

COVID-19

CONSOLIDATED REGIONAL AND GLOBAL INFORMATION ON ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) AGAINST COVID-19 AND OTHER UPDATES

Forty-third report

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Consolidated reports of adverse events reported in the Region of the Americas in 2021 and 2022, by country

The following table is a compilation of the number and rate of reports of adverse events following immunization (AEFI), by country and year reported to VigiBase, for COVID-19 vaccines used in the general population in the Region in 2021 and 2022.

Year	2021					2022				
Country	Total doses	*N total	**Rate total	*N serious	**Rate serious	Total doses	*N total	**Rate total	*N serious	**Rate serious
Argentina	76 524 614	363	0.5	54	0.1	35 630 826	689	1.9	133	0.4
Barbados	298 361	553	185.3	71	23.8	82 652	57	69.0	15	18.1
Bolivia (Plur. State of)	9 949 740	577	5.8	5	0.1	5 675 203	27	0.5	2	0.0
Brazil	320 000 000	22 484	7.0	9780	3.1	177 693 134	7264	4.1	4419	2.5
Chile	44 166 888	0	-	0	-	19 576 173	16 743	85.5	872	4.5
Colombia	64 449 062	16 338	25.4	782	1.2	25 524 954	678	2.7	314	1.2
Costa Rica	7 756 348	8500	109.6	109	1.4	4 910 376	3 664	74.6	142	2.9
Ecuador	27 501 719	3417	12.4	121	0.4	11 818 861	396	3.4	35	0.3
El Salvador	9 531 117	4080	42.8	30	0.3	1 848 484	3230	174.7	48	2.6
Honduras	9 589 064	283	3.0	11	0.1	7 199 761	133	1.8	14	0.2
Jamaica	1 208 785	570	47.2	91	7.5	297 897	399	133.9	121	40.6
Mexico	148 562 902	11 762	7.9	1013	0.7	73 663 391	3758	5.1	645	0.9
Panama	6 245 648	865	13.8	81	1.3	2 451 263	89	3.6	7	0.3
Paraguay	6 833 614	2335	34.2	335	4.9	2 672 098	22	0.8	12	0.4
Peru	50 325 715	18 691	37.1	169	0.3	36 022 375	37 703	104.7	463	1.3
United States	501 207 401	975 211	194.6	162 821	32.5	153 004 279	553 836	362.0	123 168	80.5
Uruguay	6 963 555	1584	22.7	77	1.1	1 798 216	305	17.0	39	2.2
Regional total	1 370 608 874	1 067 613	77.9	175 550	12.8	593 090 382	628 993	106.1	130 449	22.0

*N= number of reports

**Rate per 100 000 doses administered

Source: Doses obtained from the Vaccination in the Americas dashboard, available from: https://ais.paho.org/imm/IM_DosisAdmin-Vacunacion.asp. Accessed 18 June 2022; Number of reports: VigiBase data, accessed 15 May 2023.

Clarification: Doses for 2021 are from epidemiological week 4 to epidemiological week 52, while doses for 2022 are from epidemiological week 1 to epidemiological week 52.

Safety of COVID-19 vaccines during pregnancy: A systematic review and meta-analysis

On 7 June a study was published to evaluate the safety of COVID-19 vaccines during pregnancy. For this purpose, a systematic review and meta-analysis were conducted. In addition to looking at human studies, animal research was included to supplement the available evidence. Extensive searches of literature databases, COVID-19 vaccine websites, and references to other systematic reviews and studies were also carried out.

From the 8837 records collected, 71 studies involving a total of 17 719 495 pregnant people and 389 pregnant animals were selected. The majority of the studies (94%) were conducted in high-income countries, and consisted of cohort studies (51%).

