THE NATIONAL PHARMACOVIGILANCE PROGRAM

NEWSLETTER

LEBANON

ISSUE 6

APRIL 2023

Prepared by
Pharmacovigilance Team
at the Ministry of Public Health

I. Sharing the Knowledge

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

Onsite Educational Visits

As part of the Lebanese National Pharmacovigilance Program (LNPVP)'s educational activities, the Pharmacovigilance (PV) team was invited to "Rafic Al Hariri University Hospital" and "Al Rassoul Al-Aazam Hospital" to host an educational session introducing the Program's PV operations. The first event was held on January 25th, 2023 at Rafic Al Hariri Hospital auditorium in Jinah, Beirut. The second educational session was held on February 22nd, 2023 at Al Rassoul Al-Aazam Hospital Auditorium in Airport Road, Beirut.

In both hospitals, healthcare professionals, medical staff including nurses, residents, pharmacists, and quality and safety persons have joined the sessions. Under the title of "Introduction to Pharmacovigilance Operations: Reporting and Data Management", the 2-hour sessions introduced the staff to the scope of the LNPVP's operations and activities. The objectives were threefold: Introducing the concept of Pharmacovigilance, sharing the implementation steps and objectives of the Lebanese Pharmacovigilance Program, and finally 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 were 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. The audience was then reminded of the general concepts of PV by Dr. Carla Allam, a PV officer, who presented a general overview of its importance and operations within healthcare systems worldwide. The Senior Clinical and Technical Manager at the LNPVP, Dr. Abeer Zeitoun then gave an insight on the adverse events to be reported and the available means to report them. In a fourth presentation, Dr. Sara Al Sayed, a PV officer, shared an overview of the program's workflow when handling the received cases. In a final presentation, the practical aspect of VigiFlow was presented by the PV officer, Dr. Aya Ibrahim. In an attempt to bring the audience closer to the LNPVP's everyday tasks, the different sections of VigiFlow were covered in a hands-on manner. 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.Series of Training Sessions to Enhance Reporting

Virtual Meeting

As part of the Lebanese National Pharmacovigilance Program (LNPVP)'s educational activities, the Pharmacovigilance (PV) team initiated a series of training sessions targeting pharmaceutical companies and drug distributors aiming to enhance reporting and improve the quality of the received case reports to the LNPVP.

The first training session of the series was held online on the 24th of March, 2023. A total of 14 personnel have joined the session including the regulatory manager, quality manager, and medical representatives. Under the title of "Lebanese National Pharmacovigilance Program: Training Session" the 2-hour session introduced the participants to the scope of the LNPVP's operations and activities. The objective of the session was to sensitize the audience to the local Pharmacovigilance program and its means of reporting. This will in turn aid in increasing the number of the received reports and improve their quality.

Three presentations were provided by the PV team members revolving around the operations performed at the LNPVP. These presentations aimed to share with participants the identified gaps in the received case reports. Detailed examples were provided by the PV team where an open discussion was held to share opinions related to possible causes of the identified gaps. Finally, recommendations targeting the discussed issues were addressed by the PV team members, and questions and inquiries received from the audience were answered.

The session was initiated and welcome remarks were 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. Pre-assessment poll questions were shared with the audience, and results were then discussed. The aim of the poll was to assess the background knowledge of the audience in relation to pharmacovigilance, adverse drug reactions, reporting forms available at the LNPVP, and participants' reporting practices. Dr. Karam then outlined the roadmap to the program's success and acquainted the audience with its mission, vision, and values.

Dr. Abeer Zeitoun, the Senior Clinical and Technical Manager at the LNPVP, described the efforts done to increase reporting.

lastly, Dr. Aya Ibrahim, a PV officer at the LNPVP, gave an overview of the reporting activities done at the LNPVP. Finally, she shared the gaps identified in the received reports providing detailed examples with an interactive session, where she discussed how the causality assessment of these reports can be affected by the presented gaps.

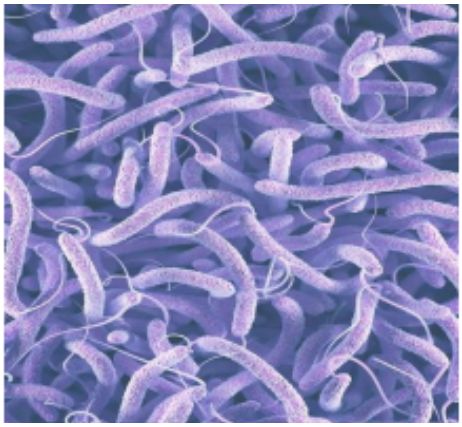
The training session concluded with a summary of the identified gaps and recommendations for every debated issue. The audience was encouraged to leverage their daily contact with the patients and other relevant stakeholders, to raise awareness of the importance of adverse event reporting and pharmacovigilance in general. Post-assessment poll questions were shared and inquiries received from the audience were answered.

