Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Descriptive report of Adverse event following immunization (AEFIs)

Data in Saudi Arabia, Q2 2025

DATA CAPTURE SECTION

NATIONAL PHARMACOVIGILANCE CENTER

General notes:

Data Report: National Pharmacovigilance Centre

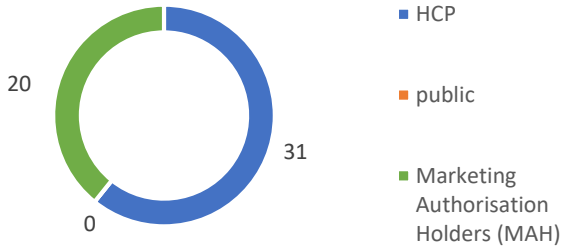
- **Source:** Spontaneous Vigilance System, National Pharmacovigilance Centre
- **Scope:** Adverse event reports following immunization. These are medical occurrences noted after the administration of a vaccine, but do not necessarily imply a direct causal link to the vaccine.
- **Parameters:**

    1. Routine and COVID-19 vaccine reports (Drug reports excluded)
    2. Data extract from 1 April to 30 June 2025.

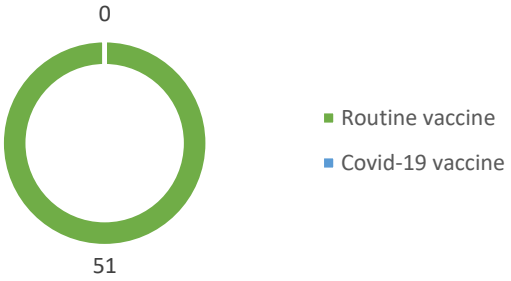
Understanding Pharmacovigilance:
The National Pharmacovigilance Centre plays a crucial role in post-market vaccine safety monitoring. By collecting and analyzing adverse event reports following immunization, it helps identify serious issues and facilitates interventions to protect public health.

Important Notes:
It is important to understand that reports of adverse events following immunization do not automatically prove that the vaccine caused the event. Careful assessment is necessary to establish any potential relationship.

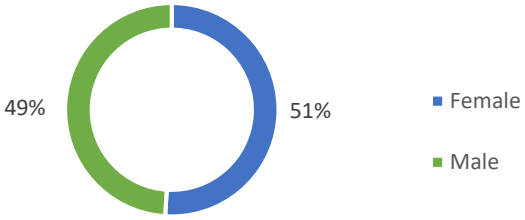
Number of reports based on organization type