Nine specific studies on COVID-19 vaccines, with a total participation of 309 164 pregnant people, were identified. These studies focused on the use of mRNA-platform vaccines. Of the nine studies, three involved only the BNT162b2 vaccine; 3 other studies combined the BNT162b2 vaccine with the mRNA-1273 vaccine; one study included the BNT162b2 vaccine along with the mRNA-1273 and Ad26.COV2.S vaccines; another study combined the BNT162b2 vaccine with the mRNA-1273 and ChAdOx1 vaccines; and one study analyzed only the ChAdOx1 vaccine.

The following outcomes were analyzed: miscarriage, stillbirth, fetal growth retardation, gestational diabetes, hypertensive disorders, small for gestational age, preterm birth, maternal death, any congenital malformation, neonatal death, postpartum hemorrhage, suspected chorioamnionitis, prenatal bleeding, neonatal infections, newborn respiratory distress syndrome, injection site reactions, fever, headache, gastrointestinal disturbances, myalgia, fatigue, vomiting, nausea, chills, and joint pain.

Meta-analysis of these studies, adjusted for possible confounders, showed no association between vaccination during pregnancy and adverse events, regardless of vaccination or trimester of vaccination.

Reported adverse outcome rates and reactogenicity of COVID-19 vaccines did not exceed expected baseline rates.

The only exception found was an increase in postpartum hemorrhage after COVID-19 vaccination (10.40%, 95% CI, 6.49–15.10%), based on data from two studies. However, the comparison with unexposed pregnant women, data available in one study, showed no statistically significant

differences (adjusted OR 1.09, 95% CI, 0.56–2.12). Animal studies showed results consistent with the findings in pregnant people.

The study's authors conclude that, in this study, no significant concerns were found regarding the safety of COVID-19 vaccines administered during pregnancy.

Source: Ciapponi A, et al. Safety of COVID-19 vaccines during pregnancy: A systematic review and meta-analysis. *Vaccine*. 2023 Jun 7;41(25):3688–3700. doi: 10.1016/j.vaccine.2021.03.038. Epub 2023 Mar 27. PMID: 37012114; PMCID: PMC10040368.

Medical outcomes of children with neurodevelopmental disorders after SARS-CoV-2 vaccination: A six-month follow-up study

An observational, longitudinal case-control study was published on 29 May comparing adverse outcomes after SARS-CoV-2 vaccination in children younger than age 12 with neurodevelopmental disorders (NDDs), such as attention-deficit/hyperactivity disorder (ADHD), autism spectrum disorder (ASD), communication disorders, intellectual disability, and tic disorders, compared with healthy children serving as a control group. The study was conducted in the outpatient department of Child and Adolescent Psychiatry at Chang Gung Memorial Hospital in Kaohsiung, Taiwan.

A total of 1335 children who were recruited for the study received the COVID-19 vaccine (762 children with NDDs and 573 healthy children). All participants were followed for 180 days, and outcome events were defined as outpatient-department visits (OVs) or visits to emergency departments (ERs) during follow-up.

Multivariate Cox proportional hazards regression models were used to identify potential differences in outcomes between the propensity-score-matched NDDs group (n = 311) and the control group (n = 311), and to explore factors associated with outcomes among all children with NDDs (n = 762).

Compared with the control group, children with NDDs were found to be more likely to make subsequent visits to ERs and urgent care (UC) centers, as well as visits to pediatric neurology centers after receiving the first dose of the vaccine. However, the study found that only a small proportion of children needed to go to an ER or UC center due to vaccination-related adverse effects.

Within the group of children with NDDs, those with communication disorders showed a higher likelihood of making visits to an ER or UC center. In addition, visits to pediatric neurology centers were seen to be associated with communication disorders, intellectual disability, and the use of medications such as methylphenidate and aripiprazole. No association was found between either ADHD or ASD and adverse outcomes after SARS-CoV-2 vaccination.

The authors conclude that, based on the findings of this study, no specific diagnosis of neurodevelopmental disorders or the use of medications increased the risk of adverse effects of SARS-CoV-2 vaccination in the study population.

