



THE NATIONAL PHARMACOVIGILANCE PROGRAM NEWSLETTER

LEBANON

Issue 2

April 2022

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

OUTLINE

- I. Meet the Team
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- III. Means of Reporting: Together for Better Health Outcomes
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- VI. Risk Minimization Initiatives: Prevent and Reduce AEFIs
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MEET 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 19th of February 2022, the total number of registered persons was 6,017,418 and 5,134,093 was the total administered doses. Out of the total 6,808 reported case reports (corresponding to 24,837 AEFIs), 93.4% 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 four COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik V, and Sinopharm) 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 35.46% 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 (41.8%) followed by Beirut (29.6%) which is in alignment with the number of administered vaccination doses.



You can access the report using this link:

<https://www.moph.gov.lb/userfiles/files/Quality%26Safety/PharmacovigilanceSystemInLebanon/Pharmacovigilance%20Report%209.pdf>

MEANS OF REPORTING: TOGETHER FOR BETTER HEALTH OUTCOMES

Several means of reporting were created to report AEFIs by both the public and healthcare professionals/vaccination centers.

For the Public	For the Healthcare Professionals/Vaccination Centers
<ul style="list-style-type: none">1214 Hotline Call CenterIMPACT Platform	<ul style="list-style-type: none">Kobo Toolbox: AEFIs Software for Reporting <p>https://ee.kobotoolbox.org/x/um9QwK2N</p>

To enhance public awareness about the importance of reporting, new educational material including posters, brochures, and rollups were prepared by the PV team, and distributed to the health facilities/vaccination centers. These educational materials detail the different means of reporting, and present instructions to facilitate this process.

Poster Format

COVID-19 VACCINE اللقاح المضاد لكوفيد-19

If you experience any adverse event following your vaccination, you can report it via one of the following methods:

في حال شعرت بأي من الأحداث الجانبية بعد تلقي اللقاح يمكنك الإبلاغ عنها عبر الوسائل التالية:

1. Refer to the link you received from MoPH when you registered for vaccination: covox.moph.gov.lb
• Enter your mobile phone number and code received
• Click on «Notification about side effects»
• Click on the adverse event you are experiencing
2. OR أو
Call the hotline on **1214**
إتصل على الخط الساخن **1214**
3. OR أو
Report back to your vaccination center
التواصل مع المركز الذي تلقيت فيه اللقاح

REPUBLIC OF LEBANON MINISTRY OF PUBLIC HEALTH
الجمهورية اللبنانية وزارة الصحة العامة

Rollup Format

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NATIONAL AND GLOBAL WEBINARS: SHARING THE KNOWLEDGE

On a National Level

With the beginning of the new year 2022, the Pharmacovigilance (PV) program at the MoPH was pleased to discuss the role of the national PV program in Lebanon in the context of COVID-19 vaccines in reputable hospitals, namely Aboujaoudé Hospital and Hotel-Dieu De France Hospital. The audience who attended were healthcare professionals. Several topics were tackled during these presentations, starting with the introduction of Adverse Events Following Immunization (AEFIs) with COVID-19 vaccines, followed by detailing each step of the COVID-19 vaccine AEFI surveillance cycle, moving to the management of serious and non-serious AEFIs at a national level, and ending up with the analysis of the collected AEFI data. In addition, several important sections of the report entitled “Adverse Events Following Immunization with COVID-19 Vaccines in Lebanon”, published on the MoPH website, were also highlighted.



HOPITAL Aboujaoudé

JEUDI MEDICAL
27 JANVIER 2022 18:00
Auditorium "Dr Farid Z. Aboujaoudé"

باللغة العربية

zoom

YouTube

VACCINATION /EFFETS SECONDAIRES /DÉCLARATION /COMITÉ DE PHARMACOVIGILANCE
Aggravation d'une épilepsie après la vaccination :coïncidence ou effet secondaire?

