



# COVID-19 VACCINE VIGILANCE: COMPARATIVE STUDY BETWEEN HOSPITAL, REGIONAL AND NATIONAL DATA



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## BACKGROUND AND IMPORTANCE:

Following AIFA's authorization of first mRNA vaccine, on 27/12/2020 COVID-19 vaccination campaign starts in Italy.

Simultaneously, many activities of vaccine vigilance start to individuate the main expected and unexpected adverse events following immunization (AEFIs) and to evaluate the benefit/risk balance of vaccination.

## AIM AND OBJECTIVES:

The aim of this work is comparing reports of vaccine vigilance in our Hospital from December 2020 to June 2022 to national and regional data.

## MATERIALS AND METHODS:

Starting from data of the National System of Pharmacovigilance (RNFV), we analysed reports by age, sex, severity of reaction, reporter and by System Organ Class (SOC) involved (using Meddra classification system). Finally, we compared results obtained with those of the twelfth vaccine surveillance report published on June 2022 by the Italian Agency of Drugs (AIFA) and those of the 2021 annual regional report.

## RESULTS:

In the period our Hospital administered about 111000 doses (99% Comirnaty, 0.6% Spikevax, 0.3% Vaxzevria).

176 reports were collected: 69 (39%) concerned Covid vaccination with a Reporting Rate (RR) of 0,06%.

52 (75,4 %) were not severe and 17 (24,6%) were severe; among those severe, 2 cases of ineffective vaccination (Comirnaty) were included, 1 case of heart attack (Spikevax), 1 case of adrenal hematoma (Vaxzevria) and 1 episode of deep vein thrombosis (Comirnaty).

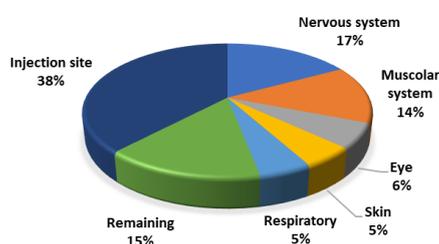
59 (85,5%) involved women and 10 (14,5%) involved men.

65 (94,4%) reports are related to Comirnaty vaccine (23% were severe, and further 9% of severe reaction were given by the association with other drugs) with RR 0,06%; 2 (2,9%) were related to Spikevax vaccine (50% were severe) with RR 0,6% and the last few 2 (2,9%) were from Vaxzevria vaccine, (50% were severe) with RR 0,3%.

### PATIENT'S CHARACTERISTICS

Number of REPORTS	69
<b>Severe</b>	17 (24,6%)
<b>Not Severe</b>	52 (75,4%)
<b>Women</b>	59 (85,5%)
<b>Men</b>	10 (14,5%)
<b>Age (Average)</b>	43
<b>First dose</b>	35 (51%)
<b>Second dose</b>	32 (46%)
<b>Third dose</b>	2 (3%)

### SOC OF AEFIS



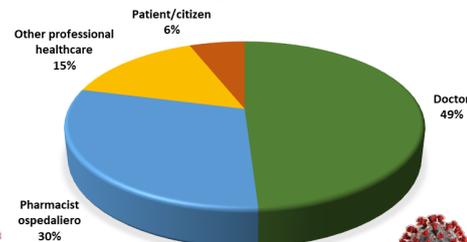
216 AEFIs were collected; 83 (38%) general diseases and conditions related to site of injection (13 fever, 9 asthenia); 37 (17%) nervous system diseases (26 headache); 30 (14%) generalized muscular pains (8 myalgia). Little percentage involved also vision, skin and respiratory system.

49% of reports were from doctors, 30% from pharmacist, 15% from other health worker and last 6% were from patients.

35 (51%) AEFIs were from the first dose, 32 (46%) from the second dose and 2 (3%) from the third one.

Almost all reports involved age range 18-64.

### REPORTER



## CONCLUSION AND RELEVANCE:

Results obtained from analysis conducted on Comirnaty vaccine are generally in line with twelfth AIFA's reports and with the annual report of Marche region; data from Spikevax and Vaxzevria vaccine show instead altered percentage because of little number of reports. Reporting rates are comparable.

Most of reports concerned not severe reaction, mainly related to site of injection.

It is important to underline the essential role of vaccine vigilance to identify red flags for public health in order to contain main severe reactions.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

"Rapporto sulla Sorveglianza dei vaccini anti-COVID-19 (27/12/2020 – 26/06/2022)" AIFA

ANALISI delle SEGNALEZIONI di REAZIONI AVVERSE da VACCINI COVID19 nella REGIONE MARCHE - Anno 2021

