



THE NATIONAL PHARMACOVIGILANCE PROGRAM NEWSLETTER

LEBANON

Issue 1

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Prepared by
Pharmacovigilance Team
at The Ministry of Public Health

MONTHLY REPORT: THE PHARMACOVIGILANCE'S WAY OF COMMUNICATING

Within the scope of the Adverse Events Following Immunization (AEFI) surveillance related to the available COVID-19 Vaccines in Lebanon, a monthly report is prepared by the team as a mean of communicating the result 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 to 19th of November 2021, the total number of registered persons was 4,083,747 and 3,627,736 was the total administered doses. Vaccine recipients had the highest reporting rate (85.5%). Regarding the case reports, 93.3% of the cases were non serious. Of the total received AEFIs, the five most frequently reported AEFIs with the four COVID-19 vaccines available in Lebanon were injection site pain, fatigue, general pain which may correspond to body pain or joint pain, headache, and pyrexia. 40.84% of the total registered persons have completed their primary COVID-19 vaccination series.

Investigation of vaccination safety signals is one of the major tasks in PV. Signals are generated from several sources such as spontaneous reports, clinical studies, and the scientific literature.

The PV team has adopted both the ANSM and WHO for identifying signals associated with AEFIs following Pfizer-BioNTech and AstraZeneca COVID-19 Vaccines:

You can access the report using this link:

<https://www.moph.gov.lb/userfiles/files/Quality%26Safety/PharmacovigilanceSystemInLebanon/Pharmacovigilance%20Report%207.pdf>



CONFIRMED SIGNALS FROM ANSM* AND WHO-UMC**

**Pfizer-
BioNTech
Vaccine**

Hypertension
Trigeminal Neuralgia
Tinnitus
Pericarditis
Photophobia

**AstraZeneca
Vaccine**

Flu-like symptoms
Immune thrombocytopenia
Thrombosis associated with
thrombocytopenia
Trigeminal Neuralgia
Tinnitus
Photophobia

*L'Agence nationale de sécurité du médicament et des produits de santé

** World Health Organization-Uppsala Monitoring Center

CAPACITY BUILDING: SHARING THE KNOWLEDGE



In November 2021, the PV program conducted a capacity building to raise awareness about PV in the context of COVID-19 vaccines. The webinar combined short presentations by specialists, with structured discussion on identifying and reporting the AEFIs post COVID-19 vaccines.

The three-day webinar comprised 6 speakers. The panelists included Dr. Rita Karam, Dr. Madonna Matar, Dr. Atika Bery, Dr. Katia Iskandar, Dr. Myriam Watfa, Dr. Abeer Zeitoun. The targeted audience were vaccination centers, hospital facilities and healthcare providers.

This capacity building was the second of a series of webinars. The targeted outcome was to tackle the most important step in the PV process which is reporting. It was made clear that serious and non-serious adverse events should be reported and that both the public and health care professionals can report. The panelists made sure to explain how the serious AEFIs undergo investigation and causality assessment. A special committee that includes a group of experts helps in the final decision of the causality assessments.

Stay posted for our upcoming capacity building!

You can access the briefing of the capacity building on:

<https://www.moph.gov.lb/userfiles/images/QualityandSafety/Pharmacovigilance/2.jpg> <https://www.moph.gov.lb/userfiles/images/QualityandSafety/Pharmacovigilance/3.jpg>

VACCINATION SITE VISITS:

TOGETHER FOR BETTER HEALTH OUTCOMES

As part of the immunization campaign against COVID-19 in Lebanon, vaccination centers were launched across the country. The PV team planned to conduct field visits to these facilities to collaborate with them and to optimize the vaccination process. The aim was to visit in each governorate at least 25% from each of the AstraZeneca and the Pfizer-BioNTech COVID-19 vaccination centers. Hence, randomly selected facilities across Lebanon, including Beirut, Mount Lebanon, Akkar, Baalbek - Hermel, Beqaa, Nabatiyeh, South and North Lebanon were visited. The team provided educational materials to encourage the public to register for and obtain COVID-19 vaccines, as well as to report any adverse events that may occur after receiving these vaccines. In addition, all vaccination centers' contact information were retrieved to relay the most recent updates from the PV program. Finally, a report was written at the end of each site visit and shared with the corresponding vaccination center upon request to express our views and recommendations.

The PV program highly appreciates all vaccination centers for their collaboration and cooperation.



ADVERSE EVENTS FOLLOWING COVID-19 VACCINES:

WHY REPORT?