Thyroidite post vaccin ?
Myocardite et Péricardite post-vaccin
Mammographie et vaccination ce que vous devez savoir
Trouble de règles et vaccination /vrai ou faux
Allergies et vaccination quelle protection prendre ?
Effets secondaires post vaccination déclaration et comment faire la part des choses
Comité de pharmacovigilance libanais

Sami Rahi
Antoine Klouy
Elisabeth Aboujaoudé
Miche Rahed
Nabil Helou
Imad Aboujaoudé
Marlene Saad
Rita Karam

VACCINATION ET OMICRON
Ya t'il plus de cas après vaccination ? Sommes-nous plus protégés par le vaccin ?

Racha Dib

Aboujaoudé Hospital Meeting Program

FDF HOTEL-DIEU DE FRANCE

USJ Université Saint-Joseph de Beyrouth

18^{ème} CONGRÈS du CLIN en ligne

COVID-19 TOUS FACE À LA PANDEMIE!
samedi 4 décembre de 9h00 à 12h20

9h00 - 9h20 L'histoire des pandémies Dr Christian TAGOUTEL

9h20 - 9h40 La réaction de l'HDF face à la pandémie de COVID-19 Dr Dania CHELALA

9h40 - 10h00 La réaction du laboratoire de microbiologie de l'HDF face à la pandémie Dr Nadim AZAR

10h00 - 10h05 Pause

10h05 - 10h25 Le COVID long Dr Jérôme LARCHÉ

10h25 - 10h45 Médicaments et COVID-19 Dr May FAKHOURY

10h45 - 11h05 Nouvelles épidémies bactériennes associées aux soins par pandémie Dr Moussa RIACHI

11h05 - 11h10 Pause

11h10 - 11h30 Changements virologiques du SARS-CoV-2 (mutations) et implications Dr Yazdan YAZDANPANAH

11h30 - 11h50 Vaccinations anti SARS-CoV-2 : mythes et réalités Dr Jacques CHOUCAIR

11h50 - 12h10 la pharmacovigilance nationale en période de Covid Dr Rita MOUAWAD

12h10 - 12h20 L'antibiothérapie dans l'ère du COVID-19 Dr Elie HADDAD

Hotel-Dieu De France Hospital Meeting Program

On a Global Level



Early 2021, Lebanon has joined the World Health Organization (WHO) Program for International Drug Monitoring (PIDM) as a full member. The WHO PIDM is a forum for WHO member states to collaborate in the monitoring of drug safety. The Pharmacovigilance Advisory Network (PAN) in Eastern Mediterranean countries invited Lebanon to be a member of this network along with Egypt, Iran, Iraq, Jordan, Morocco, Pakistan, Syria, Sudan, Saudi Arabia, and the UAE. Members of this network were requested to share their experiences and the pharmacovigilance strategy for COVID-19 vaccines used in their countries. The PV program in Lebanon was one of the first countries to share its experience. Many activities were highlighted throughout the presentation including strengths and weaknesses of the Lebanese PV program, components of the AEFI surveillance cycle, and finally AEFI management. Positive feedback about the improvement and achievements of the PV program in Lebanon were received from different members of the PAN and the WHO Advisory Committee as a whole.

In addition, the Lebanese PV program is a member of the International Society of Pharmacovigilance (ISOP). On March 23rd, 2022, Dr. Rita Karam, the team lead of the Lebanese PV program, was invited to take part of the ISOP Middle East Chapter, to discuss the experience of Lebanon regarding the safety of COVID-19 vaccines and their surveillance in Arab countries.

SHOULD MY CHILD WEAR A MASK?

RAISING AWARENESS

According to European news, the French Prime Minister Jean Castex announced that further COVID-19 restrictions would soon be removed in France. Indeed, from March 14, 2022, face masks were only required on public transport. However, following an upsurge in cases, students are wearing their masks again. In addition, the mask is already making a comeback in most of indoor places where it has no longer been mandatory.

Consequently, the importance of wearing masks should always be highlighted. More details are shared in the below infographic.

Children of all ages (WHO and UNICEF recommendations)

5
years and
under

Do not need to wear a mask.
They may not be able to properly wear it without help or supervision

6-11
years

Are recommended to wear a well-fitted mask in areas where COVID-19 Virus is spreading

12
years or older

Should follow the same WHO recommendations for mask use as adults

- Mask use should be flexible, so that children can continue play, education and everyday activities.
- No child should be denied access to school or activities because of lack of a mask.
- If the child is in contact with a sick or at-risk person, he/she should not wear the mask for a long duration or without supervision.
- Children do not need to wear a mask when playing sports or doing physical activities, such as running, jumping, or playing, as it may affect their breathing.