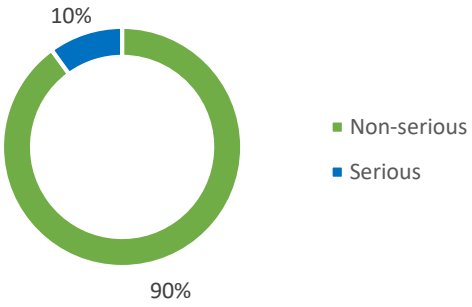
Number of reports based on report type



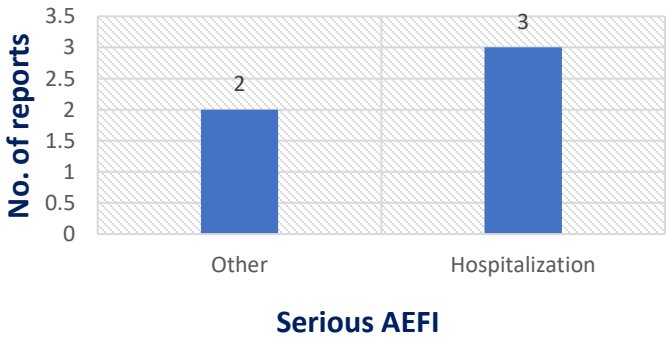
Gender



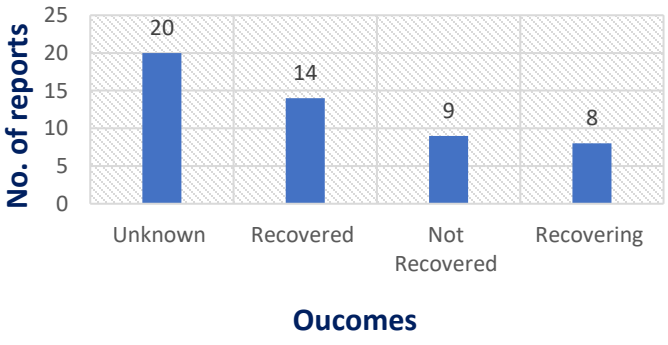
Report seriousness

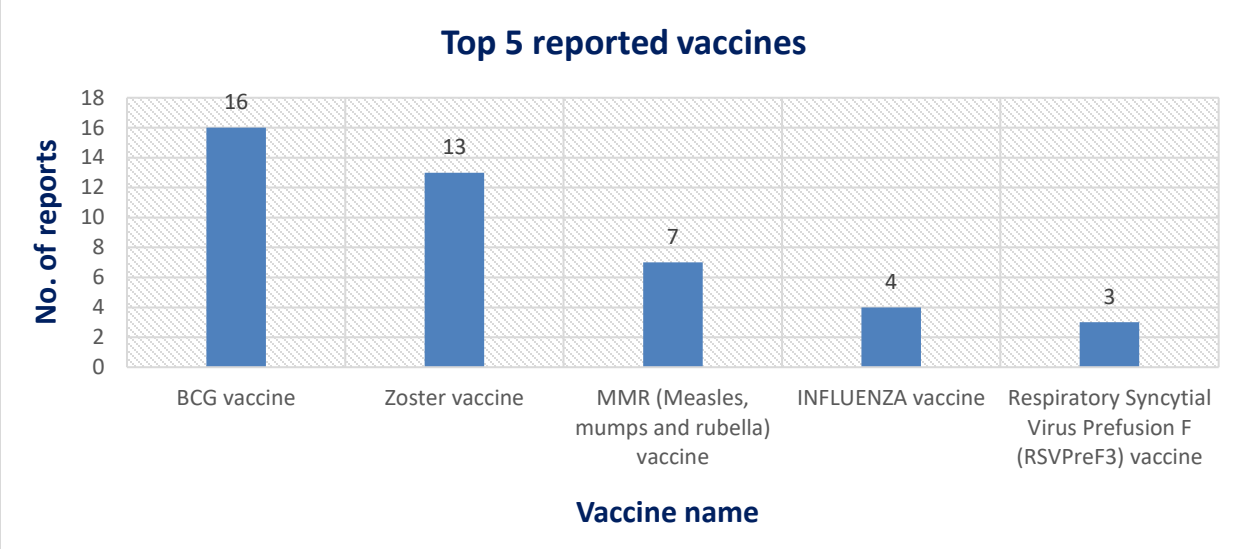


Number of reports by Serious AEFI

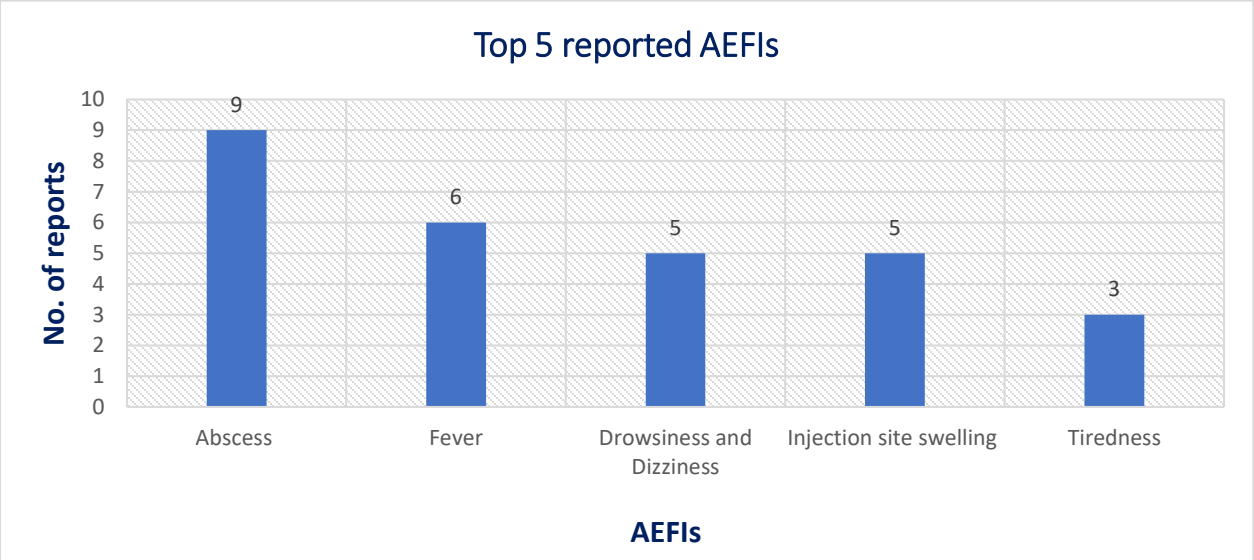


Number of reports by oucomes

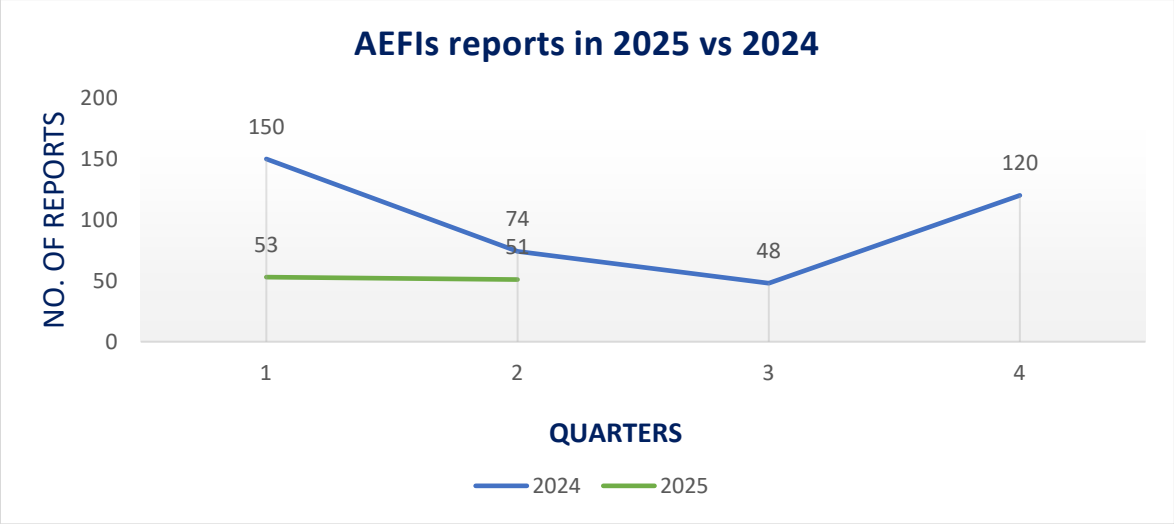




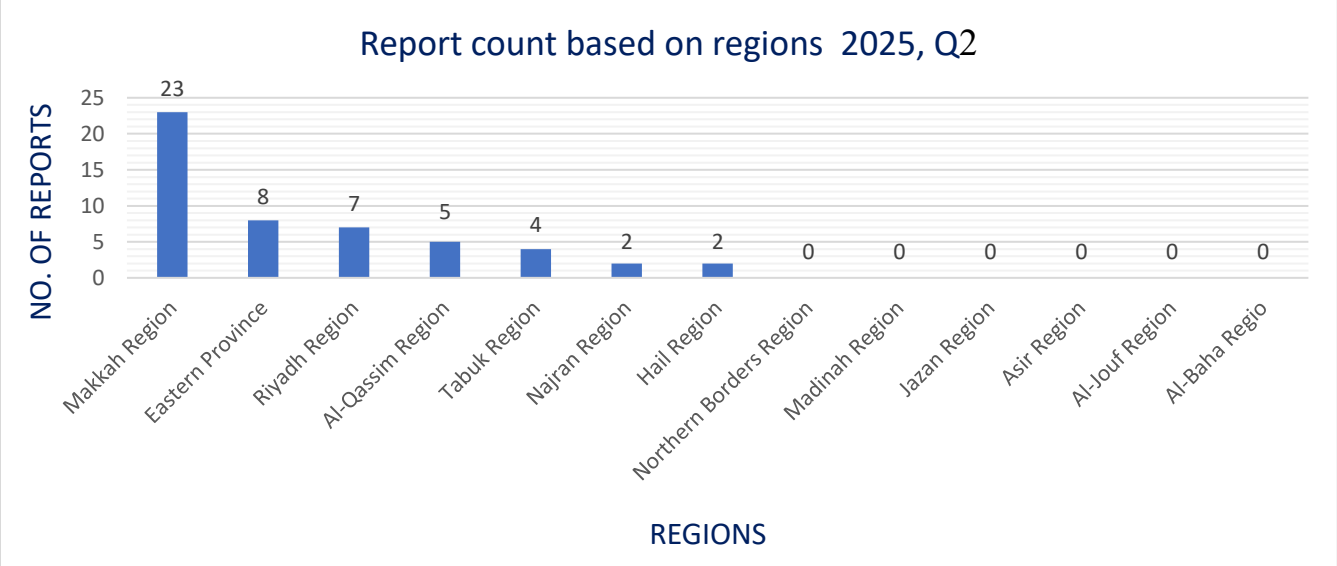
The top 5 Vaccines reported in Q2 2025.



The top 5 AEFIs reported in Q2 2025



AEFIs reports in 2025 vs 2024



Reports count based on regions for year 2025, quarter 2

Recommendation:

After reviewing the reports and statistics the second quarter of 2025, the recommendation suggests conducting in-person visits or remote meetings in the silent regions of Kingdom of Saudi Arabia to continue achieving the goals outlined in the reporting process. The purpose of these meetings would be to share best practices, address any remaining challenges, and celebrate successes