Source: Wang, J., Tsai, S., Chou, J., Li, J., Lee, Y., Chen, C., & Lin, C. (2023). Medical outcomes of children with neurodevelopmental disorders after SARS-CoV-2 vaccination: A six-month follow-up study. *Vaccine*, 41(29), 4267–4273.

<https://doi.org/10.1016/j.vaccine.2023.05.067>.

Risk of new retinal vascular occlusion after mRNA COVID-19 vaccination within aggregated electronic health record data

This retrospective, population-based cohort study, published on 13 April, was designed to investigate the frequency of retinal vascular occlusion (RVO) after vaccination with mRNA COVID-19 vaccine, compared with influenza vaccines and acellular triple bacterial (DTaP) vaccine.

The TriNetX Analytics platform was used; this is a global network of healthcare organizations that collects anonymized electronic health record data from more than 103 million patients in 77 healthcare organizations in nine countries, including 54 healthcare organizations in the United States. Data were compiled and analyzed on 20 October 2022. A search was conducted for vaccination data and recorded cases of new RVO diagnoses that occurred within 21 days after vaccination.

Propensity score matching based on demographic characteristics (age, sex, race, and ethnicity) and comorbidities (diabetes, hypertension, and hyperlipidemia) was performed to assess relative risks (RR).

The results showed that of the 3 108 829 people who received the mRNA COVID-19 vaccine, 104 people (0.003%, 95% CI, 0.003%-0.004%) were diagnosed with RVO within 21 days after

vaccination. After matching for propensity scores, no significant difference was found in the relative risk of developing RVO after the first dose of COVID-19 vaccine compared with influenza vaccine (RR, 0.74, 95% CI, 0.54–1.01) or DTaP vaccine (RR, 0.78, 95% CI, 0.44–1.38). However, this risk was higher compared with the second dose of COVID-19 vaccine (RR, 2.25, 95% CI, 1.33–3.81). The authors suggest that the increased risk of RVO after the first dose may be explained by a possible immune response that increases the likelihood of triggering a hyperviscosity state related to the pathophysiology of RVO. However, they also suggest that this finding could be attributable to a reluctance to receive the second dose, due to symptoms experienced after the first dose, uncontrolled differences in patient populations, or variations in vaccination event recording practices.

It was noted that the number of patients registered on the platform who received a second dose of the mRNA COVID-19 vaccine was less than half the number of those who received a first dose (1 108 006 versus 3 108 829).

According to the authors, this study suggests that diagnosed cases of RVO after mRNA COVID-19 vaccination occur very infrequently, at rates similar to those seen with two widely used vaccines, the influenza vaccine and the DTaP vaccine. There was no evidence to suggest a possible association between mRNA COVID-19 vaccination and the diagnosis of RVO.

Source: Ian Dorney et al. Risk of New Retinal Vascular Occlusion After mRNA COVID-19 Vaccination Within Aggregated Electronic Health Record Data. JAMA Ophthalmol. 2023;141(5):441–447. doi:10.1001/jamaophthalmol.2023.0610.

Association of SARS-CoV-2 Vaccination or Infection with Bell Palsy. A Systematic Review and Meta-analysis.

This systematic review and meta-analysis, published on 27 April, compared the incidence of Bell's palsy (BP) of people who received the SARS-CoV-2 vaccine with those who were not vaccinated or received a placebo.

A systematic search of MEDLINE, Web of Science, Scopus, Cochrane Library, and Google Scholar, from December 2019 to 15 August 2022, was conducted. Included were articles reporting the incidence of BP with SARS-CoV-2 vaccination. The study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guideline and used random-effects and fixed-effects models, applying the Mantel-Haenszel method. The quality of the studies was assessed using the Newcastle-Ottawa Scale.

The results of interest compared the incidence of BP among (1) SARS-CoV-2-vaccinated individuals; (2) unvaccinated individuals; (3) different types of SARS-CoV-2 vaccines; and (4) SARS-CoV-2-infected individuals versus SARS-CoV-2-vaccinated individuals.