Children with medical conditions

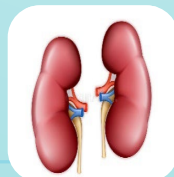
The use of a medical mask is recommended for children with a higher risk of severe complications from COVID-19. This includes children with the following conditions:



Obesity



Cardiac Diseases



Chronic Kidney Diseases



Chronic Lung Disease



Diabetes

Other medical conditions: A child with disabilities, Immunosuppression, HIV, Mental Disorders and Cancer

How to wear a mask?



Children should be encouraged to clean their hands before putting on their mask and after taking it off



Children should wear a well-fitted mask that covers the nose, mouth and chin



Children should be taught not to share masks with others

DOs and DON'Ts

DO

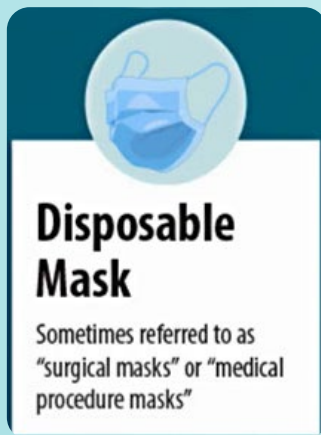


DON'T



Types of masks

There are three types of masks that WHO recommends for the public:



CDC. Use and care of masks.

<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings>.

Alternatives of wearing a mask



Face shields may be considered an alternative to masks, but they do not provide the equivalent protection in keeping the virus from being transmitted to others.

Where to wear a Mask?

6-11
years

In Indoor Settings

- Where ventilation is poor or unknown, even if physical distancing of at least 1 meter can be maintained
- With adequate ventilation when physical distancing of at least 1 meter cannot be maintained

12
years or older

In Indoor Settings

- Where ventilation is known to be poor or cannot be assessed
- Where ventilation system is not properly maintained, regardless of whether physical distancing of at least 1 meter can be maintained
- With adequate ventilation if physical distancing of at least 1 meter cannot be maintained; or

In Outdoor Settings where physical distancing of at least 1 meter cannot be maintained

The golden rule about protecting a child from COVID-19 infections

A safe environment should be created for children who are not able to tolerate a mask, including requirements for caregivers, teachers or other adults interacting with the child to wear a mask and to be vaccinated against COVID-19 according to national vaccination policies.



References

Adapted from:

World Health Organization (WHO). Coronavirus disease (COVID-19): Children and masks. March 2022. <https://www.who.int/news-room/questions-and-answers/item/q-a-children-and-masks-related-to-covid-19>. Accessed March, 21, 2022

1. <https://www.euronews.com/2022/03/03/covid-in-europe-france-to-scrap-face-masks-and-vaccine-passes-on-14-march>
2. <https://www.tf1.fr/tf1/jt-20h/videos/rebond-de-lepidemie-de-covid-19-le-masque-fait-son-retour-38967865.html>