Reporting: “A Remarkable Source of Information”

In the literature, reporting has been described as noteworthy source of new information about the drug and vaccine safety. In fact, the reporting of suspected AEFI is the backbone of post-licensure vaccine surveillance for early detection of rare, new, and serious AEFIs. In the context of COVID-19 vaccines, two means of reporting are accessible to the vaccine recipients: the 1214 Hotline call center and the IMPACT platform. As for health-care facilities and vaccination centers, another tool, the “Kobo Toolbox: AEFIs Software for Reporting” has been shared with concerned parties to report any AEFI that may occur at their facility or that is reported to them by vaccine recipients.

Reporting is a crucial step in the PV process. It adds new information which increases the knowledge about AEFIs and leads to the strengthening of safety signals. Case reports received by vaccination centers are as important as case reports received by vaccine recipients because they complement each other.

The subjective data reported help reinforce the current PV system and leads to a better understanding of the impact of reported AEFIs on vaccine recipients' daily lives. Even though means of reporting are available to the public to facilitate reporting, the reporting rate is still not high enough. For that reason, it is very important for health-care professionals and vaccination

كيفية الإبلاغ عن الآثار الجانبية بعد تلقي لقاح الكوفيد-19

بعد تلقي لقاح الكوفيد-19، وفي حال شعرت بأي آثار جانبية، يجب الإبلاغ عنها من خلال احدي الطرق التالية:

covax.moph.gov.lb

١ منصة اللقاحات المضادة لفيروس كوفيد-19 COVAX وذلك باتباع الخطوات التالية:

- أ. الرجوع الى الرابط الذي تلقينه في الرسالة النصية عندما قمت بالتسجيل على منصة اللقاح COVAX
- ب. ادخال رقم هاتفاك الخليوي ورمز المرور
- ج. الضغط على المحور التالي: "الإبلاغ عن حادث جانبي"
- د. الضغط على "أضف"
- هـ. الإجابة عن الأسئلة الواردة في الاستمارة بحسب الآثار الجانبية التي تعاني منها

أو ٢ الاتصال بالخط الساخن للقاح 1214

أو ٣ التواصل مع المركز الذي تلقيت فيه اللقاح

centers to raise awareness so that vaccine recipients become aware and more engaged when it comes to reporting their AEFIs. This awareness can be done through education materials such as brochures, roll-ups, or posters, provided by the PV program to the sites of vaccination. It can also be implemented in the education that nurses provide to vaccine recipients in the observation room about expected adverse events following COVID-19 vaccines, and through a video that was prepared for the public to introduce them to the different means of reporting.

- You can access this video using this link:

<https://www.youtube.com/watch?v=eTqW7QOt90k>

- You can access the “Kobo Toolbox: AEFIs Software for Reporting” using this link:

<https://ee.kobotoolbox.org/x/um9QwK2N>

ADVERSE EVENTS FOLLOWING COVID-19 VACCINES:

RAISING AWARENESS

Immunization Stress-Related Response OR Anaphylaxis?

	ANAPHYLAXIS	ACUTE STRESS RESPONSE	
		General	Vasovagal Reaction with Syncope
Onset	Usually, 5 min after immunization but may be delayed up to 60 min	Sudden, occurs before, during or shortly after (< 5 min) immunization	Sudden, occurs before, during or shortly after (< 5 min) immunization. May present after 5 min if the individual stands suddenly.
Cardiovascular	HR ↑ BP ↓ Circulatory arrest	HR ↑ Normal or ↑ systolic BP	heart rate ± transient ↓ ↓ in blood pressure
Respiratory	Persistent cough, noisy breathing, and airway constriction: wheeze, stridor. If very severe, respiratory arrest.	Hyperventilation (rapid, deep breathing)	Normal to deep breaths
Skin	Generalized urticaria or generalized erythema, angioedema, localized or generalized, generalized pruritus ± skin rash, generalized prickle sensation, localized injection site urticaria, red and itchy eyes	Pale, sweaty, cold, clammy	Pale, sweaty, cold, clammy
Gastrointestinal	Nausea, vomiting, abdominal cramps	Nausea	Nausea, vomiting
Neurological and other symptoms	Uneasiness, restlessness, agitation, loss of consciousness, little response when supine or lying flat	Fearfulness, light-headedness, dizziness, numbness, weakness, tingling around the lips, spasms in hands, feet	Transient loss of consciousness, good response once supine or lying flat, with or without tonic-clonic seizure

HR: Heart Rate, BP: Blood Pressure

It is important to differentiate immunization stress-related response from anaphylaxis and other diagnoses. According to the WHO, the table below lists the differences between anaphylaxis, and acute stress response. At the vaccination centers, a physician should always be present in case of any severe reaction following immunization to be able to diagnose it properly and take the correct measures.

