	33	1.3%
SOC: Eye disorders	34	1.4%
SOC: Gastrointestinal disorders	518	20.6%
SOC: General disorders and administration site conditions	2,061	82.1%
SOC: Immune system disorders	14	0.6%
SOC: Infections and infestations	40	1.6%
SOC: Injury, poisoning and procedural complications	11	0.4%
SOC: Investigations**	68	2.7%
SOC: Metabolism and nutrition disorders	11	0.4%
SOC: Musculoskeletal and connective tissue disorders	230	9.2%
SOC: Nervous system disorders	858	34.2%
SOC: Psychiatric disorders	11	0.4%
SOC: Renal and urinary disorders	4	0.2%
SOC: Reproductive system and breast disorders	12	0.5%
SOC: Respiratory, thoracic and mediastinal disorders	251	10.0%
SOC: Skin and subcutaneous tissue disorders	160	6.4%
SOC: Surgical and medical procedures	1	0.0%
SOC: Vascular disorders	76	3.0%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0)
**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 increased blood pressure, abnormal blood pressure, decreased blood pressure, increased systolic blood pressure, increased intraocular pressure, decreased oxygen saturation, irregular heart rate, increase glucose level, decreased weight, decreased urine output, red blood cells in the urine, and cases who tested positive for SARS COVID 1 and 2 or had a positive PCR.*

Table 10. Number and percentage of reported AEFIs (top 10) by symptom Preferred Term (PT)* related to AstraZeneca COVID-19 Vaccine in Lebanon, February 14, 2021 to August 1st , 2021

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
PT: Fatigue	1,013	57.8%
PT: Injection site pain	946	54.0%
PT: Pain	898	51.2%
PT: Headache	872	49.7%
PT: Chills	773	44.1%
PT: Pyrexia	761	43.4%
PT: Nausea	406	23.2%
PT: Abdominal pain	176	10.0%
PT: Injection site swelling	163	9.3%
PT: Diarrhoea	150	8.6%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0)
**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. Number and percentage of reported non-serious AEFIs by System Organ Class (SOC)* related to AstraZeneca COVID-19 Vaccine in Lebanon, February 14, 2021 to August 1st , 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Blood and lymphatic system disorders	8	0.5%
SOC: Cardiac disorders	39	2.2%
SOC: Ear and labyrinth disorders	16	0.9%
SOC: Endocrine disorders	1	0.1%
SOC: Eye disorders	45	2.6%
SOC: Gastrointestinal disorders	598	34.1%
SOC: General disorders and administration site conditions	1,571	89.6%
SOC: Immune system disorders	9	0.5%
SOC: Infections and infestations	16	0.9%
SOC: Injury, poisoning and procedural complications	27	1.5%
SOC: Investigations**	35	2.0%
SOC: Metabolism and nutrition disorders	17	1.0%
SOC: Musculoskeletal and connective tissue disorders	209	11.9%
SOC: Nervous system disorders	982	56.0%
SOC: Psychiatric disorders	19	1.1%
SOC: Renal and urinary disorders	3	0.2%
SOC: Reproductive system and breast disorders	16	0.9%
SOC: Respiratory, thoracic and mediastinal disorders	194	11.1%
SOC: Skin and subcutaneous tissue disorders	159	9.1%
SOC: Vascular disorders	78	4.4%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0)
**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 increased blood pressure, abnormal blood pressure, decreased blood pressure, increased systolic blood pressure, decreased oxygen saturation, increased heart rate, decreased weight, increased blood PH, increased level of Fibrin D dimer, and cases who tested positive for SARS COVID 1 and 2 or had a positive PCR.*

Table 12. Number and percentage of reported AEFIs (top 10) by symptom Preferred Term (PT)* related to Sputnik V Vaccine in Lebanon, February 14, 2021 to August 1st 2021

