COVID-19

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

Thirty-ninth Report

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OPS Organización Panamericana de la Salud
Organización Mundial de la Salud
OFICINA REGIONAL PARA LAS Américas
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Number and reporting rate of adverse events following immunization (AEFI), by country, for all COVID-19 vaccines administered to the general population

Data drawn from public reports available as of 19 December 2022. The dates on which the bulletins were analyzed vary according to the country; all dates are given in the sources.

Country	Doses administered	Non-serious		Serious	
		N*	Rate**	N*	Rate**
Argentina[1]	109 916 975	60 084	54.7	3006	2.7
Barbados[2]	380 962	520	136.5	86	22.6
Canada[3]	93 171 073	41 842	44.9	10 361	11.1
Colombia[4]	89 120 782	55 697	62.5	1590	1.8
Haiti[2]	510 611	1	0.2	0	0.0
Jamaica[2]	1 503 943	744	49.5	208	13.8
Paraguay[5]	9 449 337	2282	24.1	467	4.9
Peru[6]	84 468 527	52 435	62.1	246	0.3
Mexico[7]	133 972 266	37 600	28.1	1157	0.9
Saint Vincent and the Grenadines[2]	72 979	17	23.3	6	8.2
Total	**522 567 455**	**251 222**	**48.1**	**17 127**	**3.3**

* N = number of reports

** Rate per 100 000 doses administered

Source:

1. Ministry of Health of Argentina. 19th Vaccine safety surveillance report. National COVID-19 Vaccination Campaign. November 2022 (reporting period from 29/12/2022 to 21/10/2022)
2. The Caribbean Public Health Agency (CARPHA). Caribbean Regulatory System. VigiCarib News. 15 December 2022. Additional information available from: https://carpha.org/What-We-Do/CRS/VigiCarib.
3. Public Health Agency of Canada. Canadian COVID-19 vaccine safety report. Ottawa: Public Health Agency of Canada; 25 November 2022, with data up to and including 11 November 2022. https://health-infobase.canada.ca/covid-19/vaccine-safety/.
4. Ministry of Health of Colombia, National Institute of Health. Bulletin #18: October 2022. Surveillance of Adverse Events Following Immunization (AEFI) with COVID-19 vaccines in Colombia. Reporting period: 17 February 2021 to 11 October 2022. Available from: https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/ED/PSP/boletin12-farmacovigilancia-vacunas-abr2022.pdf.
5. Paraguayan Ministry of Public Health and Social Welfare. 88th Information Bulletin on Surveillance of AEFI related to COVID-19 Vaccination. National Program on Immunopreventable Diseases and Expanded Program on Immunizations, 11 November 2022 (reporting period from 22/02/2021 to 11/11/2022). https://pai.mspbs.gov.py/wp-content/uploads/2022/11/88-Boletin-Epidemiologico-ESAVI.pdf.
6. Ministry of Health. General Directorate of Medicines, Supplies, and Drugs. Pharmacovigilance report. Reported adverse events following immunization (AEFI) attributed to vaccination with COVID-19 vaccines. Reporting period: 9 February 2021 to 30 September 2022. Available from: https://repositorio.digemid.minsa.gob.pe/handle/DIGEMID/307.
7. Undersecretariat of Prevention and Health Promotion, General Directorate of Epidemiology. Directorate of Epidemiological Surveillance of Communicable Diseases. Report on COVID-19 AEFI, September 2022. Published on 7 October 2022 (reporting period from 24/12/2020 to 01/10/2022). Available from: https://www.gob.mx/cms/uploads/attachment/file/725076/REPORTE_ESAVI_04_2022.pdf.

Consolidated information on AEFI and serious AEFI following administration of COVID-19 vaccines in the Region of the Americas (cumulative data as of 15 August 2022)

Vaccine	Doses administered	AEFI		Serious AEFI	
		N*	Rate**	N*	Rate**
AstraZeneca	266 926 177	146 263	54.8	9024	3.4
CanSino	17 324 561	2014	11.6	99	0.6
Bharat	195 652	157	80.2	114	58.3
Gamaleya	45 912 988	45 523	99.2	897	2.0
Janssen	56 482 357	108 154	191.5	17 339	30.7
Moderna	291 425 347	519 018	178.1	69 643	23.9
Pfizer	795 614 041	1 025 994	129.0	192 564	24.2
Sinovac	180 008 355	69 506	38.6	5774	3.2
Sinopharm	55 899 326	21 986	39.3	679	1.2
Totals	**1 709 788 804**	**1 938 615**	**113.4**	**296 133**	**17.3**

* N= number of reports

** Rate per 100 000 doses administered

- A total of 1 709 788 804 doses of vaccine were administered in the following 21 countries: Argentina, Barbados, Brazil, Bolivia (Plurinational State of), Canada, Chile, Colombia, Costa Rica, Ecuador, El Salvador, United States, Guatemala, Honduras, Jamaica, Mexico, Panama, Paraguay, Peru, Saint Vincent and the Grenadines, Uruguay, and Venezuela (Bolivarian State of) (excluding countries that have not reported adverse events or have not disaggregated doses administered, by vaccine). The number of administered doses indicated in the table corresponds to those for which information was provided on the vaccine administered, along with any reports of adverse events.
- The data source for administered doses is the Dashboard on COVID-19 vaccination in the Americas, containing cumulative data as of 17 August 2022.
- The data sources for reported events are: (1) public reports available as of 15 August 2022; and (2) VigiBase (Unduplicated version of VigiBase). Reports of individual cases reported between 14 November 1967 and 15 August 2022; 3) Regional vaccination system (cumulative data as of 15 August 2022).
- Reported rates are based on no more than one week between an administered dose and a reported events.

