The National Pharmacovigilance Program Newsletter

Lebanon

Prepared by
Pharmacovigilance Team
at the Ministry of Public Health

ISSUE 5
January 2023

OUTLINE

I Sharing the Knowledge

1. Capacity Building: Introduction to Pharmacovigilance Operations: Reporting & Data Management

2. Hands-On Training: Med Safety App & E-Reporting

II Safety Reports: The Pharmacovigilance's Way of Communicating

1. Adverse Events Following Immunization with COVID-19 Vaccines in Lebanon

2. Adverse Events Following Immunization with Oral Cholera Vaccines in Lebanon

III A New Milestone: Recent Publication of the National PV Team

Vaccination process evaluation at COVID-19 vaccination centers in Lebanon: a national study

IV Testimonial

I. Sharing The Knowledge

1. Capacity Building: Introduction to Pharmacovigilance Operations: Reporting & Data Management

Onsite Educational Visit

Session Topics

Implementation of the Lebanese National Pharmacovigilance Program: how did it start?

A global overview of Pharmacovigilance: what are the operations and importance?

Adverse events & means of reporting: what, where and how to report?

Handling cases: how does the Program handle cases related to vaccines and medications use?

VigiFlow: what is it and how do we use it?

December 2nd, 2022

8:00 A.M. – 10:00 A.M.

Aboujaoudé Hospital,
Jal El Dib

As part of the Lebanese National Pharmacovigilance Program (LNPVP)'s educational activities, the Pharmacovigilance (PV) team was invited to Aboujaoudé Hospital to host an educational session introducing the Program's PV operations.
The event was held on December 2nd, 2022 at the Aboujaoudé Hospital auditorium in Jal El Dib.

A total of 30 healthcare professionals of the hospital's medical staff including nurses, residents, pharmacists, quality and safety persons have joined the session. For maximal reach, the session was also broadcasted virtually through Zoom, where 25 additional staff members joined the session.
Under the title of "Introduction to Pharmacovigilance Operations: Reporting and Data Management", the 2-hour session introduced the staff to the scope of the LNPVP's operation and activities. The objectives were threefold:

- Introducing the concept of Pharmacovigilance
- Sharing the implementation steps and objectives of the Lebanese Pharmacovigilance Program
- Encouraging the reporting of the adverse events following the use of medications and vaccines

Five presentations were provided by the PV team members revolving around the operations performed at the LNPVP, as detailed previously.
The aim was to share with participants what, when, where and how to report. For a better understanding of the subsequent steps of data management, the handling of serious cases was also discussed. To close the loop, the audience were introduced to the national database management system: VigiFlow.

The session was initiated and welcome remarks delivered by the Director of the Quality Assurance of Pharmaceutical Products Programs and the National Pharmacovigilance Program Coordinator Dr. Rita Karam, who introduced the Lebanese PV System with an opening presentation. She outlined the roadmap to the program's success, and acquainted the audience with its mission, vision and values. The implementation of the program from its activation in 2018 to its incorporation in the WHO Programme for International Drug Monitoring (WHO-PIDM) in 2021 was detailed. The program's partners, stakeholders, and activities were identified and shared.

The audience was then reminded of the general concepts of PV by Dr. Carla Allam, a PV officer, who presented a general overview on its importance and operations within healthcare systems worldwide. A brief historical background was displayed to showcase the importance of PV in ensuring patient safety. Dr. Allam then acknowledged the pivotal role that healthcare professionals play in the patient safety cycle. Finally, the presentation was concluded with an overview on signal detection, which is an important PV aspect to communicate any important information that adds to previous safety knowledge about a medicine.

In a third presentation, the adverse events to be reported and the available means to report them were covered by Dr. Sarah Reda El Sayed, a PV officer at the LNPVP. The different terminologies used to distinguish between what is being reported were presented. A useful overview of the available reporting means was later presented covering the paper reporting form, the e-reportingform, the KoboToolbox AEFIs Software for reporting, the direct contact with the Ministry of Public Health, the hotline call centers, the Med Safety App, and the IMPACT Platform. For every tool presented, an overview, the target audience, and the benefits were extensively detailed.