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
PT: Fatigue	141	63.8%
PT: Pain	109	49.3%
PT: Chills	105	47.5%
PT: Injection site pain	105	47.5%
PT: Headache	103	46.6%
PT: Pyrexia	92	41.6%
PT: Nausea	48	21.7%
PT: Diarrhoea	19	8.6%
PT: Cough	13	5.9%
PT: Dyspnoea	13	5.9%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0)
**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. Number and percentage of reported non-serious AEFIs by System Organ Class (SOC)* related to Sputnik V Vaccine in Lebanon, February 14, 2021 to August 1st, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Blood and lymphatic system disorders	2	0.9%
SOC: Cardiac disorders	2	0.9%
SOC: Ear and labyrinth disorders	4	1.8%
SOC: Eye disorders	2	0.9%
SOC: Gastrointestinal disorders	65	29.4%
SOC: General disorders and administration site conditions	203	91.9%
SOC: Infections and infestations	4	1.8%
SOC: Injury, poisoning and procedural complications	1	0.5%
SOC: Investigations**	1	0.5%
SOC: Musculoskeletal and connective tissue disorders	17	7.7%
SOC: Nervous system disorders	116	52.5%
SOC: Reproductive system and breast disorders	1	0.5%
SOC: Respiratory, thoracic and mediastinal disorders	22	10.0%
SOC: Skin and subcutaneous tissue disorders	18	8.1%
SOC: Vascular disorders	4	1.8%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0)
**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)*
***Investigation Cases are cases who tested positive for SARS COVID 2*

Table 14. Number and percentage of reported AEFIs (top 10) by symptom Preferred Terms (PT)* related to Sinopharm Vaccine in Lebanon, February 14, 2021 to August 1st, 2021

Reported Preferred Terms (MedDRA)	COUNT	PERCENTAGE
PT: Fatigue	7	43.8%
PT: Injection site pain	5	31.3%
PT: Pain	5	31.3%
PT: Nausea	4	25.0%
PT: Chest pain	3	18.8%
PT: Dyspnoea	3	18.8%
PT: Pyrexia	3	18.8%
PT: Cough	2	12.5%
PT: Dizziness	2	12.5%
PT: Headache	2	12.5%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0)
**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 15. Number and percentage of reported non-serious AEFIs by System Organ Class (SOC)* related to Sinopharm Vaccine in Lebanon, February 14, 2021 to August 1st, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
SOC: Cardiac disorders	1	6.3%
SOC: Eye disorders	2	12.5%
SOC: Gastrointestinal disorders	4	25.0%
SOC: General disorders and administration site conditions	12	75.0%
SOC: Infections and infestations	1	6.3%
SOC: Investigations**	1	6.3%
SOC: Musculoskeletal and connective tissue disorders	2	12.5%
SOC: Nervous system disorders	7	43.8%
SOC: Respiratory, thoracic and mediastinal disorders	3	18.8%
SOC: Skin and subcutaneous tissue disorders	1	6.3%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0)
**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)*
***Investigation Cases are cases who tested negative for SARS COVID 2 despite having COVID 19 symptoms*

Table 16: Summary of number and percentage of reported AEFIs (top 10) by symptom Preferred Term (PT)* related to the four available vaccines in Lebanon, February 14, 2021 to August 1st , 2021

Reported Preferred Terms (MedDRA)	Pfizer-BioNTech		AstraZeneca		Sputnik V		Sinopharm	
	COUNT	%	COUNT	%	COUNT	%	COUNT	%
PT: Injection site pain	950	37.8%	946	54%	105	47.5%	5	31.3%
PT: Pain	968	38.6%	898	51.2%	109	49.3%	5	31.3%
PT: Fatigue	777	30.9%	1,013	57.8%	141	63.8%	7	43.8%
PT: Headache	712	28.4%	872	49.7%	103	46.6%	2	12.8%
PT: Chills	599	23.9%	773	44.1%	105	47.5%	1	6.3%
PT: Pyrexia	544	21.7%	761	43.4%	92	41.6%	3	18.8%
PT: Nausea	305	12.1%	406	23.2%	48	21.7%	4	25%
PT: Injection site swelling	240	9.6%	163	9.3%	13	5.9%	0	0%
PT: Abdominal pain	10	0.4%	176	10%	12	5.4%	0	0%
PT: Diarrhoea	152	6.1%	150	8.6%	19	8.6%	1	6.3%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0).
**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.*

d. Serious Adverse Events Following Immunization

According to 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 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 classification:*** *This include 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 classification:*** *This include cases that resulted in death, hospitalization, disability, congenital abnormalities, or were life threatening. These are investigated and evaluated for causality assessment.*

d.i: Other Medically Important Events Following Immunization Per WHO Definition:

Tables 17, 18, 19, 20, and 21 summarize the other medically important events for the four COVID-19 vaccines: Pfizer-BioNTech Vaccine, AstraZeneca Vaccine, Sputnik Vaccine, and Sinopharm Vaccine.

