



THE NATIONAL PHARMACOVIGILANCE PROGRAM NEWSLETTER

LEBANON

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Prepared by
Pharmacovigilance Team
at the **Ministry of Public Health**

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THE TEAM



Dr. Rita Karam
Team Lead



Dr. Abeer Zeitoun
Senior Clinical and Technical Manager



Dr. Carla Allam



Dr. Sirine Chehade



Dr. Maya Helali



Dr. Aya Ibrahim

Pharmacovigilance Officers (by alphabetical order)



Dr. Katia Iskandar



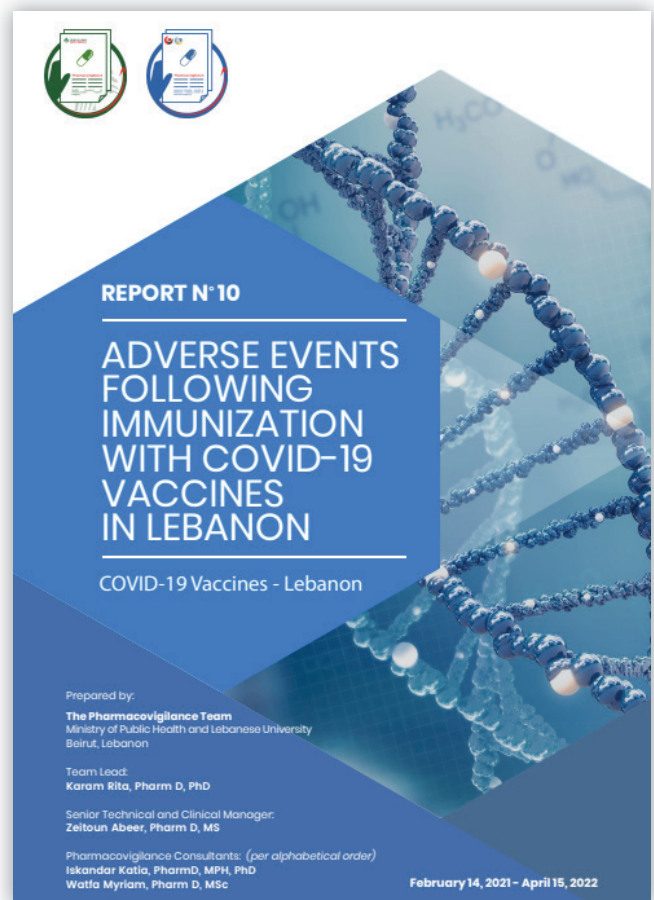
Dr. Myriam Watfa

Pharmacovigilance Consultants (by alphabetical order)

MONTHLY REPORT: THE PHARMACOVIGILANCE'S WAY OF COMMUNICATING

Within the scope of the Adverse Events Following Immunization (AEFIs) surveillance related to the available COVID-19 Vaccines in Lebanon, a monthly report is prepared by the team as a mean of communicating results of the data received to the Pharmacovigilance (PV) program since the deployment of COVID-19 vaccines in Lebanon. The surveillance aims to establish a rigorous safety profile regarding the COVID-19 vaccines administered in Lebanon.

In the latest report covering the period of 14th of February 2021 to 15th of April 2022, the total number of registered persons was 6,207,837 and 5,332,315 was the total administered doses. Out of the total 6,918 reported case reports (corresponding to 25,108 AEFIs), 93.2% were non-serious. Vaccine recipients had the highest reporting rate (83.9%). AEFIs were mostly reported in vaccine recipients aging between 18 and 44 years old (55.0%), with females reporting more than males (60.7% vs. 39.3%). Of the total received AEFIs, the five most frequently reported with the five COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik V, Sinopharm, and Moderna) available in Lebanon were injection site pain, fatigue, general pain which may correspond to body pain or joint pain, headache, and pyrexia. It is worth noting that 35.82% of the total registered persons have completed their primary COVID-19 vaccination series (dose 1 and 2). Finally, among the five main Lebanese governorates (Beirut, Mount Lebanon, South, North, and Bekaa/Baalbek-Hermel), Mount Lebanon governorate had the highest reporting rate (41.6%) followed by Beirut (29.59%) which is in alignment with the number of administered vaccination doses.