Fifty studies were included, of which 17 were used in quantitative synthesis. Results showed that in the grouping of four randomized phase 3 clinical trials, there was a significant increase in BP in those vaccinated against SARS-CoV-2 compared to the placebo (unvaccinated) group (77 525 vaccine recipients vs. 66 682 placebo recipients; odds ratio, 3.00; 95% CI, 1.10-8.18); $I^2 = 0\%$). However, no significant increase in BP was found after administration of mRNA SARS-CoV-2 vaccine in eight pooled observational studies (13 518 026 doses vs. 13 510 701 unvaccinated; OR, 0.70; 95% CI, 0.42-1.16); $I^2 = 94\%$). No significant differences in BP were found between recipients of the first dose of Pfizer-BioNTech vaccine and recipients of the first dose of the Oxford-AstraZeneca vaccine (OR, 0.97; 95% CI, 0.82-1.15; $I^2 = 0\%$). Bell's palsy was significantly more common after SARS-CoV-2 infection ($n = 2\,822\,072$) than after SARS-CoV-2 vaccination ($n = 37\,912\,410$) (RR, 3.23; 95% CI, 1.57-6.62); $I^2 = 95\%$).

According to the authors, this systematic review and meta-analysis suggests a higher incidence of BP among groups vaccinated against SARS-CoV-2 compared with unvaccinated groups. No significant differences in BP were found between those vaccinated with the Pfizer-BioNTech vaccine and those vaccinated with the Oxford-AstraZeneca vaccine. SARS-CoV-2 infection would appear to pose a significantly higher risk of BP than SARS-CoV-2 vaccination. Source: Ali Rafati et al. Association of SARS-CoV-2 Vaccination or Infection with Bell Palsy. A systematic and meta-analysis. *Otolaryngol Head Neck Surg.* 2023;149(6):493–504. doi:10.1001/jamaoto.2023.0160.

Statement by the European Medicines Agency (EMA) and the European Center for Disease Prevention and Control (ECDC) on updating COVID-19 vaccines

On 6 June, the EMA and ECDC issued a statement with updates on COVID-19 vaccines, to address new variants of the SARS-CoV-2 virus. Selected highlights are described below.

- Currently licensed vaccines continue to be effective in preventing hospitalization, severe illness, and death from COVID-19. However, protection against the virus decreases over time as new variants of SARS-CoV-2 emerge.
- According to the conclusions of the meeting between international regulators and WHO, held at the end of May, the EMA's Emergency Working Group recommends updating COVID-19 vaccines, taking account of XBB strains, a subvariant family of Omicron, which have become dominant in Europe and other parts of the world.
- The EMA and ECDC consider monovalent vaccines, targeting a single strain such as XBB.1.5, to be a reasonable option in providing protection against emerging and currently dominant strains.
- Manufacturers should adapt to the simplified immunization schedule, in accordance with national recommendations:
 - For individuals older than age 5, when vaccination is recommended, a single dose of the newly updated vaccine is indicated.
 - For children under age 5, with no history of vaccination or previous SARS-CoV-2 infection, a primary series consisting of two or three doses is indicated, depending on the newly updated vaccine to be administered.
 - People with weakened immune systems may need additional doses.
 - For re-vaccination, a minimum interval of four months between doses may be considered. Available evidence has shown a high level of protection against severe disease for at least four months after vaccination.
- The ECDC and EMA advise that future vaccination campaigns, ahead of the next cold season, should prioritize people at higher risk of developing severe disease: people age 60 and above; people with weakened immune systems and underlying conditions, regardless of age; and people who are pregnant. Vaccination of health care workers should also be considered.

Additional information available from: <https://www.ema.europa.eu/en/news/ema-ecdc-statement-updating-covid-19-vaccines-target-new-sars-cov-2-virus-variants>.

Recommendations from the U.S. Food and Drug Administration (FDA) Advisory Committee on Vaccines and Related Biological Products (VRBPAC) for updating COVID-19 Vaccines

On 15 June, the FDA published VRBPAC recommendations for updating COVID-19 vaccines, to be used in the United States beginning in fall 2023.