Table 17. Number and percentage of reported top (30) "Other Medically Important Events" following immunization by symptom Preferred Terms (PT)* for the four COVID-19 vaccines available in Lebanon, February 14, 2021 to August 1st, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
PT: Hypertension	36	20.3%
PT: Tachycardia	26	14.7%
PT: Hypotension	19	10.7%
PT: Contusion	12	6.8%
PT: Chest pain	10	5.6%
PT: Hypoaesthesia	9	5.1%
PT: Blood pressure increased	7	4.0%
PT: Hyperhidrosis	7	4.0%
PT: Syncope	7	4.0%
PT: Vision blurred	7	4.0%
PT: Angioedema	6	3.4%
PT: Swelling face	6	3.4%
PT: Tinnitus	6	3.4%
PT: Thrombosis	5	2.8%
PT: Herpes zoster	4	2.3%
PT: Palpitations	4	2.3%
PT: Urticaria	4	2.3%
PT: Hypoaesthesia oral	4	2.3%
PT: Blood pressure decreased	3	1.7%
PT: Hypersensitivity	3	1.7%
PT: Laryngospasm	3	1.7%
PT: Muscle spasms	3	1.7%
PT: Paraesthesia	3	1.7%
PT: Balance disorder	3	1.7%
PT: Respiratory symptom	3	1.7%
PT: SARS-CoV-2 test positive	3	1.7%
PT: Asthma	2	1.1%
PT: Bell's palsy	2	1.1%
PT: Chest discomfort	2	1.1%
PT: Hyperventilation	2	1.1%
PT: Hypoglycaemia	2	1.1%
PT: Oxygen saturation decreased	2	1.1%
PT: Pericarditis	2	1.1%

Data Source: Vigil.yze (Dataset date: 01/08/2021, MedDRA version: 24)
**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 18. Number and percentage of top 10 reported "Other Medically Important Events" following immunization by symptom Preferred Terms (PT)* for the Pfizer-BioNTech COVID-19 Vaccine available in Lebanon, February 14, 2021 to August 1st, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
PT: Hypertension	26	22.6%
PT: Tachycardia	16	13.9%
PT: Hypotension	11	9.6%
PT: Angioedema	6	5.2%
PT: Hypoaesthesia	6	5.2%
PT: Blood pressure increased	4	3.5%
PT: Chest pain	4	3.5%
PT: Influenza like illness	4	3.5%
PT: Tinnitus	4	3.5%
PT: Herpes zoster	3	2.6%

Data Source: VigiLyze (Dataset date: 01/08/2021, MedDRA version: 24)
**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 19. Number and percentage of top 10 reported "Other Medically Important Events" following immunization by symptom Preferred Terms (PT)* for the AstraZeneca COVID-19 Vaccine available in Lebanon, February 14, 2021 to August 1st, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
PT: Hypertension	10	20.0%
PT: Tachycardia	9	18.0%
PT: Contusion	9	18.0%
PT: Hypotension	5	10.0%
PT: Chest pain	3	6.0%
PT: Hyperhidrosis	3	6.0%
PT: Swelling face	3	6.0%
PT: Thrombosis	3	6.0%
PT: Arthralgia	2	4.0%
PT: Hypersensitivity	2	4.0%
PT: Hypoaesthesia	2	4.0%
PT: Tinnitus	2	4.0%

Data Source: VigiLyze (Dataset date: 01/08/2021, MedDRA version: 24)
**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 20. Number and percentage of top 10 reported "Other Medically Important Events" following immunization by symptom Preferred Terms (PT)* for Sputnik V COVID-19 Vaccine available in Lebanon, February 14, 2021 to August 1st, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
PT: Hypotension	3	33.3%
PT: Chest pain	2	22.2%
PT: Arrhythmia	1	11.1%
PT: Hyperhidrosis	1	11.1%
PT: Hypoaesthesia	1	11.1%
PT: Nervous system disorder	1	11.1%
PT: Syncope	1	11.1%
PT: Tachycardia	1	11.1%
PT: Contusion	1	11.1%
PT: SARS-CoV-2 test positive	1	11.1%