Adverse Events Following Immunization in Pregnant Women

There were 7 case reports among pregnant women in Lebanon. Out of these 7 case reports 5 were following the Pfizer-BioNTech vaccine and the remaining 2 were following the AstraZeneca vaccine. All 7 case reports included non-serious AEFIs such as injection site pain, fever, and chills.

According to the American College of Obstetricians and Gynecology, injection site pain, fever, muscle pain, joint pain, headache, and fatigue are the most common AEFIs among pregnant women. This is in accordance with the data presented in the monthly report. In addition, no evidence of adverse maternal or fetal effects from vaccinating pregnant individuals with the COVID-19 vaccine was reported, and a growing body of data demonstrates the safety of their use.

COVID-19 Vaccines and Pregnancy: Conversation Guide for Clinicians [Internet]. [cited 2022 May 18]. Available from: <https://www.acog.org/en/covid-19/covid-19-vaccines-and-pregnancy-conversation-guide-for-clinicians>

You can access the report using this link: <https://www.moph.gov.lb/userfiles/files/Quality%26Safety/PharmacovigilanceSystemInLebanon/Pharmacovigilance%20Report%209.pdf>

Webinar Briefing

EVALUATION OF COVID-19 VACCINATION PROCESS AT VACCINATION CENTERS: NATIONAL DESCRIPTIVE STUDY IN LEBANON



Sharing the experience

DATE

8 June 2022

ORGANIZED BY

The National Pharmacovigilance System

AUDIENCE

COVID-19 Vaccination Centers across Lebanon

AIM

Sharing the experience of COVID-19 vaccination process in Lebanon

7 Panelists

Dr. Rita Karam

Dr. Atika Bery

Dr. Abeer Zeitoun

Dr. Sirine Chehade

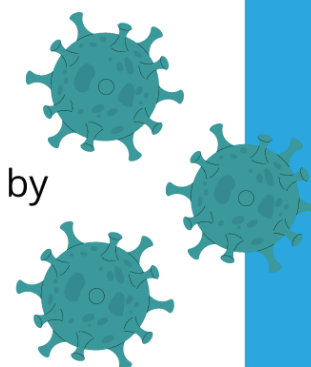
Dr. Carla Allam

Dr. Aya Ibrahim

Dr. Maya Helali

Topics Discussed

- COVID-19 vaccine fourth dose in people > 12 years old and vaccination in the age group between 5 and 11 years old
- Presentation of the **national descriptive study** conducted by the PV team which evaluated COVID-19 vaccination centers
 - Study introduction and rationale
 - Methodology of the study
 - Findings and recommendations for improvement



Objectives

- Decrease vaccine-related harm
- Build awareness on the importance of reporting adverse events to improve medication safety
- Encourage healthcare providers to be actively involved in the use of the various reporting means provided by the PV system
- Strengthen the public's trust in the Lebanese health-care system



Visit our site at www.moph.gov.lb

COVID-19 SHARPS CONTAINER DISPOSAL:

DO NOTs

DO NOT
throw loose
sharps in trash



DO NOT
put sharps in
recycling



DO NOT
flush sharps
down toilet



DO NOT
of reach of
children



DO NOT
force sharps into
container



DO NOT
put fingers inside
container



DO NOT
remove needle



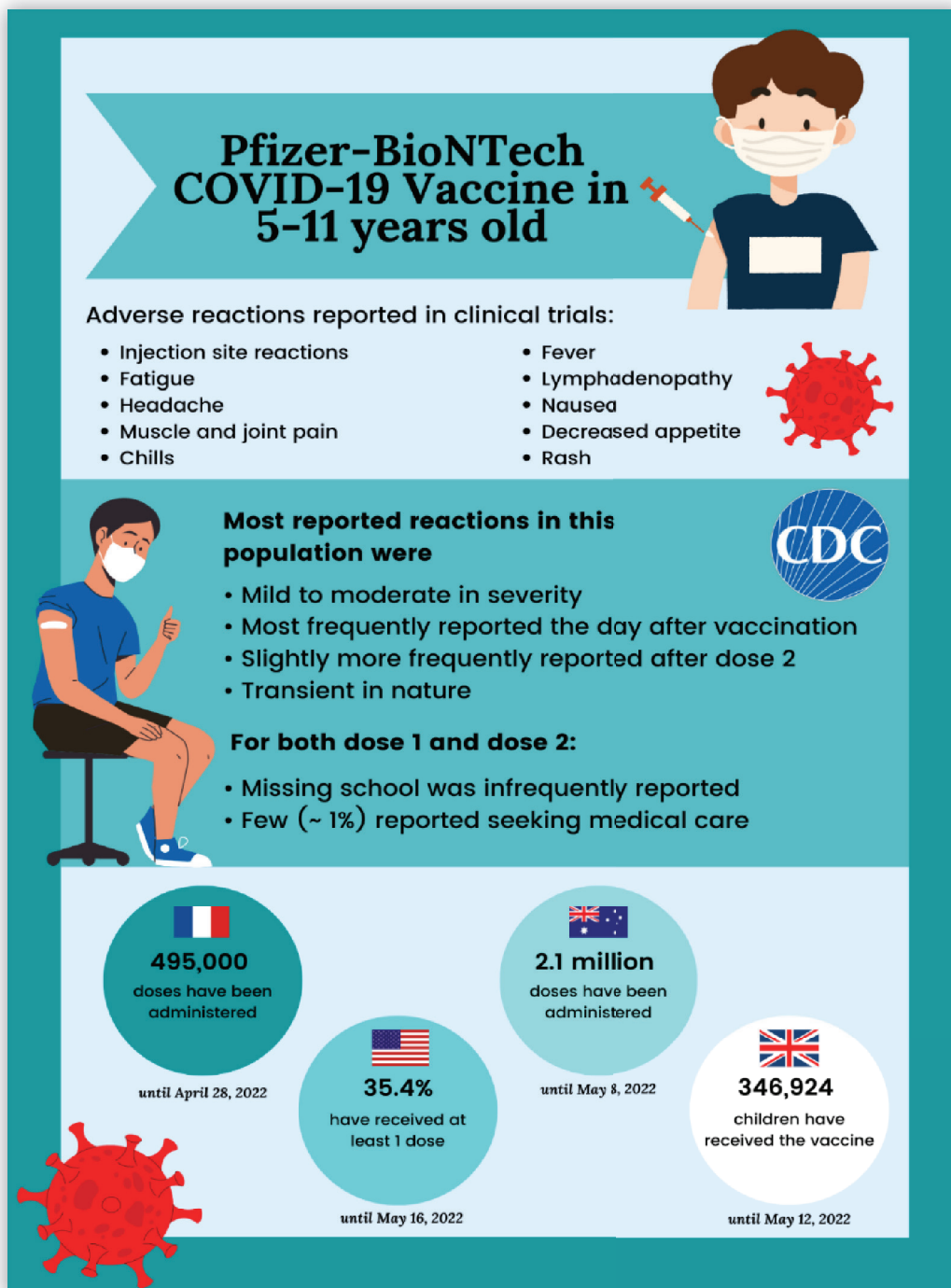
DO NOT
bend or break
needle



DO NOT
recap needle





COVID-19 VACCINES FOR CHILDREN 5-11 YEARS OLD: RAISING AWARENESS



References:

- <https://ansm.sante.fr/actualites/point-de-situation-sur-la-surveillance-des-vaccins-contre-la-covid-19-periode-du-22-04-2022-au-05-05-2022>
- <https://stacks.cdc.gov/view/cdc/112668>
- <https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends>
- <https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-12-05-2022>
- <https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-vaccinations/>
- https://www.cvdvaccine-lb.com/files/7_FS_for_Providers_Dilute_Before_Use_5-11_Orange.pdf