RISK MINIMIZATION INITIATIVES: PREVENT AND REDUCE AEFIs

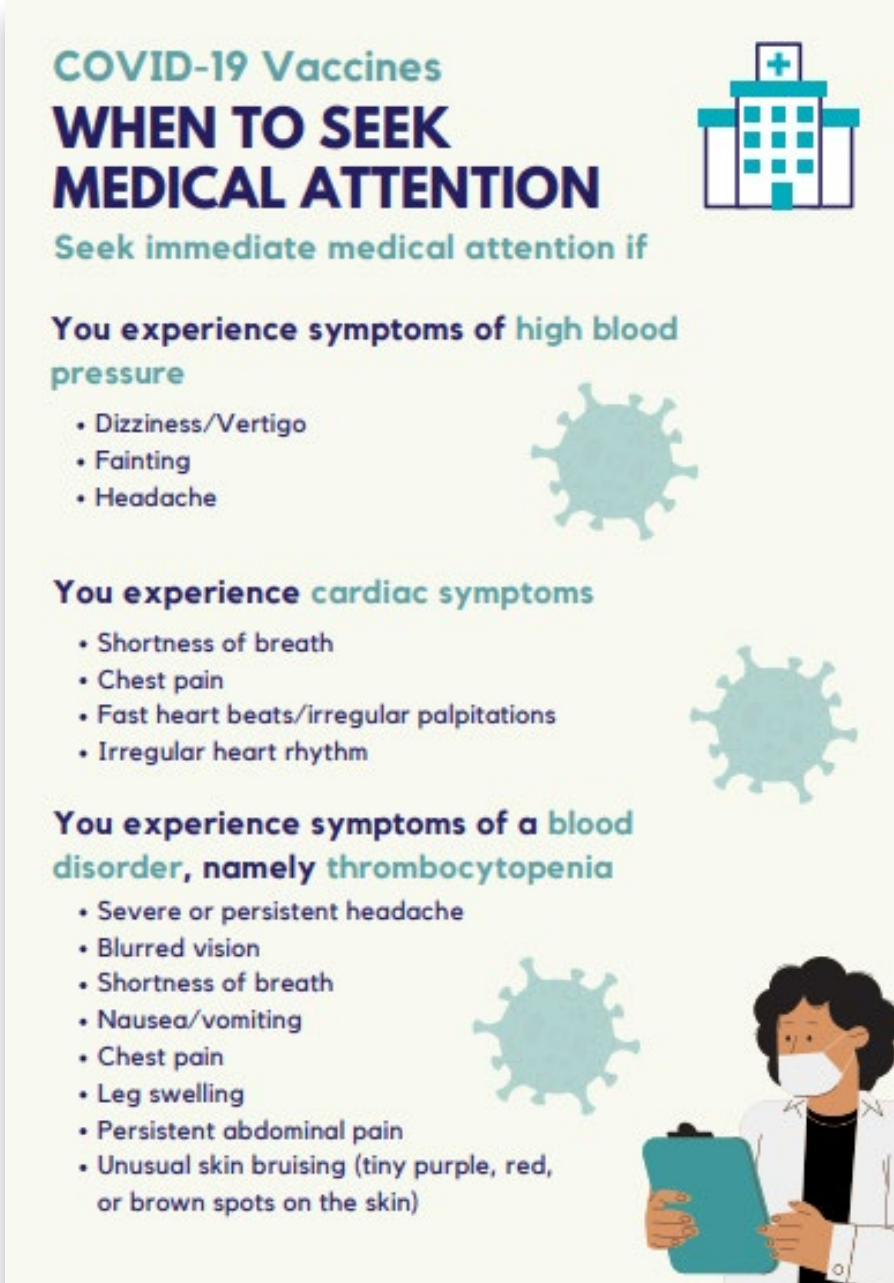
“Risk minimization measures are interventions intended to prevent or reduce the occurrence of adverse reactions associated with the exposure to a medicine.” – European Medicines Agency (EMA)

Two risk minimization initiatives were taken by the national PV program. One was addressed to the public and the second was addressed to healthcare professionals.

1. To the Public

The full document reviewing the “Overview on Adverse Events Following Immunization (AEFIs) in Lebanon” based on the ANSM and the WHO is shared on the MoPH website that can be accessed through the following link: <https://www.moph.gov.lb/en/Pages/4/44742/pharmacovigilance-system-lebanon>

It is essential to raise awareness on when to seek medical attention following the receipt of COVID-19 vaccines.