Data Source: VigiLyze (Dataset date: 01/08/2021, MedDRA version: 24)
**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 21: Number and percentage of top 10 reported "Other Medically Important Events" following immunization by symptom Preferred Terms (PT)* for Sinopharm V COVID-19 Vaccine available in Lebanon, February 14, 2021 to August 1st, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
PT: Pain	2	66.7%
PT: Back pain	1	33.3%
PT: Chest pain	1	33.3%
PT: Fatigue	1	33.3%
PT: Muscle spasms	1	33.3%
PT: Nausea	1	33.3%
PT: Neuritis	1	33.3%
PT: Paraesthesia	1	33.3%
PT: Vision blurred	1	33.3%
PT: Musculoskeletal discomfort	1	33.3%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0).
**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 22: Summary of number and percentage of (top 10) reported other medically important event by symptom Preferred Term (PT)* related to the four available vaccines in Lebanon, February 14, 2021 to August 1st , 2021

Reported Preferred Terms (MedDRA)	Pfizer-BioNTech		AstraZeneca		Sputnik V		Sinopharm	
	COUNT	%	COUNT	%	COUNT	%	COUNT	%
PT: Hypertension	26	22.6%	10	20%	0	0%	0	0%
PT: Tachycardia	16	13.9%	9	18%	1	11.1%	0	0%
PT: Hypotension	11	9.6%	5	10%	3	33.3%	0	0%
PT: Contusion	2	1.7%	9	18%	1	11.1%	0	0%
PT: Chest pain	4	3.5%	3	6%	2	22.2%	1	33.3%
PT: Hypoaesthesia	6	5.2%	2	4%	1	11.1%	0	0%
PT: Blood pressure increased	4	3.5%	3	6%	0	0%	0	0%
PT: Hyperhidrosis	3	2.6%	3	6%	1	11.1%	0	0%
PT: Syncope	2	1.7%	4	8%	1	11.1%	0	0%
PT: Vision blurred	4	3.5%	2	4%	0	0%	1	33.3%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0).
**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.*

dii. Serious Cases:

Serious cases are cases that resulted in death, hospitalization, disability, congenital abnormalities, or were life threatening. These cases were followed up with causality assessment in order to evaluate the potential relationship between the AEFI and the vaccine and to implement the appropriate actions.

A total of 89 case reports were classified as serious. Out of these 89 cases, 37 case reports fit the WHO definition of seriousness criteria but did not require onsite investigation and were followed up by phone only. 52 cases were serious reports that required full investigation. Of the 52 serious cases, 30 reports have been completed with a final decision by the Serious AEFI Special Committee at the Ministry of Public Health. The remaining 22 case reports are still under assessment by the PV team.

The tables below show detailed description of the 52 serious cases.

Table 23: Summary of 30* serious case reports by gender, age groups, dose number and time of AEFI occurrence (TTO)

Vaccine	All Cases	Pfizer - BioNtech	AstraZeneca	Sinopharm
Number of case report (%)	30	25 (83.4)	4 (13.3)	1 (3.3)
Age Years	12- 17 years	0	0	0
	18 - 44 years	2	1	1
	45 - 64 years	2	3	0
	65 - 74 years	2	0	0
	≥ 75 years	19	0	0
Median Age (years)(range)		84 (25-95)	54.5 (29-56)	43
Sex (%)	Male	8 (32)	2 (50)	0 (0)
	Female	17 (68)	2 (50)	1 (100)
Dose number(%)	1st	16 (64)	4 (100)	1 (100)
	2nd	9 (36)	0 (0)	0 (0)
Median TTO ** (days)(range)		5 (0-26)	9.5 (2-15)	20
Median TTO (days)per dose (range)	1st	5 (0-26)	9.5 (2-15)	20
	2nd	3 (1-19)	0	0
Mean TTO (days) per dose(SD)***	1st	8.28 (7.62)	9 (6.4)	20
	2nd	7.3 (7.4)	0	0
Seriousness Criteria (%)	Fatal(N=16)	12 (48)	3 (75)	1 (100)
	Hospitalized(N=14)	13 (52)	1 (25)	0
AEFI committee decision(%)	Coincidental	18 (72)	1 (25)	1 (100)
	Indeterminate	7 (28)	1 (25)	0
	Consistent	0	2(50)	0