World Health Organization. (2019). Immunization stress-related response: a manual for program managers and health professionals to prevent, identify and respond to stress-related responses following immunization. World Health Organization <https://apps.who.int/iris/handle/10665/330277>.

Activities To Avoid After COVID-19 Vaccines

 **Examples of intense physical activities to avoid**

 Jogging/Running	 Swimming	 Cycling
 Lifting Heavy Weight	 Competitive Sports/Physical Education	 Playing Ball/Racket Games

 **Examples of safe activities**

 Stretching/Working while standing	 Casual Walking	 Housework
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It is recommended that everyone avoids intense physical activity, especially adolescents and younger men (< 30 years old), for 7 days after the first and second doses of COVID-19 vaccine. Always seek immediate medical attention if you develop any chest pain, shortness of breath or abnormal heart beats during this time.

ASK THE EXPERT

Dr. Madonna Matar, Head of Infectious Diseases and Infection Control at Notre Dame des Secours University Hospital, Lebanon

Can we mix and match COVID-19 vaccines?

COVID-19 vaccines are safe and highly effective. They are expected and proven to protect against severe disease, hospitalizations, and deaths. Breakthrough infections in people who are fully vaccinated are likely to occur in case the virus is contracted. Many reports have shown that mixing and matching two different types of vaccines will confer higher levels of antibodies than receiving the same type of vaccine. Mixing and matching has been recommended in different countries however, it hasn't been yet included in official vaccination guidelines.



The COVID-19 Vaccine and The Flu Vaccine

Influenza and COVID-19 are both contagious respiratory illnesses. With the surge of COVID-19 cases worldwide, the 2020-2021 flu season was almost undetectable. However, influenza virus is spreading again this year to compete with the COVID-19 virus. In both cases, patients can present with similar clinical symptoms that cannot be distinguished unless confirmed by PCR tests. Co-infection with both viruses can also occur and patients will present with more severe disease. Flu and COVID-19 vaccines are both available and safe to be administered together. Getting both vaccines is recommended to protect patients with comorbidities, immunosuppressive diseases, pregnant women, children between 6 months and 5 years old, adults above 65 years old as well as healthcare workers.

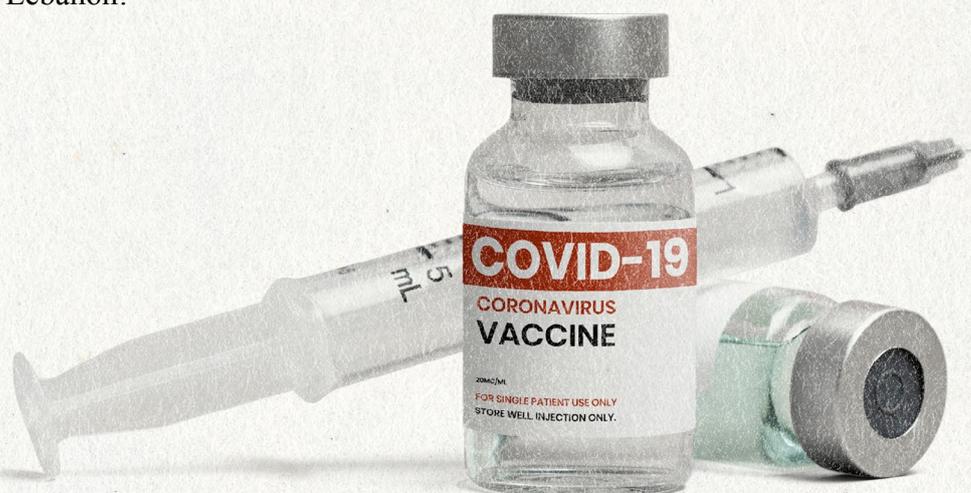


Sibline Governmental Hospital



Sibline Governmental Hospital's vaccination center went beyond the PV program's expectations. Despite the limited resources, they were able to handle difficult situations and maximize reporting on the standardized reporting tool shared with all hospital facilities and vaccination centers across Lebanon, "The Kobo toolbox". In fact, the PV team is proud to announce that Sibline Governmental Hospital was and still is the vaccination center with the highest reporting rate in the past 2 months. The efforts done by their team show resilience and allow them to deliver a smooth vaccination process to the community that gets vaccinated at their site. The quality of their work is unprecedented as they work both hard and smart.

Sibline Governmental Hospital, the PV program appreciates your problem-solving skills and thanks your dedication which is at the heart of the success of the COVID-19 vaccination campaign in Lebanon!