.

The Senior Clinical and Technical Manager at the LNPVP, Dr. Abeer Zeitoun then gave an insight on the program's workflow when handling the received cases. The Adverse Drug Reactions (ADRs) and the Adverse Events Following Immunization (AEFIs) management protocols were explained. The received ADRs are sorted, imported to VigiFlow, cleaned and validated by PV team members, assessed to confirm or reject the causal relationship with the administered drug, and finally acknowledged to the reporting entity. On the other hand, the received AEFIs are classified per seriousness according to WHO criteria, cleaned and validated. Investigation and close follow-up using WHO tools are initiated for serious cases only.

In a final presentation, the practical aspect of VigiFlow was presented by the PV officer, Dr. Aya Ibrahim. In the attempt to bring the audience closer to the LNPVP's everyday tasks, the different sections of VigiFlow were covered in a hands-on manner. Dr. Ibrahim explained that a successfully-imported case report would be presented in VigiFlow with information on the report itself, the reporter, the patient, the reaction, the drug, and the final assessment. To wrap up, one reported ADR and one AEFI were accessed and explained as a practical example. Identified gaps in each section were highlighted and corrected to emphasize the importance of reporting correctly.

The session was concluded with Dr. Karam's closing remarks on the importance of the collaboration between healthcare professionals and the LNPVP. The audience was encouraged to leverage their daily contact with the patients and other relevant stakeholders, in order to raise awareness on the importance of adverse event reporting and pharmacovigilance in general.

Finally, questions and inquiries received from the audience were answered.

In a final note, hospital officials expressed their appreciation for the team's effort towards the presented session, and in safeguarding Lebanon's public health safety in general.

I. Sharing The Knowledge

2. Hands-On Training: Med Safety App, E-Reporting

An introduction to the pharmacovigilance operations including the reporting and data management activities were presented during a capacity building session held on the 2nd of December at the Aboujaoudé Hospital. Healthcare providers were the main target audience consisting of the hospital's medical staff.

Following this capacity building, the chief pharmacist Dr. Chantal Haddad asked for a hands-on training session. Her aim was to get the staff directly involved in reporting using the discussed tools. Since the hospital had already documented a number of adverse events, the LNPVP support and help was needed to enhance accurate data entry.

Consequently, a hands-on session was scheduled on the 27th of December in order to provide a focused training to the personnel directly involved in the reporting and to enhance their experience on how to report adverse events using the Med Safety App and the e-reporting tool.

The session took place at the Aboujaoudé hospital. Healthcare professionals from different departments including pharmacists, nurses and quality personnel joined this session. A brief video introducing the Med Safety App was presented and then a practical training was followed.

Afterwards, the personnel downloaded the application on their phones in order to practice how to enter a case into the application. The pharmacovigilance officers guided the audience on the steps to follow in order to complete a reported case.

To close the loop and to clarify what happens with a submitted case, an overview on VigiFlow: the national PV database, was presented and the causality assessment was also explained.

Following the Med Safety App practice, the e-reporting tool was also introduced to the audience. A step-by-step guide was provided in order to submit a case using the e-reporting tool.

This session allowed healthcare professional to have a clearer idea about the type of cases that should be reported and an in-depth understanding on how to use different reporting tools to submit adverse events to the LNPVP.

II. Safety Reports: The Pharmacovigilance's Way of Communicating

1. Adverse Events Following Immunization with COVID-19 Vaccines in Lebanon

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 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 14th of December 2022, the total number of registered persons was 6,420,891 and 5,602,239 was the total administered doses. Out of the total 7,188 reported case reports (corresponding to 25,841 AEFIs), 92.6% were non-serious. Vaccine recipients had the highest reporting rate (83.0%). AEFIs were mostly reported in vaccine recipients aging between 18 and 44 years old (54.5%), with females reporting more than males (61.0% vs. 39.0%). 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. Finally, among the five main Lebanese governorates (Beirut, Mount Lebanon, South, North, and Bekaa/ Baalbek-Hermel), Mount Lebanon governorate had the highest reporting rate (40.45%) followed by Beirut (28.91%) 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.