**30 case reports assessment have been completed by PV team and Serious AEFI Special Committee decision at MoPH*
***TTO: Time to onset*
****SD: Standard deviation*

Table 24: Summary of reported AEFIs for the 30* serious cases by Vaccine

Vaccine / AEFI	Pfizer BioNtech N=25	AstraZeneca N=4	Sinopharm N=1
Cardiac Arrest	6	1	0
Fatal Atrial Fibrillation	1	0	0
Severe Allergic Reaction	1	0	0
Atrial Fibrillation with Ischemic Cerebrovascular accident (CVA)	1	0	0
Oxygen desaturation with Dyspnea	1	0	0
Ischemic Cerebrovascular accident (CVA)	10	0	0
Hyper stimulation of Immune System	1	0	0
Thrombosis of left Axillary Artery	1	0	0
Myocardial Infarction	1	0	0
Atypical Pneumonia	1	0	0
Pulmonary Edema	1	0	0
Cerebral Hemorrhage	0	1	0
Bleeding Cerebrovascular accident (CVA)	0	1	0
Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT)	0	1	0
Polypnea with cyanosis and hypotension	0	0	1

**30 case reports assessment have been completed by PV team and Serious AEFI Special Committee at MoPH*

Table 25: Summary of 22* serious case reports by gender, age groups, dose number and time of AEFI occurrence

Vaccine	All Cases	Pfizer - BioNtech	AstraZeneca
Number of case report (%)	22	17 (77.3)	5 (22.7)
Age Years	12- 17 years	0	0
	18 - 44 years	4	0
	45 - 64 years	6	4
	65 - 74 years	3	1
	≥ 75 years	4	0
Median Age (years)(range)		63 (19-80)	60 (49-65)
Sex (%)	Male	15 (88.2)	3 (60)
	Female	2 (11.8)	2 (40)
Dose number(%)	1st	10 (58.8)	4 (80)
	2nd	7 (41.2)	1 (20)
Median TTO ** (days)(range)		2 (0-21)	10 (1-32 days)
Median TTO (days)per dose (range)	1st	2 (0-21)	12.5 (3-32)
	2nd	3 (0-16)	1
Mean TTO (days) per dose(SD)***	1st	6.4 (7.3)	15 (12.4)
	2nd	4.1 (5.3)	1
Seriousness Criteria (%)	Fatal(N=3)	3	0
	Hospitalized(N=19)	14	5

**22 serious case reports that are still under assessment by the PV team*
***TTO: Time to onset*
****SD: Standard deviation*

diii. Important Medical Events Per EMA Classification:

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. Among the 266 serious cases, EMA has highlighted 114 case reports as important medical event according to the above definition.

Table 26: Number and percentage of Important Medical Event (EMA classification) symptoms Preferred Terms (PT)* for the four COVID-19 vaccines available in Lebanon, February 14, 2021 to August 1st, 2021

Reaction (MedDRA)	COUNT	PERCENTAGE
PT: Syncope	27	23.5%
PT: Cerebrovascular accident	13	11.3%
PT: Angioedema	8	7.0%
PT: Thrombosis	8	7.0%
PT: Cardiac arrest	7	6.1%
PT: Arrhythmia	4	3.5%
PT: Depressed level of consciousness	4	3.5%
PT: Myocardial infarction	4	3.5%
PT: Anaphylactic shock	2	1.7%
PT: Atrial fibrillation	2	1.7%
PT: Bell's palsy	2	1.7%
PT: Cellulitis	2	1.7%
PT: Facial paralysis	2	1.7%
PT: Loss of consciousness	2	1.7%
PT: Pancreatitis	2	1.7%
PT: Pericarditis	2	1.7%
PT: Vein rupture	2	1.7%
PT: Acute myocardial infarction	1	0.9%
PT: Appendicitis	1	0.9%
PT: Atypical pneumonia	1	0.9%
PT: Blindness	1	0.9%
PT: Bradycardia	1	0.9%
PT: Cerebral haemorrhage	1	0.9%
PT: Cerebral ischaemia	1	0.9%
PT: Deafness	1	0.9%
PT: Glaucoma	1	0.9%
PT: Haemorrhage intracranial	1	0.9%
PT: Hallucination	1	0.9%
PT: Hemiparesis	1	0.9%
PT: Hypokalaemia	1	0.9%
PT: Laryngeal oedema	1	0.9%
PT: Mental impairment	1	0.9%
PT: Neuropathy peripheral	1	0.9%
PT: Paralysis	1	0.9%
PT: Pneumonia	1	0.9%
PT: Pulmonary oedema	1	0.9%
PT: Pyelonephritis	1	0.9%
PT: Seizure	1	0.9%
PT: Uterine haemorrhage	1	0.9%
PT: Herpes zoster infection neurological	1	0.9%
PT: Infarction	1	0.9%
PT: Chorioretinopathy	1	0.9%