COVID-19 Vaccines
WHEN TO SEEK MEDICAL ATTENTION

Seek immediate medical attention if

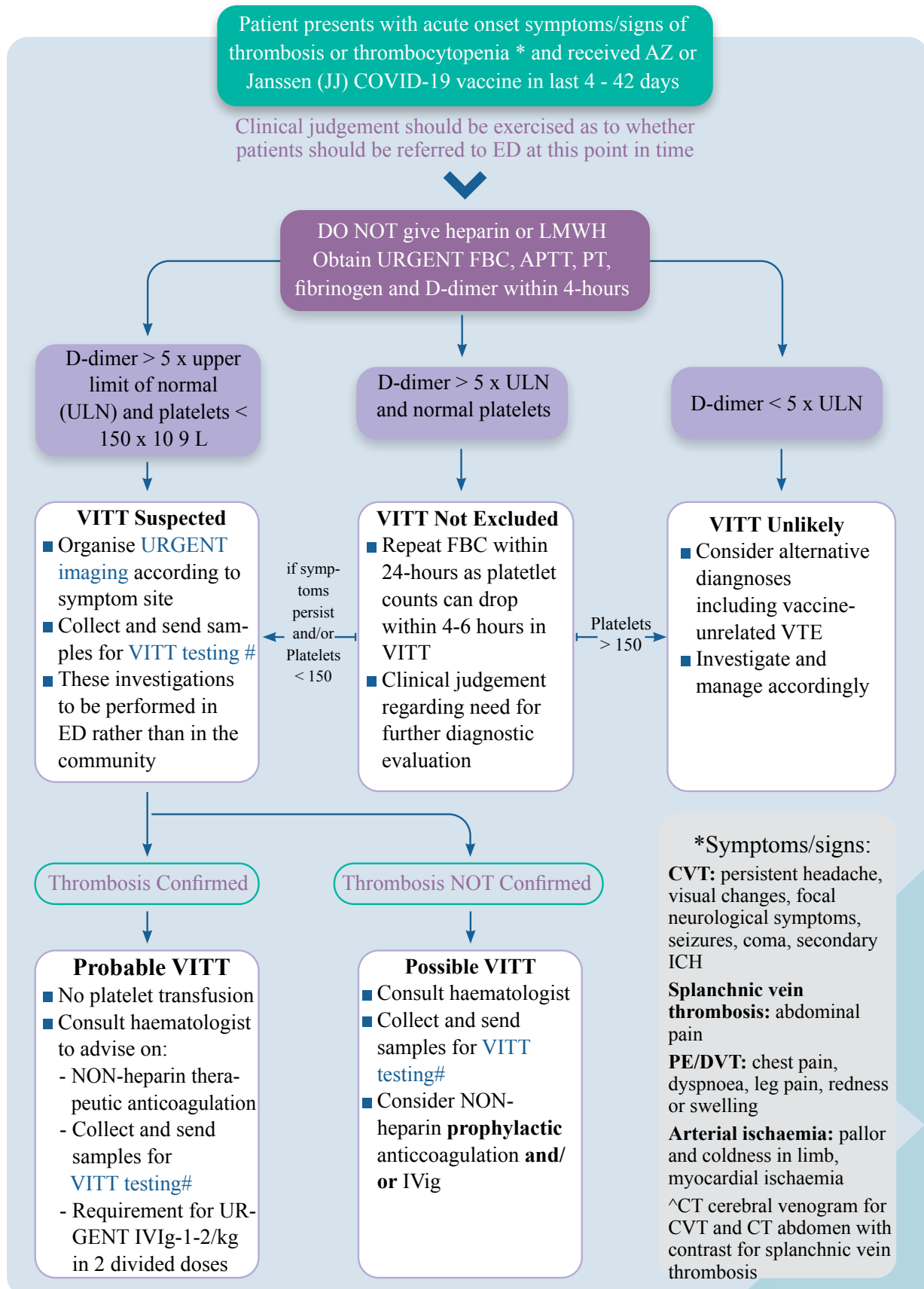
- You experience symptoms of high blood pressure**
 - Dizziness/Vertigo
 - Fainting
 - Headache
- You experience cardiac symptoms**
 - Shortness of breath
 - Chest pain
 - Fast heart beats/irregular palpitations
 - Irregular heart rhythm
- You experience symptoms of a blood disorder, namely thrombocytopenia**
 - Severe or persistent headache
 - Blurred vision
 - Shortness of breath
 - Nausea/vomiting
 - Chest pain
 - Leg swelling
 - Persistent abdominal pain
 - Unusual skin bruising (tiny purple, red, or brown spots on the skin)

The infographic includes a hospital icon at the top right, a blue triangle on the left, and a doctor with a clipboard at the bottom right. There are also three virus icons scattered throughout the text.