TESTIMONIALS



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“The national pharmacovigilance webinar was successful and very well organized. It involved experts in the field of Infectious Diseases, Pharmacology and Public Health, who have discussed all aspects of COVID-19 vaccination adverse events and the Lebanese reporting system in collaboration with the Ministry of Public Health. It was held on three different days on November the 1st, 3rd and 8th, to increase the opportunity of strengthening the capacity building of different groups of healthcare workers.”

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– Dr. Madonna Matar



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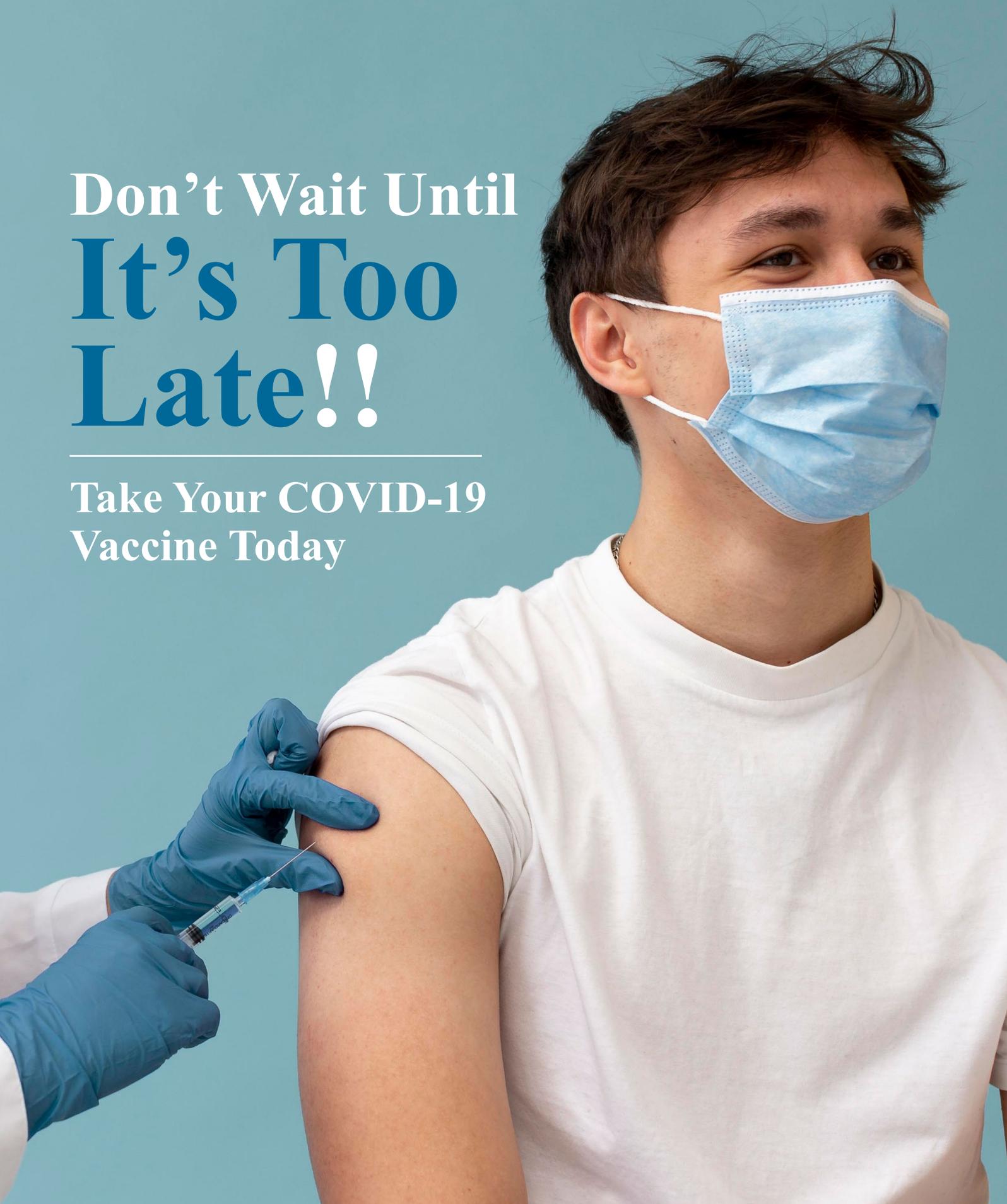
“The workshop was beneficial and easy to understand. It gave us the detailed AEFI reporting journey and the objective of the PV program in a comprehensive way. It showed us the importance of the COVID-19 vaccine in preventing the disease despite its adverse events. It showed us how to use the vaccine in a safe way and identify its adverse events that might take place, and the importance of reporting them.”

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- Alaeddine Hospital Team

Don't Wait Until It's Too Late!!

Take Your COVID-19
Vaccine Today



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