ABSTRACT

Analysis of vaccine utilization and spontaneous adverse events reports in influenza vaccine

Author: Markéta Podskalská

Supervisor: PharmDr. Eva Zimčíková, Ph.D.

Department of Social and Clinical Pharmacy, Faculty of Pharmacy in Hradec Králové, Charles University

Introduction and goal: Influenza is a contagious disease of the respiratory system. It is caused by influenza viruses and appears in annual outbreaks. The best form of influenza prevention is vaccination against influenza viruses on yearly basis. The vaccination has many benefits, but some side effects may appear as well. Goal of this thesis was to analyse and evaluate reports of side effects of influenza vaccination between years 2004–2017 and to evaluate the use of influenza vaccines from 2004 to 2022.

Methodology: The Central Database of Adverse Events Reporting of the State Institute for Drug Control was used as the data source. Reports with the ATC code J07BB in the period from 2004 to 2017 were evaluated. Information about the patient, reporting person, the region where the notification was filed, the method of reporting and details concerning adverse events were analysed. These details included the number and severity of adverse effects, their predictability and final outcome. Data on influenza vaccine usage were provided by SÚKL. Vaccine usage from 2004 to 2022 was assessed, measured in the number of packages per individual years and within individual ATC groups.

Results: During the given period, 317 events were reported. In total 1194 suspected events were reported. The majority of reported reactions belonged to the following organ systems: “General disorders and application site conditions” (32,6 %), “Musculoskeletal and connective tissue issues" (13,1 %), “Nervous system disorders” (10,5 %), “Respiratory, thoracic, and mediastinal disorders” (7,3 %), “Gastrointestinal disorders” (7 %) and “Disorders of skin and underlying tissue” (6 %). Huge amount of severe side effects (71,9 %) that were reported, ended up resolving on their own (48,3 %). Most reports were reported by doctors (92,2 %), with only one report by a pharmacologist (0,3 %). In 5 reports, identified adverse effects were suspected to be related to patient´s death. During the assessment of the predictability of side effects, a total number of 537 unexpected adverse effects were identified.

Conclusion: Spontaneous reporting of adverse effects is an important source of information for monitoring the safety and effectiveness of medicinal products. The results are not comprehensive enough to decisively evaluate the safety and effectiveness of influenza vaccines. Unexpected adverse effects that occurred repeatedly were identified and these could be considered as signals for another evaluation. The overall influenza vaccine use has increased every year since 2014, with the highest usage observed in 2021. However, the use in 2022 decreased by nearly half as compared to 2021.