Data Source: VigiLyze (Dataset date: 1/08/2021, MedDRA version: 24.0).
**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.*

DESCRIPTION OF ADVERSE EVENTS FOLLOWING IMMUNIZATION

The age group of vaccine recipients who mostly reported AEFIs was between 18 to 44 years old (48.3%), with females reporting more AEFIs than males (62.9% vs. 37.1%) (Table 4). The majority of the reporters were the vaccine recipients (85%).

The most reported AEFIs for all COVID-19 vaccines per symptom were injection site pain (44.6% of total reported AEFIs), general pain (44% of total reported AEFIs), fatigue (43.1% of total reported cases) and headache (37.5% of total reported AEFIs) (Table 6).

The most reported AEFIs by System Organ Class (SOC) were General Disorders and Administration Site Conditions (85.5% of total reported AEFIs per SOC), followed by Nervous System Disorders (43.6% of total reported AEFIs per SOC) and Gastrointestinal Disorders (26.3% of total reported AEFIs per SOC) (Table 7).

General pain, reflecting body or joint pain, was the most frequently reported non-serious adverse event for the Pfizer-BioNTech Vaccine (38.6% of total reported AEFIs). Fatigue was the most common adverse event following all other vaccines: 57.8% of the total reported AEFIs related to AstraZeneca Vaccine, 63.8% of the total reported AEFIs related to Sputnik V Vaccine, and 43.8% of the total reported AEFIs related to Sinopharm Vaccine. (Tables 8, 10, 12, 14)

Among the other medically important events, the most reported AEFIs that required close monitoring were: *(section d.i, Tables 17, 18, 19, 20, 21)*

For Pfizer BioNTech Vaccine

- Hypertension including cases of Increased Blood Pressure and Irregular Blood Pressure (31 case reports)
- Tachycardia including cases of Palpitations and Irregular Heart Rates (19 case reports)
- Angioedema including Lip and Face Swelling/Laryngospasm (15 case reports)
- Chest pain including cases of Chest Discomfort (6 case reports)
- Hypoesthesia including cases of Burning, Hypoesthesia Oral, Facial Paralysis and Peripheral Neuropathy (13 case reports)
- Tinnitus (4 case reports), Herpes Zoster (3 case reports), Flue Like Symptoms (4 case reports), Thrombosis (2 case reports), Contusion/Ecchymosis (3 case reports), and Pericarditis (2 case reports)

For AstraZeneca Vaccine

- Hypertension including cases of Increased Blood Pressure (13 case reports)
- Tachycardia including cases of Palpitations (11 case reports)
- Hypoesthesia including cases of Paresthesia and Hypoesthesia oral (6 case reports)
- Hypersensitivity including cases of Rash and Erythema (8 case reports)
- Contusion (9 case reports), Thrombosis (4 case report), Tinnitus (2 case reports), Bell's Palsy (1 case report), Influenza Like Symptoms (3 case reports), Chest Pain (3 case reports), and Swelling Face (3 case reports)

For Sputnik V Vaccine
- Hypotension (3 case reports), Arrhythmias (1 case report) and Contusion (1 case report)

For Sinopharm Vaccine
- Chest pain and Paresthesia (one case report), Blurred vision (one case report) and Neuritis (one case report)

It is worth noting that some of the reported AEFIs are sometimes automatically converted by Vigiflow into their Preferred Term of reporting. For example, all cases of Bruising were reported as Contusion, and cases of Numbness as Hypoesthesia as per MedDRA Preferred Terms by the Vigilyze system.

