Three seasons of enhanced safety surveillance of a cell culture-based quadrivalent influenza vaccine

Alexander Domnich[1], Daniela Amicizia[2], Piero Lai[2], Matilde Ogliastro[2], Maria Piedrahita-Tovar[3], Andrea Orsi[2], Giancarlo Icardi[2], and Donatella Panatto[2]

[1]IRCCS Ospedale Policlinico San Martino
[2]University of Genoa
[3]CSL Seqirus

January 23, 2023

Abstract

Background: Enhanced safety surveillance (ESS) of seasonal influenza vaccines is required by the European Medicines Agency (EMA). ESS is conducted during each Northern Hemisphere (NH) influenza season and aims to monitor the reactogenicity of influenza vaccines early in the season. A cell culture-based quadrivalent influenza vaccine (QIVc; Flucelvax® Tetra), which has an advantage of avoiding egg-adaptive mutations that may reduce vaccine effectiveness, has been available in Europe since the 2019/20 influenza season. The objective of this manuscript is to summarize ESS activity across three seasons for QIVc in all age groups. Methods: As per EMA guidelines, an enhanced passive safety surveillance (EPSS) approach was adopted. The EPSS envisages near-real-time surveillance of adverse events (AEs) that are reported spontaneously by vaccinees. The EPSS was conducted in primary care setting in Genoa (Italy) during the seasons 2019/20, 2020/21 and 2021/22. All AEs registered within the first 7 days following immunization were analyzed by season, type, age group and seriousness. Results: Over three seasons, a total of 3,603 QIVc exposures were recorded within EPSS. No safety signals were identified. The overall reporting rates of individual case safety reports (ICSRs) for the seasons 2019/20, 2020/21 and 2021/22 were 1.75% (18/1030), 0.48% (5/1032) and 0.40% (4/1001), respectively. The average number of AEs per ICSR was similar (range 3.3–3.8) across the three seasons. Most AEs were reactogenic in nature. The rate of AEs was similarly low in all age groups. Conclusions: These results support the favorable safety profile of QIVc in all indicated age groups.

Hosted file

`EPSS_Flucelvax_IORV.docx` available at https://authorea.com/users/438310/articles/620669-three-seasons-of-enhanced-safety-surveillance-of-a-cell-culture-based-quadrivalent-influenza-vaccine