VACCINES SAFETY IN CHILDREN AND IN GENERAL POPULATION: A PHARMACOVIGILANCE STUDY ON ADVERSE EVENTS FOLLOWING IMMUNIZATION IN ITALY

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Introduction: The fear of adverse events following immunization (AEFI), often supported by anti-vaccination movements and devoid of any scientific plausibility, have eroded confidence in vaccines. Thus, the aims of the present study were to characterize AEFI in general population, in terms of frequency, preventability and seriousness, and to define predictors of their seriousness in children.

Material and methods: A retrospective study was performed on suspected AEFI reports collected in Tuscany (Italy) in 2017. Patients' characteristics, suspected vaccines, and AEFI description were collected. Causality and preventability were assessed using validated algorithms, and logistic regression was used to estimate the reporting odds ratios of potential predictors of AEFI seriousness in children.

Results: A total of 223suspected AEFI reports were collected, and the majority of them were defined as non-serious (76.7%). Reports were mostly related to one vaccine, and to a median of 2-5strains/toxoids. The total number of simultaneously administered strains/toxoids and the presence of allergens did not correlate with AEFI seriousness. Considering vaccines with a high number of administered doses (≥60,000 doses), the rates estimated for serious AEFI reports were always very low, ranging between 0.01and 0.2/1,000 doses. Twenty-four vaccines (8,993doses) were not related to any AEFI.

Discussion and conclusion: Results of present study show that AEFI are very rare, the vast majority of them is non-serious and, despite the claims of anti-vaccination movements, the simultaneous administration of vaccines is safe and does not influence the risk of reporting a serious AEFI, particularly in children.