Adverse Events Following Immunization in Children and Adolescents

As for case reports among adolescents aging 12 t0 17 years old, a total of 266 case reports were identified with male more than females (52.6% vs. 47.4%). Out of the 266 cases, 247 (92.85%) were non-serious. The most commonly reported AEFIs included fever, injection site pain, headache, fatigue, and dizziness. This is consistent with the global patterns.
Finally, a total of three non-serious case reports were received for children aging between 5 and 11 with males more than females (66.7% vs. 33.3%). Hypotension, syncope and dizziness were the reported reactions, and all were recovered.

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

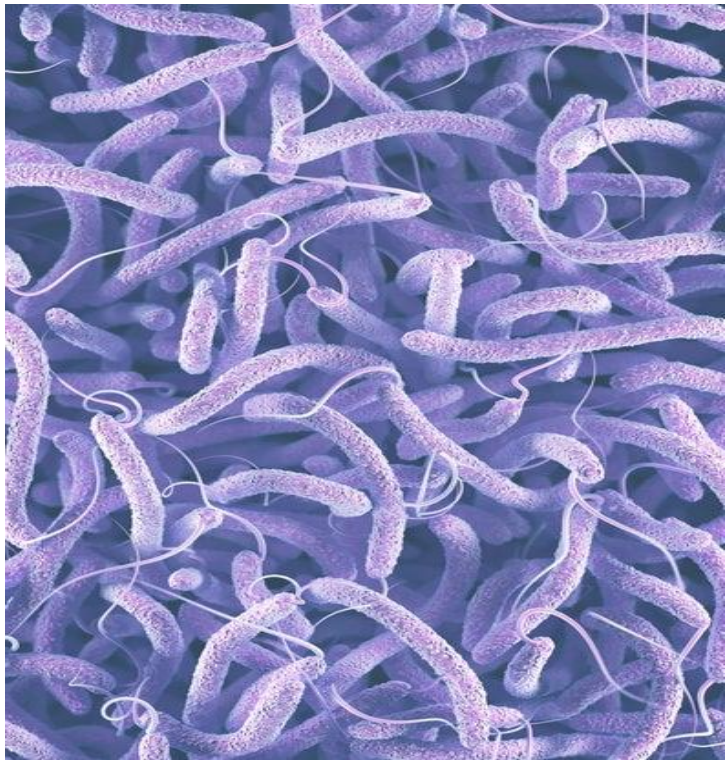
Safety of COVID-19 Pfizer-BioNTech (BNT162b2) mRNA vaccination in adolescents aged 12-17 years: A systematic review and meta-analysis [Internet]. [cited 2023 January 5]. Available from: https://www.tandfonline.com/doi/full/10.1080/21645515.2022.2144039

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

II. Safety Reports: The Pharmacovigilance's Way of Communicating

2. Adverse Events Following Immunization with Oral Cholera Vaccines in Lebanon

Period covered: Phase I: November 12th, 2022 to December 7th, 2022



On October 6th 2022, Lebanon recorded its first confirmed case of cholera since 1993. The outbreak spread across eight governorates and 19 out of the 26 districts in Lebanon. The number of the suspected cases gradually increased across all affected areas to reach 4,966 cases and 23 deaths by the end of the period covered by this report.

This executive summary provides an overview of the Adverse Events Following Immunization (AEFIs) that were temporally associated to the Oral Cholera Vaccines (OCVs) available in Lebanon during phase I of the national immunization campaign, in the period between November 12th, 2022, and December 7th, 2022. Within the scope of the multi-sectorial response to contain the cholera outbreak, the Lebanese National Pharmacovigilance Program (LNPVP) was the main entity concerned with monitoring and evaluating AEFIs with OCVs during the campaign, in the aim of ensuring patient and medication safety.

The objective of this report is to document serious and non-serious AEFIs caused by the OCV deployed during phase I: Euvichol-Plus, and to take the necessary remedial actions by investigating and determining the possible causes.