PFIZER-BIONTECH COVID-19 VACCINE IN ADULTS VS. CHILDREN: PREVENTING ERRORS

Description	Dilute Before Use	Dilute Before Use
Age Group	12 years of age and older	5 through 11 years of age
Vial Cap Color	 Purple	 Orange
Dosage	30 mcg	10 mcg
Dose Volume	0.3 mL	0.2 mL
Amount of diluent Needed per Vial	1.8 mL	1.3 mL
Storage Conditions		
Freezer [-25°C to -15°C]	2 weeks	DO NOT STORE
Refrigerator [2°C to 8°C]	1 month	10 weeks
Room Temperature [8°C to 25°C]	2 hours prior to dilution (Including any thaw time)	12 hours prior to dilution (Including any thaw time)
After First Puncture [2°C to 25°C]	Discard after 6 hours	Discard after 12 hours

MANAGEMENT OF ANAPHYLAXIS POST COVID-19 VACCINES: PREPARING AN EMERGENCY KIT

Should be available at all locations

Epinephrine
(e.g., prefilled syringe, autoinjector)*

H1 antihistamine
(e.g., diphenhydramine, cetirizine)†

Blood pressure monitor

Timing device to assess pulse

If feasible, include at locations

Pulse oximeter

Oxygen

Bronchodilator (e.g., albuterol)

H2 antihistamine
(e.g., famotidine, cimetidine)

Intravenous fluids

Intubation kit

Pocket mask with one-way valve (also known as cardiopulmonary resuscitation [CPR] mask) sized for adults and children

COVID-19 vaccination centers should have **at least 3 doses** of age-appropriate epinephrine available at all times. They should be able to quickly obtain additional doses to replace supplies after epinephrine is administered to a patient.

†May be given as adjunctive treatment but should not be used as initial or sole treatment for anaphylaxis

Adapted from: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html#:~:text=Patients%20who%20experience%20a%20severe,either%20Pfizer%2DBioNTech%20or%20Moderna>

ASK THE EXPERT

Durriyah Sinno,MD

*Clinical Associate Professor in Pediatrics
Director of Out Patient Department
Pediatrician at the Primary Care Group, University
Health Services
Department of Pediatrics and Adolescent Medicine
American University of Beirut Medical Center*



Q: To what extent are COVID-19 vaccines safe for the age group of 5-11?

A: COVID-19 vaccines are safe and immunogenic in this age group, and this was confirmed by the CDC guidelines.

Q: How would you convince parents to immunize their kids against COVID-19?

A: Kids should take the vaccine since they can easily get infected with COVID-19. They cannot be strict with the precautions (masks, social distancing, and hand washing). Although the illness may be mild for them, but they can transmit the disease to older adults such as their parents and/or grandparents who might suffer from a more severe illness.

Q: What is the recommended time interval between COVID-19 vaccines and the regularly scheduled ones?

A: In my opinion, spacing is important, and a four-week interval between COVID-19 vaccines and other vaccines is needed.

TESTIMONIAL



Iraqi Pharmacovigilance Center
المركز العراقي لليقظة الدوائية

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“It is my pleasure to write this testimony regarding the pharmacovigilance (PV) system in Lebanon.

In general, countries need a lot of time and effort to build an effective PV system. Indeed, a successful system should take into account many aspects including the availability of a reporting system, the definition of roles and responsibilities, the implementation of a good communication strategy... In the case of Lebanon, surprisingly, and against all the odds, colleagues were able to meet all these criteria in no time! Lebanon was announced as the 143rd member of the WHO Program for International Drug Monitoring (PIDM) in 2021.

From my perspective, the reason behind this is the good planning and the professionalism of colleagues working with the Lebanese PV system in addition to the collaboration of all parties, specifically the MoPH. This collaboration was further highlighted during the monitoring of COVID-19 vaccines' safety amidst the pandemic. I can see that the pandemic has strengthened the PV system of Lebanon, and now it is steadily growing.

I expect that the Lebanese PV system is going to be one of the best systems in the region soon!

Keep up the good work Dr. Rita Karam, we are learning from you and your team!”

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- Dr. Manal Younus
Head of Iraqi Pharmacovigilance Center
| ISoP Advisory Board Member | ISoP
Middle East Chapter Vice President



PV Team Members at The MoPH:

Dr. Rita Karam - Dr. Abeer Zeitoun
Dr. Aya Ibrahim - Dr. Carla Allam
Dr. Maya Helali - Dr. Sirine Chehade
Dr. Myriam Watfa - Dr. Katia Iskandar