

Descriptive analyses of Individual Case Safety Reports related to vaccines in the Campania Region (Italy) from 2001 to 2019

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Objective:

To perform a descriptive and statistical analysis on Individual Case Safety Reports (ICSRs) related to all vaccines in the Campania Region Pharmacovigilance Center, Italy.

Methods:

Using the Italian pharmacovigilance database (Rete Nazionale di Farmacovigilanza – RNF) all ICSRs relating to a suspected vaccine (ATC J07) in the Campania Pharmacovigilance Regional Center from January 1st, 2001 to December 2019 were extracted and analyzed.

Findings:

From January 1st, 2001, to December 31st 2019, 1185 ICSRs related to vaccines were sent to Campania Pharmacovigilance Regional Center. Nine hundred and four ICSRs reported AEFIs that were not serious, while two hundred and eighty-one reported AEFIs that were considered as serious. The descriptive analysis made on the ICSRs reported date, seriousness, suspected vaccine, gender, age group, outcome and reported source uncovered the predominant types and patterns while the statistical analysis found multiple associations that are statistically significant.

Conclusion:

A comprehensive characterization of the reported AEFIs for suspected vaccines in the Campania region has been performed. The results can be used to improve the continuously pharmacovigilance monitoring, to draw safety concerns or can be further investigated into subsequent trials.

Biography

Mirabela Veliscu has completed her MSc degree in [Pharmacovigilance](#) and Pharmacovigilance through EU2P European training programme in [Pharmacoepidemiology](#) and Pharmacovigilance at the age of 31 years from University of Bordeaux. She also completed University of [Pharmacy](#) from University of Medicine and Pharmacy UMF Carol at 23 years and she is an Associate Manager Patient Safety Solutions in a top multinational company. She has 9 years experience in Pharmacovigilance and pharmacy, including as pharmacist manager and she has been the representatives of the students at Bordeaux University.

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