Finally, participants assessed the session through a shared evaluation form link. Positive feedback was received valuing the shared knowledge and the professionalism of all speakers.

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

Report 2: Adverse Events Following Immunization with Oral Cholera Vaccines in Lebanon

Period covered: November 12th, 2022 to January 22nd, 2023



On October 6th 2022, Lebanon recorded its first confirmed case of cholera since 1993. The number of the suspected cases gradually increased across all affected areas to reach 6,408 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 Phases I and II of the national immunization campaign, in the period between November 12th, 2022, and January 22nd, 2023..

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 AEFI with the OCV deployed during Phases I and II: Euvichol-Plus®. A total of 38 case reports corresponding to 97 AEFIs were received following the administration of 1,025,000 doses of Euvichol-Plus® in Lebanon between November 12th, 2022, and January 22nd, 2023. This is equivalent to a reporting rate of 0.037 case reports and 0.094 AEFIs per 1,000 doses administered. The majority of case reports were received through the 1787 hotline (60.5%), followed by the landline, (29.0%), then the KoboToolbox: AEFIs Software for Reporting (10.5%), and mostly originated from the Baalbeck-El Hermel governorate (36.9%).

The age groups of vaccine recipients who mostly reported AEFIs were between 2 and 11 years old and between 18 and 44 years old (34.2% each), with females reporting more than males (60.5 % vs.39.5%). Only 8 case reports (21.1%) were classified as serious as per the WHO seriousness classification criteria. Most of the reported cases (73.7%), belonged to the "Gastrointestinal Disorders" System Organ Class with vomiting (34.2%) being the most reported AEFI. 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. Networking: Exchanging the Experience

Second Oman Pharmacovigilance Symposium

On Wednesday, March 15th, 2023, the Sultanate of Oman, represented by the Ministry of Health, hosted the Second Oman Pharmacovigilance Symposium and Qualified Person for Pharmacovigilance meeting. It was organized by the Drug Vigilance and Information Department of the General Directorate of Pharmacy and Drug Control.

The symposium was attended by representatives of pharmacovigilance centers and pharmacovigilance experts from several Arab countries, including Saudi Arabia, Kuwait, Iraq, Bahrain, Egypt, Lebanon, Yemen, and Jordan, in addition to speakers and experts from pharmaceutical companies at the Grand Millennium Muscat Hotel/Oman.

The conference aims to exchange experiences and regional developments in drug safety and pharmacovigilance, emphasizing the importance of communication and open exchange of information and opinions about drug safety.

Pr. Rita Karam and Dr. Abeer Zeitoun, two representatives from the Lebanese National Pharmacovigilance Program (LNPVP) at the Ministry of Public Health attended this symposium. Professor Rita Karam, Coordinator of the National Pharmacovigilance Program in Lebanon, participated with a lecture entitled "Management of Adverse Drug Reactions: The Lebanese Experience". Her presentation shed light on the LNPVP activities and gave an overview of how this program handles adverse drug reactions.

The LNPVP efforts were presented through a descriptive analysis that compared the data with neighboring Arab countries. Pr. Rita Karam was honored for her outstanding efforts and participation in the symposium.

III. Networking: Exchanging the Experience

Second Oman Pharmacovigilance Symposium

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

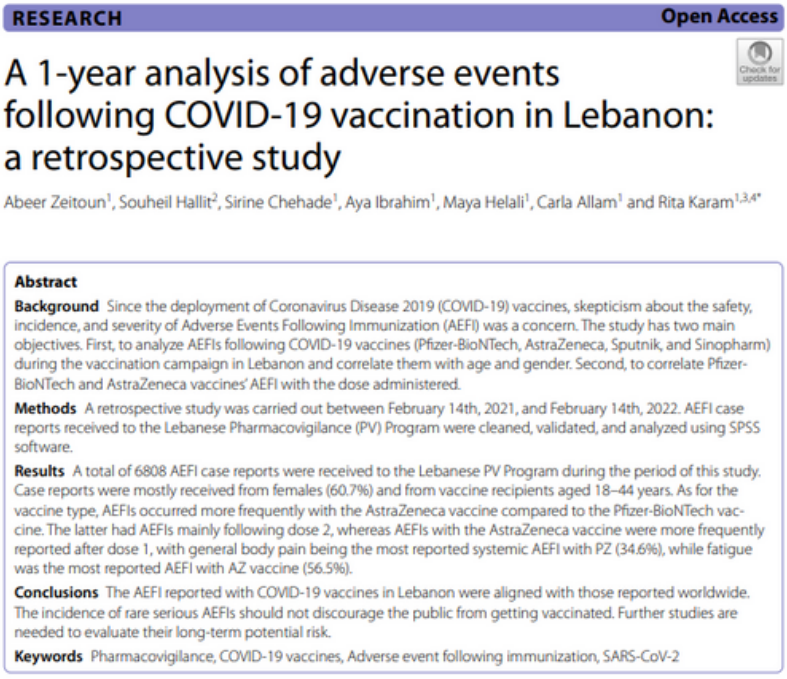
A 1-Year Analysis of Adverse Events Following COVID-19 Vaccination in Lebanon: A Retrospective Study

The article "A 1-Year Analysis of Adverse Events Following COVID-19 Vaccination in Lebanon: A Retrospective Study" was published in February 2023 in the Journal of Pharmaceutical Policy and Practice.

