



THE NATIONAL PHARMACOVIGILANCE PROGRAM

NEWSLETTER

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Prepared by

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at the Ministry of Public Health

OUTLINE

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Recent Publication of the National PV Team

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I. A NEW MILESTONE

RECENT PUBLICATION OF THE NATIONAL PV TEAM

Karam et al. *BMC Public Health* (2024) 24:2905
<https://doi.org/10.1186/s12889-024-20297-z>

BMC Public Health

RESEARCH

Open Access



Serious adverse events following immunization with COVID-19 vaccines in Lebanon: a retrospective analysis of the National Pharmacovigilance Database

Rita Karam^{1,2}, Katia Iskandar³, Myriam Watfa² and Abeer Zeitoun^{2*}

The article “Serious adverse events following immunization with COVID-19 vaccines in Lebanon: a retrospective analysis of the National Pharmacovigilance Database” was published on the 21st of October 2024 in the BMC Public Health journal.

The objective of this study was to analyze the characteristics and prevalence of serious adverse events following immunization (AEFIs) with inactivated COVID-19 vaccines. The study aims were to investigate AEFIs based on System Organ Class (SOC), age, and sex in order to better understand the safety profile of these vaccines, guide vaccination strategies, and inform public health policy.

The study was a retrospective observational analysis conducted between February 14th, 2021, and June 30th, 2022. It evaluated serious adverse events following immunization (AEFIs) for inactivated COVID-19 vaccines, specifically comparing AEFIs across different factors such as vaccine type (ChAdOx1 vs. BNT162b2), age, sex, and SOC. Causality assessments were carried out following World Health Organization guidelines.

The study concludes that ongoing surveillance is essential for detecting potential safety signals and ensuring confidence in vaccination programs through evidence-based decision-making.

Read More at:



Karam R, Iskandar K, Watfa M, Zeitoun A. Serious adverse events following immunization with COVID-19 vaccines in Lebanon: a retrospective analysis of the National Pharmacovigilance Database. *BMC Public Health*. 2024 Oct 21;24(1):2905.

II. STAY VIGILANT, STAY SAFE

IMPORTANCE OF REPORTING

1. What is the importance of reporting?

A. Benefit to Public Health and Medication Safety



Identify safety risks associated with medications



Withdrawing un-safe medication



Updating drug labels



Issuing warnings

B. Benefit to individual patients



Switch medication



Treat the reaction



Adjust the dose



Prevent occurrence in the future

II. STAY VIGILANT, STAY SAFE

IMPORTANCE OF REPORTING

2. What to Report?



Reporter Identifier

- Pharmacist
- Physician
- Other Healthcare Workers
- Patient



Patient Identifiers

- Initials
- Age
- Gender



Reaction Details

- The reaction as it is
- Onset Date
- Recovery Date



Medication/ Vaccine Details

- Name of the Drug
- Dose
- Date of Uptake
- Action taken with the Drug



- Other Details (Medication and Medical History, Allergies, etc..)
- Case Narrative (Detailing the reaction in a timely manner)

II. STAY VIGILANT, STAY SAFE

IMPORTANCE OF REPORTING

3. How to Report?



Patients



1. Med Safety Mobile Application

1. Search App Store or Google Play for Med Safety App
2. Install the App to your device
3. Select Lebanon as a region
4. Select the language

&



Healthcare Professionals



2. Electronic Reporting

By clicking the link below, you will be directed to the main reporting page.

<https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=LB>



3. Direct Contact with the Lebanese National Pharmacovigilance Program



+961-1-830-254



pv@moph.gov.lb

pv.moph@gmail.com



Drug Companies



ICH E2B R2/R3 in the Form of an XML File

In accordance with the ministerial resolution #180/181

XML file is sent to pv@moph.gov.lb

III. KNOWLEDGE CORNER

WHAT IS PATIENT SAFETY DAY





World Patient Safety Day, marked annually on September 17, was established by the World Health Organization (WHO) in 2019, following the adoption of resolution WHA72 by the World Health Assembly.


Patient safety refers to preventing and reducing risks, errors, and harm that patients may experience during healthcare provision. The goal of World Patient Safety Day is to raise awareness about the importance of patient safety in healthcare systems worldwide.

The theme for this year's World Patient Safety Day is centered on enhancing diagnosis for patient safety, under the slogan "Get it right, make it safe!"


This year, the Lebanese National Pharmacovigilance Program (LNPVP) took part in the World Patient Safety Day by producing a series of videos focused on the importance of reporting, what to report, and how to report safety concerns in healthcare. To ensure widespread awareness, they invited hospital pharmacovigilance focal points to disseminate these videos in their respective hospitals and to play them on waiting room screens, aiming to educate both healthcare professionals and patients about the significance of reporting in enhancing patient safety.


 What are Adverse Drug Reactions?
ما هي الآثار الجانبية للأدوية؟






“ ما هي الأدوية المزورة أو المقننة ”



 What to Report?
عن ماذا تبلغ؟



IV. ACKNOWLEDGMENT

SPOTLIGHT ON TOP-REPORTING HOSPITALS

We are grateful to the dedicated individuals who have been actively involved in the Adverse Event reporting process.

We extend special thanks to the below hospitals with their pharmacovigilance focal points and healthcare professionals for their exceptional contributions to this important process.



Rafic Hariri Governmental Hospital



Haykal Hospital



Abou Jaoude Hospital

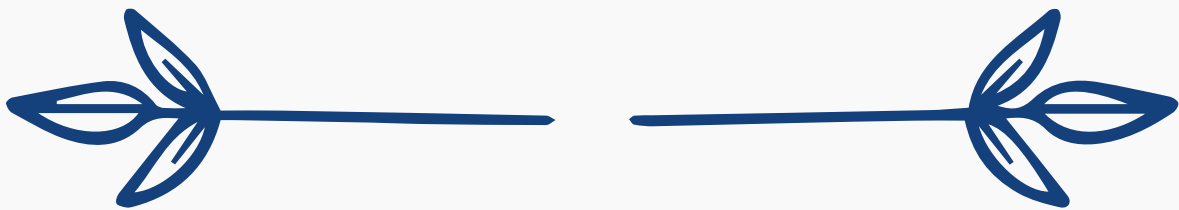


St. George Hospita

Their collaboration have made a significant impact, and we deeply appreciate their outstanding efforts in ensuring a safer healthcare environment.



PV Team Members at The MoPH



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