The Advisory Committee is considering: manufacturing lead times; available data on the circulation of SARS-CoV-2 virus variants; vaccine effectiveness in relation to new circulating variants; animal immunogenicity data for new vaccine candidates; preliminary human immunogenicity data for a candidate vaccine based on the XBB.1.5 strain, recommended for the 2023-2024 formulation of COVID-19 vaccines; and the development of monovalent vaccines based on the XBB lineage of the Omicron variant, preferably the XBB.1.5 strain.

Based on this recommendation, the FDA has advised manufacturers to update their COVID-19 vaccines by developing a monovalent formulation using the XBB 1.5 strain.

Additional information available from: <https://www.fda.gov/vaccines-blood-biologics/updated-covid-19-vaccines-use-united-states-beginning-fall-2023>.

EMA modifies the marketing authorization for the Comirnaty COVID-19 vaccine

On 22 June, the EMA announced that, in accordance with the report of the Committee for Medicinal Products for Human Use (CHMP), it was changing marketing authorization for the BioNTech Manufacturing GmbH Comirnaty Original/Omicron BA.4-5 vaccine. The authorized changes consist of extending the existing indication to include use as follows:

- **Comirnaty Original/Omicron BA.4–5 (5/5 micrograms/dose)**
 - People age 12 and older who have not previously received at least a primary vaccination course against COVID-19.

This vaccine had been indicated for people age 12 and older who had previously received at least a primary vaccination course against COVID-19.

- **Comirnaty Original/Omicron BA.4–5 (5/5 micrograms/dose)**

- Children ages 5 to 11 who have not previously received at least a primary vaccination course against COVID-19.

This vaccine had been indicated in children age 5 to 11 who had previously received at least a primary vaccination course against COVID-19.

- **Comirnaty Original/Omicron BA.4–5 (1.5/1.5 micrograms/dose)**

- Infants and children age 6 months to 4 years.

Additional information available from:

<https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty>

Brazil's National Health Surveillance Agency (ANVISA) authorizes registration of the (Original/Omicron) bivalent COVID-19 Spikevax vaccine

On 26 June, ANVISA announced that it was authorizing the registration of Moderna's (Original/Omicron) bivalent COVID-19 vaccine. It is the first definitive registration granted to a bivalent COVID-19 vaccine in Brazil.

Bivalent Spikevax vaccine (Original/Omicron) is approved as a booster dose in people 6 years and older.

ANVISA indicated that, in the application for registration, the manufacturer submitted complete data from non-clinical, clinical, and production studies, demonstrating the quality, safety, and efficacy of the bivalent Spikevax vaccine (Original/Omicron) compared with the monovalent Spikevax (Original) vaccine.

Additional information available from: <https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2023/anvisa-aprova-registro-de-vacina-bivalente-contra-covid-19>.

International Coalition of Medicines Regulatory Authorities (ICMRA) confirms safety of COVID-19 vaccines

On 5 July, the EMA reported that it was endorsing the joint ICMRA statement related to the safety of COVID-19 vaccines. This statement highlights the devastating impact of false and misleading information about the safety of COVID-19 vaccines on public health, and encourages people to obtain information from trusted sources, such as health professionals, scientific sources, and medicines regulators.

Evidence from more than 13 billion doses of COVID-19 vaccines administered worldwide demonstrates that these vaccines, intended to protect people from severe COVID-19 disease, have a very good safety profile in all age groups, including children, people with underlying medical conditions, immunocompromised individuals, patients, and pregnant people.

The statement also highlights that vaccines reduce the impact of long COVID, according to several studies with real-world data, and that there is no safety signal to suggest that this condition is a possible side effect of COVID-19 vaccination.

Additional information available from: <https://www.ema.europa.eu/en/news/global-regulators-confirm-good-safety-profile-covid-19-vaccines>.