The objective of the study is to describe AEFIs following COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik, and Sinopharm vaccines) reported during the national vaccination campaign through passive surveillance system and correlate them with age and gender. Since Pfizer-BioNTech and AstraZeneca vaccines were mainly administered in Lebanon, correlation between these vaccines and dose number administered was also performed. The aim of the latter is to prompt policymakers to develop recommendations and guidelines.

In summary, a total of 6,808 AEFI case reports were received to the Lebanese PV Program during the period of this study. Case reports were mostly received from females (60.7%) and from vaccine recipients aged 18–44 years. As for the vaccine type, AEFIs occurred more frequently with AstraZeneca vaccine compared to Pfizer-BioNTech vaccine. The latter had AEFIs mainly following dose 2, whereas AEFIs with the AstraZeneca vaccine were more frequently reported after dose 1, with general body pain being the most reported systemic AEFI with Pfizer-BioNTech (34.6%), while fatigue was the most reported AEFI with AstraZeneca vaccine (56.5%). Use the following link to access the full article:

https://joppp.biomedcentral.com/articles/10.1186/s40545-023-00528-1



RESEARCH Open Access

A 1-year analysis of adverse events following COVID-19 vaccination in Lebanon: a retrospective study

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

Abstract

Background Since the deployment of Coronavirus Disease 2019 (COVID-19) vaccines, skepticism about the safety, incidence, and severity of Adverse Events Following Immunization (AEFI) was a concern. The study has two main objectives. First, to analyze AEFIs following COVID-19 vaccines (Pfizer-BioNTech, AstraZeneca, Sputnik, and Sinopharm) during the vaccination campaign in Lebanon and correlate them with age and gender. Second, to correlate Pfizer-BioNTech and AstraZeneca vaccines' AEFI with the dose administered.

Methods A retrospective study was carried out between February 14th, 2021, and February 14th, 2022. AEFI case reports received to the Lebanese Pharmacovigilance (PV) Program were cleaned, validated, and analyzed using SPSS software.

Results A total of 6808 AEFI case reports were received to the Lebanese PV Program during the period of this study. Case reports were mostly received from females (60.7%) and from vaccine recipients aged 18–44 years. As for the vaccine type, AEFIs occurred more frequently with the AstraZeneca vaccine compared to the Pfizer-BioNTech vaccine. The latter had AEFIs mainly following dose 2, whereas AEFIs with the AstraZeneca vaccine were more frequently reported after dose 1, with general body pain being the most reported systemic AEFI with PZ (34.6%), while fatigue was the most reported AEFI with AZ vaccine (56.5%).

Conclusions The AEFI reported with COVID-19 vaccines in Lebanon were aligned with those reported worldwide. The incidence of rare serious AEFIs should not discourage the public from getting vaccinated. Further studies are needed to evaluate their long-term potential risk.

Keywords Pharmacovigilance, COVID-19 vaccines, Adverse event following immunization, SARS-CoV-2

V. Testimonial

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

MH/DGPA&DC/DGO/ 2123

28-08-1444 H

21-03-2023

Appreciation Letter

MS. DR. ABIR ZEITOUN

After Compliments,

Sub: ***Second Oman Pharmacovigilance Symposium (15-16 March 2023) Letter of Appreciation***

This is to thank you for your active participation in the Second Oman Pharmacovigilance Symposium which was conducted at Grand Millennium Hotel, Muscat on 15th and 16th March 2023. Your involvement and suggestions were valuable in making the event a grand success.

Yours sincerely,

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

Cc: Director of Pharmacovigilance & Drug Informati

Sultanate of Oman
Ministry of Health
ectorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
مديرية العامة للصيدلة
والرقابة الدوائية
مسقط

MH/DGPA&DC/DGO/ 2112

28-08-1444 H

21-03-2023

Appreciation Letter

MS. DR. RITA YAZBECK KARAM

After Compliments,

Sub: ***Second Oman Pharmacovigilance Symposium (15-16 March 2023) Letter of Appreciation***

This is to thank you for your active participation in the Second Oman Pharmacovigilance Symposium which was conducted at Grand Millennium Hotel, Muscat on 15th and 16th March 2023. Your involvement and suggestions were valuable in making the event a grand success.

Yours sincerely,

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

Cc: Director of Pharmacovigilance & Drug Information

PV Team Members at The MoPH

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