

## Bell's Palsy

Bell's palsy (BP) is an acute and idiopathic paralysis of the facial nerve, with an estimated incidence ranging from 11.5 per 100,000 person-years to 53.3 per 100,000 person-years in different populations (Rowhani-Rahbar et al). Recently, the public-private ADVANCE collaboration developed and tested a system to generate evidence on vaccine benefits and risks using European electronic healthcare databases. For Bell's palsy a crude incidence of 23.8/100,000 person-years (95% confidence interval 23.6–24.1) was calculated (Willame et al).

Several cases of facial paralysis including Bell's palsy have been reported following influenza vaccination. In a retrospective cohort study, excess risks among people vaccinated with Pandemrix compared with unvaccinated people were of low magnitude for Bell's palsy (hazard ratio 1.25; 95% confidence interval 1.06 to 1.48) and paraesthesia (HR 1.11; 95% CI 1.00 to 1.23) after adjustment for age, sex, socioeconomic status, and healthcare utilization (Bardage et al). Last year, Kamath et al found in the VAERS database an increased reporting rate of facial paralysis following influenza vaccination as compared with other vaccines (ROR 2.30; 95% CI 1.93-2.75). However, due to the inherent limitations of the VAERS database analysis, this disproportionality measures only indicate the presence of a signal (Kamath et al).

On the other hand, recent surveillance studies have not shown an increased risk. During the 2013-14 and 2014-2015 influenza seasons, Vaccine Safety Datalink found no increased risk after vaccination with inactivated influenza vaccines for 6 outcomes in populations that included adults (acute disseminated encephalomyelitis [ADEM], anaphylaxis, Bell's palsy, GBS, encephalitis, and transverse myelitis) (Li et al). In a cohort study included 6 Vaccine Safety Datalink sites, no increased rate of adverse events including Bell's Palsy was found following PCV13 administered in elderly compared with PPSV23 whereas PPSV23 has a well-established safety profile (Tseng et al). Furthermore, in a self-controlled case series analysis in the UK, no evidence for an increased incidence of Bell's palsy was found following seasonal influenza vaccination overall, nor for monovalent pandemic influenza vaccine in 2009 (Wijnans et al).

In the mRNA COVID-19 vaccine clinical trials, some cases of Bell's palsy were reported. However, the Food and Drug Administration (FDA) does not consider these to be above the rate expected in the general population. They have not concluded these cases were caused by vaccination. Therefore, according to the CDC, persons who have previously had Bell's Palsy may receive an mRNA COVID-19 vaccine (<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/underlying-conditions.html>).

In children, no association is found between immunization and Bell's palsy (Rowhani-Rahbar et al).

In conclusion, some studies suggest a (weak) association between influenza vaccination and the occurrence of Bell's palsy, while other studies did not find an association. For mRNA COVID-19 vaccines, post-authorization safety surveillance will be important to monitor a possible association.

## References

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