Chile's Institute of Public Health (ISP) coordinates an active pharmacovigilance project for COVID-19 vaccines

On 12 July, the ISP announced that it will conduct "Sentinel surveillance of predefined adverse events of special interest after immunization with COVID-19 vaccines", an active pharmacovigilance project in sentinel hospitals in the metropolitan region. The purpose of the project is to provide robust evidence regarding possible events related to the safety of COVID-19 vaccines, helping generate evidence that will better characterize its safety profile, debunk unfounded rumors, and contribute to confidence in vaccination. The project has support from the United States Centers for Disease Control and Prevention (CDC); it is the first of its kind in Latin America, and is currently being replicated in other countries such as Uganda, Ethiopia, and Malawi.

Additional information available from: <https://www.ispch.gob.cl/noticia/isp-coordina-proyecto-de-farmacovigilancia-activa-en-vacunas-covid-19/>.

Interim recommendations from the WHO Strategic Advisory Group of Experts on Immunization (SAGE) for the use of mRNA COVID-19 vaccines

On 19 July, WHO's SAGE published interim recommendations for the use of mRNA COVID-19 vaccines. This document is a compilation of interim recommendations published by SAGE for the Comirnaty vaccine manufactured by Pfizer and BioNTech, and for the Spikevax vaccine manufactured by Moderna. The target populations for booster doses, indicated in these recommendations, are derived from the WHO roadmap for prioritizing the use of COVID-19 vaccines, updated by SAGE in March 2023 (1).

These interim recommendations for the use of COVID-19 mRNA vaccines will include other vaccines from the same platform, if licensed.

Additional information available from:

<https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-mRNA-2023.1>.

(1) <https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccines-SAGE-Roadmap>

There are no clarifications/conclusions to report at this time.

Addition of the SKYCovione™ COVID-19 vaccine to the WHO Emergency Use Listing

On 16 June, WHO added SKYCovione™, a COVID-19 vaccine licensed to SK Bioscience Co., Ltd, of the Republic of Korea, to the Emergency Use Listing (EUL). The responsible NRA is the Ministry of Food and Drug Safety of the Republic of Korea. The characteristics of the vaccine are summarized below.

COVID-19 vaccine (EUL)	Platform	Pharmaceutical form	Presentation	Adjuvant	Indication	Half-life
SKYCovione™	Protein subunit (recombinant)	suspension for intramuscular injection	vial of 10 doses (5 mL) (0.5 mL/dose)	AS03	people 18 to 65 years old	12 months stored at 2°C to 8°C (36°F to 46°F)

Additional information available from: <https://extranet.who.int/pqweb/vaccines/skycovione>.

EMA publishes Report: How EU ensured safety of medicines during COVID-19

On 22 June, the EMA published a report on actions taken in the EU to ensure the safety of medicines during the COVID-19 pandemic. The following is a summary of aspects related to COVID-19 vaccines.

- Preparations began with the design of a comprehensive safety monitoring plan in November 2020, before any COVID-19 vaccines were authorized.
- During 2021 and 2022, almost one billion doses of vaccines were administered in the EU, and the system for collecting and analyzing information on suspected side effects, EudraVigilance, received close to two million safety reports from individual cases.
- Adverse events of special interest associated with COVID-19 vaccines, following their authorization, were monitored in near real-time.
- Holders of COVID-19 vaccine authorizations were asked to submit monthly safety reports for at least six months after authorization. In total, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) evaluated 56 safety reports up to December 2022.
- Studies detailing real-world evidence (RWE) complemented intensified monitoring activities, helping to better characterize important safety issues, while gathering more information about the impact of the vaccines and treatments on specific populations (e.g., pregnant people).
- Collaboration and information sharing with other international regulators increased significantly during the pandemic. The confidentiality agreements allowed the EMA to receive and share safety information in real time, and there was unprecedented collaboration with regulators around the world.

Additional information available from: <https://www.ema.europa.eu/en/news/report-how-eu-ensured-safety-medicines-during-covid-19>.

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