A total of 22 case reports corresponding to 50 AEFIs were received following the administration of 479,679 doses of Euvichol-Plus in Lebanon between November 12th, 2022, and December 7th, 2022. This is equivalent to a reporting rate of 0.046 case reports and 0.104 AEFIs per 1,000 doses administered.

The majority of case reports were reported through the 1787 hotline (50.0%), followed by the landline, (40.9%), then the KoboToolbox: AEFIs Software for Reporting (9.1%).

The age group of vaccine recipients who mostly reported AEFIs was between 2 and 11 years old (40.91%), with females reporting more than males (54.55% vs.45.45%). Only 5 case reports (22.73%) were classified as serious as per the WHO seriousness classification criteria. These cases are assessed by the PV program and shared with the Serious AEFI Special Committee for a final decision. An example of serious case handling is provided in annex to the full report.
Most of the reported AEFIs, 26 AEFIs (52% of the total AEFIs), belonged to the "Gastrointestinal Disorders" System Organ Class with abdominal pain (10 AEFIs,20.0%) being the most reported AEFI.

The LNPVP at the Ministry of Public Health is the reference entity of reporting concerned with AEFIs associated with OCVs. In collaboration with its partners, the PV team continues to conduct constant monitoring for the safety of the vaccines. Reporting of any encountered AEFI is highly encouraged to contain the outbreak and to reduce the strain on the health system.

III. A New Milestone: Recent Publication of the National PV Team

Vaccination process evaluation at COVID-19 vaccination centers in Lebanon: a national study

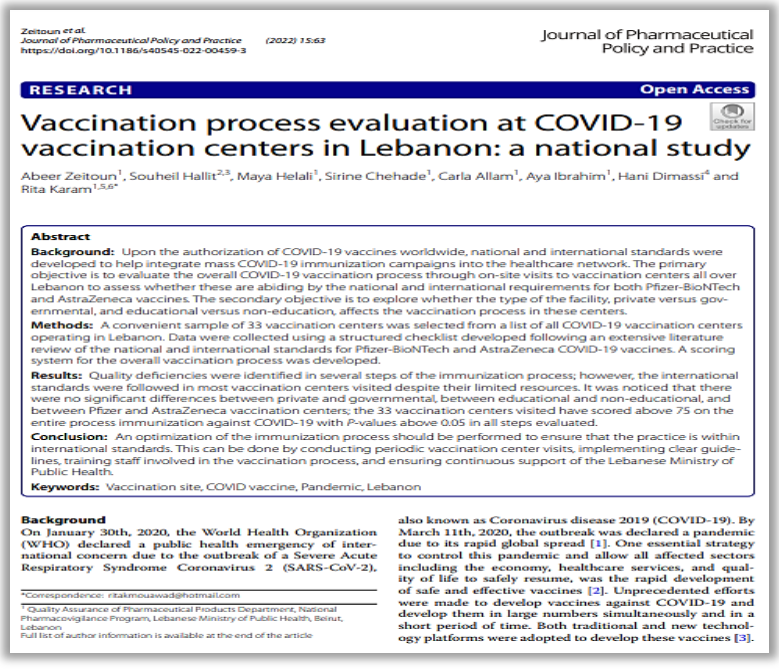
The article "Vaccination process evaluation at COVID-19 vaccination centers in Lebanon: a national study" was published in October 2022 in the Journal of Pharmaceutical Policy and Practice.

The primary objective is to evaluate the overall COVID-19 vaccination process through onsite visits to vaccination centers all over Lebanon to assess whether these are abiding by the national and international requirements for both Pfizer-BioNTech and AstraZeneca vaccines. The secondary objective is to explore whether the type of the facility, private versus governmental, and educational versus non-education, affects the vaccination process in these centers.

In summary, a sample of 33 vaccination centers was selected from a list of all COVID-19 vaccination centers operating in Lebanon. Data were collected using a structured checklist developed following an extensive literature review of the national and international standards for Pfizer-BioNTech and AstraZeneca COVID-19 vaccines. Quality deficiencies were identified in several steps of the immunization process; however, the international standards were followed in most of the vaccination centers visited despite their limited resources.