Cases of headache post AstraZeneca Vaccine were followed up to rule out any other serious AEFI such as Bleeding or Ischemic Cerebrovascular Accident (CVA)

All of the Other Medically Important Events were resolved, therefore not reclassified as serious with the exception of three case reports:

- The first case is a male patient who experienced left eye blood clot following the first dose of Pfizer-BioNTech vaccine which resulted in loss of vision in the concerned eye.
- The second case is a male patient with family history of hearing loss known to have decreased hearing. This patient had complete deafness following the first dose of Pfizer-BioNTech vaccine, which resulted in the installation of a hearing aid.
- The third case is a female who suffered from unclassified nervous system complications following the second dose of Sputnik V vaccine. No diagnosis is identified yet and she is still not recovered.

Serious AEFIs resulting in Hospitalization and Death (Tables 22, 23, 24)

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 in order 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 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 Ministry of Public Health.

In the period of time covered by this report, there were 89 case reports classified as serious per the above specification, representing 2% of all case reports and a serious AEFI reporting rate of 0.044 per 1,000 doses of vaccines. Of the 89 cases, 37 reports were followed up by the phone only without the need for further investigation. 52 cases required close follow up with investigation and causality assessment, out of which 30 cases have been already assessed by the Serious AEFI Special Committee at Ministry of Public Health and a final decision was concluded with the agreement of all members (Tables 22 and 23). The remaining 22 serious cases are still under investigation by the PV team (Table 24).

Overview of completed serious case reports (Table 22, 23)

Out of the 30 serious case reports, there are 14 cases of hospitalization and 16 cases of suspected death post vaccine.

For the 14 hospitalized cases post vaccination, (2 Males: 12 Females), the vaccines' recipients age range was between 25 and 95 years old. 10 hospitalization occurred post dose 1, while the remaining 4 hospitalization occurred post dose 2. The 14 vaccine recipients experienced AEFIs within one day to 19 days' post vaccination. The Serious AEFI Special Committee at Ministry of Public Health confirmed the coincidental causality assessment in all cases except for two case reports that were considered as indeterminate.

In the 16 death cases, (8 Males: 8 Females), the vaccines' recipients age range was between 29 and 92 years old. 11 death cases were post dose one while the remaining 5 cases were post dose 2. The 16 vaccine recipients experienced AEFIs within 20 minutes to 20 days' post vaccination. The Serious AEFI Special committee at the MoPH confirmed the coincidental causality assessment in 8 case reports, 6 case reports were considered as indeterminate, and 2 case reports showed a consistent association.

Overview of serious case reports under assessment (Table 24)

Out of the 22 serious case reports 19 cases of hospitalization and 3 cases of suspected death post vaccine.

For the 19 hospitalized cases post vaccination, (15 Males: 4 Females), the vaccines' recipients age range was between 19 and 80 years old. 12 hospitalizations occurred post dose 1, while the remaining 6 hospitalizations occurred post dose 2. There is one case report out of the 19 hospitalized patients occurred due to an error in immunization: the patient received both doses on the same day. The 19 vaccine recipients experienced AEFIs within one day to 32 days' post vaccination.

In the 3 death cases (3 Males), the vaccines' recipients age range was between 40 and 79 years. All cases were post dose 2. The 3 vaccine recipients experienced AEFIs within 2 hours to 4 days' post vaccination. (Table 24)

SIGNALS

In regards to signals (refer to Technical Notes) associated with the AEFIs by Pfizer-BioNTech and AstraZeneca Vaccine, the PV team has adopted two sources for identifying signals:

The French National Security Agency of Medicines and Health Products (ANSM) and the World Health Organization-Uppsala Monitoring Center (WHO-UMC) Classification.