Action plan for the quarters in 2025:

- **Improve Reporting Rates for Vaccines:** Focus on enhancing the reporting rate for vaccines throughout 2025.
- **Increase Meeting Frequency:** Ensure that the causality assessment committee meets at least twice every quarter.
- **Establish Criteria for Identifying Silent Reporting Regions:**

I. Any area not reaching the target for reporting (at least one report per month).
II. Areas with no reports (zero reporting) for three consecutive months.
III. Regions with no login activity in the system from regional coordinators or healthcare workers.

- After reviewing the reporting KPIs and statistics for Q2 via the AEFIs dashboard, we identified the regions of Northern Borders Region, Madinah Region, Jazan Region, Asir Region, Al-Jouf Region and Al-Baha Regio as silent, along with low reporting in Najran Region and Hail Region. We will notify the National Immunization Program (NIP) and schedule meetings with these targeted areas to discuss barriers and potential interventions.
- **Arrange Training Meetings:** Coordinate with the NIP and regional coordinators to schedule appropriate training sessions and perform all necessary activities for the silent regions.
- **Review Barriers:** Identify and assess the problems and challenges that hinder effective reporting through the vigilance system.
- **Follow-Up Reporting:** After conducting physical visits, implement a system for continuous monitoring and follow-up of reporting efforts during the 3rd, and 4th quarters of 2025.

- **Conduct Virtual Meetings:** Hold meetings for each region after every quarter to review the extent of improvement in reporting rates.

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