Use the following link to access the full article:

https://pubmed.ncbi.nlm.nih.gov/36243870/



Zeitoun et al.
Journal of Pharmaceutical Policy and Practice (2022) 15:63
https://doi.org/10.1186/s40545-022-00459-3

Journal of Pharmaceutical Policy and Practice

RESEARCH Open Access

Vaccination process evaluation at COVID-19 vaccination centers in Lebanon: a national study

Abeer Zeitoun[1], Souheil Hallit[2,3], Maya Helali[1], Sirine Chehade[1], Carla Allam[1], Aya Ibrahim[1], Hani Dimassi[4] and Rita Karam[1,5,6*]

Abstract

Background: Upon the authorization of COVID-19 vaccines worldwide, national and international standards were developed to help integrate mass COVID-19 immunization campaigns into the healthcare network. The primary objective is to evaluate the overall COVID-19 vaccination process through on-site visits to vaccination centers all over Lebanon to assess whether these are abiding by the national and international requirements for both Pfizer-BioNTech and AstraZeneca vaccines. The secondary objective is to explore whether the type of the facility, private versus governmental, and educational versus non-education, affects the vaccination process in these centers.

Methods: A convenient sample of 33 vaccination centers was selected from a list of all COVID-19 vaccination centers operating in Lebanon. Data were collected using a structured checklist developed following an extensive literature review of the national and international standards for Pfizer-BioNTech and AstraZeneca COVID-19 vaccines. A scoring system for the overall vaccination process was developed.

Results: Quality deficiencies were identified in several steps of the immunization process; however, the international standards were followed in most vaccination centers visited despite their limited resources. It was noticed that there were no significant differences between private and governmental, between educational and non-educational, and between Pfizer and AstraZeneca vaccination centers; the 33 vaccination centers visited have scored above 75 on the entire process immunization against COVID-19 with *P*-values above 0.05 in all steps evaluated.

Conclusion: An optimization of the immunization process should be performed to ensure that the practice is within international standards. This can be done by conducting periodic vaccination center visits, implementing clear guidelines, training staff involved in the vaccination process, and ensuring continuous support of the Lebanese Ministry of Public Health.

Keywords: Vaccination site, COVID vaccine, Pandemic, Lebanon

Background

On January 30th, 2020, the World Health Organization (WHO) declared a public health emergency of international concern due to the outbreak of a Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), also known as Coronavirus disease 2019 (COVID-19). By March 11th, 2020, the outbreak was declared a pandemic due to its rapid global spread [1]. One essential strategy to control this pandemic and allow all affected sectors including the economy, healthcare services, and quality of life to safely resume, was the rapid development of safe and effective vaccines [2]. Unprecedented efforts were made to develop vaccines against COVID-19 and develop them in large numbers simultaneously and in a short period of time. Both traditional and new technology platforms were adopted to develop these vaccines [3].

*Correspondence: ritakmouawad@hotmail.com

† Quality Assurance of Pharmaceutical Products Department, National Pharmacovigilance Program, Lebanese Ministry of Public Health, Beirut, Lebanon
Full list of author information is available at the end of the article

IV. Testimonial

HOPITAL Aboujaoudé

"I was happy to get to know that the Lebanese National Pharmacovigilance Program was officially launched. I strongly believe this will be a step further in quality and safety control in the Lebanese health sector. We were honored to have the whole LNPVP team members visit Aboujaoudé Hospital for an educational session. The visit was so enlightening, informative, and very well needed. It was a chance for the whole healthcare professionals at the hospital to be introduced to the pharmacovigilance operations and activities. My staff are now aware of what to report, when to report, and how to report. Special thanks to the skilled and professional pharmacovigilance team who were very supportive in guiding our different hospital staff throughout the reporting process. I look forward to see this successful onsite educational experience being applied at the different Lebanese healthcare facilities."

– Dr. Imad Aboujaoudé
Medical Director | Hospital Aboujaoudé

PV Team Members at The MoPH:

Dr. Rita Karam - Dr. Abeer Zeitoun -
Dr. Carla Allam – Dr. Aya Ibrahim
Dr. Sarah Reda El Sayed -
Dr. Myriam Watfa