I. In Lebanon, the below reported AEFIs during the time of this report, may be considered as potential or confirmed signals for both vaccines, Pfizer-BioNTech and AstraZeneca, which are aligned with the ANSM signals list:

For Pfizer BioNTech Vaccine:

- The **potential** signals include: Cardiac Rhythm disorders (Tachycardia/Atrial Fibrillation/ Palpitations/Irregular Heart Rate) (71 reported AEFIs), Rheumatoid Polyarthritis (Arthritis/ Arthralgia) (53 reported AEFIs), Menstrual Irregularities (4 reported AEFIs) and Herpes Zoster (4 reported AEFIs).
- The **confirmed** signals include: Hypertension/Increased Blood Pressure (69 reported AEFIs) and Pericarditis (2 case reports)

For AstraZeneca Vaccine:

- The **potential** signal includes: Hypertension (including Increased Blood Pressure/Increased Systolic Pressure and Abnormal Pressure) (46 reported AEFIs), Bruising/Ear hematoma/ Epistaxis/Oral Bruising/Uterine Bleeding/Heavy Menstrual Bleeding/Contusion/Oral Contusion (41 reported AEFIs), Influenza Like Syndrome/Dyspnea with Influenza (19 reported AEFIs), Bell's Palsy (1 case report) and Facial Paralysis (1 case report)
- The **confirmed** signals include: Thrombosis/Axillary Vein thrombosis/ CVA/ Myocardial Infarction (7 reported AEFIs)

II. The WHO UMC Vigibase has highlighted Trigeminal Neuralgia (refer to Technical Notes) and Hearing Loss/Tinnitus as confirmed signals with both Pfizer-BioNTech and AstraZeneca while Myocarditis was a confirmed signal for Pfizer-BioNTech. In Lebanon, both vaccines have reported AEFIs that may be considered as associated potential signals per the WHO-UMC classification.

- **For Pfizer-BioNTech Vaccine:** Paresthesia (14 reported AEFIs), Hypoesthesia Oral (19 reported AEFIs), Paresthesia Oral (4 reported AEFIs), Hypoesthesia (71 reported AEFIs), Eye Pain (9 reported AEFIs), Ear Pain (8 reported AEFIs), Facial Paralysis (1 reported AEFIs), Facial Pain (1 reported AEFI), Tinnitus (9 reported AEFIS) and Pericarditis (2 case reports)

- **For AstraZeneca Vaccine:** Paresthesia (11 reported AEFIs), Paresthesia Oral (2 reported AEFIs), Hypoesthesia Oral (24 reported AEFIs), Hypoesthesia (70 reported AEFIs), Eye Pain (5 reported AEFIs), Ear Pain (6 reported AEFIs), Jaw Pain (2 reported AEFIs) and Tinnitus (4 reported AEFIS).

COMPARISON WITH INTERNATIONAL AEFI DATA

In regards to the four COVID-19 vaccines, the most frequently reported AEFIs in the WHO UMC global database Vigibase (including to date 1,769,599 COVID-19 reported cases) were: Headache (28.1% of total reported AEFIs), Pyrexia (22.8% of total reported AEFIs), Fatigue (18.9% of total reported AEFIs), Chills (15.8% of total reported AEFIs), and Myalgia (14.7% of total reported AEFIs).

The results are compatible with the National Data which include Fatigue, Chills, Headache, and Pyrexia as the top 10 most reported AEFIs in Lebanon (Table 6).

CONCLUSION

In the scope of post-marketing surveillance conducted by the PV Program, a total of 4,508 case reports corresponding to 16,709 AEFIs were received following the administration of 2,052,456 doses of COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik V and Sinopharm) in Lebanon between the 14th of February and the 1st of August 2021. This is equivalent to a reporting rate of 2.2 case reports/8.2 AEFIs per 1,000 doses administered.

The IMPACT Platform was the main mean of reporting. The vaccine recipients were the main reporters. The age group of vaccine recipients who mostly reported AEFIs was between 18 to 44 years old, with females reporting more AEFIs than males. Most AEFIs reported at the national basis are compatible with those reported at the international database. Trigeminal Neuralgia and Tinnitus, following vaccination with Pfizer-BioNTech Vaccine and AstraZeneca Vaccine are potential signals. In addition, Hypertension, and Pericarditis are confirmed signals following Pfizer-BioNTech while Thrombosis was identified as a confirmed signal following AstraZeneca Vaccine.

The Pharmacovigilance 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 in particular 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.
- Signal: According to the World Health Organization (WHO), a "signal" is 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."
- 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.

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FOR FURTHER INFORMATION:

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