2. To Healthcare Professionals

After a thorough literature review about Vaccine-induced Thrombotic Thrombocytopenia (VITT) guidelines and after consulting the Serious AEFI Special committee and experts in the field, the PV program at the Lebanese MoPH decided to adopt the guidelines developed by the THANZ VITT Communications Committee.

Link: <https://www.thanz.org.au/documents/item/590>



ASK THE EXPERT

Dr. Atika Berry

Head of the Preventive Medicine Department and Head of the Communicable Diseases Unit at the Ministry of Public Health, Lebanon



1. If I got infected with COVID-19, when should I get vaccinated?

The Omicron variant of COVID-19 has become the dominant strain of the virus in Lebanon. It has been shown that immunity following this infection does not last beyond 2 weeks. Consequently, patients can get vaccinated 2 weeks after being actively infected with Omicron. This does not apply to the Delta variant.

2. Sinopharm and Sputnik V did not demonstrate sufficient immune response following the two doses. If I received the primary vaccination series (dose 1 and 2) with the Sinopharm or Sputnik V vaccine, am I eligible to get a booster dose?

You can take a booster dose 4 months after the second shot of Sinopharm or Sputnik V vaccines. Two doses of any other approved vaccine (AstraZeneca or Pfizer-BioNTech) may be given 6 months after the second dose. If you want to receive two doses of another type of COVID-19 vaccine before 6 months have passed, refer to your doctor to undergo an anti-spike test.

3. Who can get a COVID-19 vaccine fourth dose?

People with a weakened immune system (immunocompromised) should follow up with their doctors for the possibility of receiving a fourth dose of the vaccine.

4. What are the recommendations of the Ministry of Public Health regarding the duration of isolation and quarantine?

- If you tested positive for COVID-19 (positive PCR or Antigen Rapid Test), you need to isolate yourself for 7 days if you are not planning to repeat the PCR

test, or you can isolate yourself for 5 days then repeat the PCR test.

- If you were exposed to COVID-19 and you are not vaccinated or the duration from your last dose exceeds 6 months, you need to quarantine for 7 days if a “PCR or Antigen Rapid Test” is not done. Quarantine for 5 days if a “PCR or Antigen Rapid Test” is negative.

- If you were exposed to COVID-19 and you are up to date on COVID-19 vaccinations (received the doses in the primary series) or the duration from your last dose does not exceed 6 months, there is no need to quarantine if no symptoms are developed.

For more information, refer to the memorandum N°12: <https://www.moph.gov.lb/en/laws>

I would like to emphasize on the importance of taking your COVID-19 vaccination and following public health guidance for social distancing, wearing masks in public spaces, and limiting mass public gatherings especially with the advent of the blessed month of Ramadan, Easter and Al-Fitr holidays.

TESTIMONIALS



“

“To be honest, I am really impressed with the work of Jordan and Lebanon. I would expect this from Jordan because they have been established many years ago and have long experience and expertise. However, Lebanon became a member just last year, and I am impressed with all the great work and activities that were conducted. I was curious to ask how many people are working in pharmacovigilance, and after knowing that it is a small number of people, I can really say that it is about the quality of people working there. This is a really great work I would love to see it in other countries worldwide. The work performed in the Middle East is really very high standard. Thank you, we will continue to do these webinars because now I have the encouragement to see other great experiences from other countries. This is an amazing job, thank you Dr. Rita, and all the team that is working with you. Thanks a lot.”

”

– Dr. Thamir Alshammari,
ISOP Middle East Chapter President, Medication
Safety Research Chair, King Saud University



“

“Really impressive work, you made me today feel proud to be Lebanese, thank you so much. This is not the first time I attend an ISOP webinar. The session today was very well prepared, it showed the huge effort done in the past couple of years. يعطيكون العافية بتكبرو القلب”

”

- Dr. Nour Hajjar,
Pharmacovigilance Manager, Sanofi,
Levant Area



Get Them

Protected

Get Them

Vaccinated

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