Assessing case fatality in cases of thrombosis with thrombocytopenia following COVID-19 vaccination with AstraZeneca (Vaxzevria) in the United Kingdom: a review of spontaneously reported data

The journal Drug Safety published a descriptive study whose objective was to analyze the clinical and demographic information on thrombosis with concurrent thrombocytopenia syndrome (TTS), detailing the case fatality of reported cases of TTS by age and sex. Data used for the analysis were from the UK Yellow Card spontaneous reporting system for suspected adverse reactions to medicines and vaccines. Reports of TTS events were drawn from weekly data between 12 May 2021 and 25 May 2022. Cumulative numbers of TTS cases and deaths were recorded as totals for each weekly interval, and were stratified by age, sex, and vaccine dose.

The results of the analysis yielded a total of 443 reported cases of TTS events (81 deaths, 18.28%). Events occurred most frequently after the first dose of vaccine, with a rate of 15.74 reported cases per million first doses, and 2.12 reported TTS cases per million second doses. To date, no cases have been reported after a third dose, though Vaxzevria was not recommended for a third dose of COVID-19 vaccine in the UK.

Reports by sex were: 221 events among women and 217 among men, through 25 May 2022. As of that date, the reported case fatality rate was 20.36% (n = 45 fatal cases [95% CI, 15.26–26.28%]) for women and 16.13% (n = 35 fatal cases [95% CI, 11.45–21.71%]) for men. This suggests that there is no statistical difference in reports of TTS mortality by sex.

The authors conclude that, given the widespread use of Vaxzevria worldwide, it is important to report findings from the UK, where a large proportion of the population was exposed. Case fatality has remained stable since May 2021, when measures to minimize risk were implemented to prevent TTS in younger vaccine recipients. TTS is a very rare event following vaccination, and the benefits of immunization with Vaxzevria, as with other COVID-19 vaccines used in the UK, continue to outweigh the risks.

Source: Lane et al. Assessing Case Fatality on Cases of Thrombosis with Concurrent Thrombocytopenia Following COVID-19 Vaccine AstraZeneca (Vaxzevria) in the United Kingdom: A Review of Spontaneously Reported Data. Drug Saf. 2022; 45(9): 1003–1008.

BNT162b2 mRNA Vaccination Against COVID-19 is Associated with Decreased Likelihood of Multisystem Inflammatory Syndrome in U.S. Children Ages 5-18 Years

Multisystem inflammatory syndrome in children (MIS-C), linked to a history of SARS-CoV-2 infection, is associated with considerable morbidity. Preventing SARS-CoV-2 (COVID-19 infection) through vaccination could also decrease the likelihood of MIS-C.

A multicenter case-control study of children and adolescents between the ages of 5 and 18 hospitalized from 1 July 2021 to 7 April 2022 in different healthcare centers in the United States was published.

The objective was to compare the likelihood of being fully vaccinated (two doses of BNT162b2 vaccine ≥28 days before hospital admission) in patients with MIS-C (positive by RT-PCR, antibody, or antigen test, for current or recent SARS-CoV-2 infection) versus hospitalized patients (hospital-based controls who tested negative for SARS-CoV-2).

These associations were examined by age group, timing of vaccination, and periods of Delta and Omicron variant predominance, using multivariable logistic regression.

The study compared 304 MIS-C cases (280 [92%] unvaccinated) with 502 controls (346 [69%] unvaccinated).

MIS-C was associated with decreased likelihood of vaccination (aOR, 0.16 [95% CI, 0.10–0.26]), including among children ages 5 to 11 years (aOR: 0.22 [95% CI, 0.10–0.52]), ages 12 to 18 years (aOR: 0.10 [95% CI, 0.05–0.19]), and during the Delta (aOR: 0.06 [95% CI, 0.02–0.15]) and Omicron (aOR: 0.22 [95% CI, 0.11–0.42]) variant-dominant periods. This association persisted beyond 120 days after the second dose (aOR: 0.08 [95% CI, 0.03–0.22]) in 12-18-year-olds. Among all MIS-C patients, 187 (62%) required admission to an intensive care unit, and 280 (92%) were unvaccinated.

The authors conclude that vaccination with two doses of BNT162b2 is associated with reduced likelihood of MIS-C in children and adolescents between 5 and 18 years of age.

Source: Zambrano et al. BNT162b2 mRNA Vaccination Against COVID-19 is Associated with Decreased Likelihood of Multisystem Inflammatory Syndrome in U.S. Children Ages 5–18 Years. Clin Infect Dis. 2022 Aug 4; ciac637.

Guillain-Barré syndrome after COVID-19 vaccination in adults: A U.S. vaccine adverse event reporting system study.

This observational study investigating the association between Guillain-Barré syndrome (GBS) and COVID-19 vaccination was published on 22 September. The study used data from the U.S. Vaccine Adverse Event Reporting System (VAERS) to investigate whether there is sufficient evidence to determine an association between COVID-19 vaccines and GBS.

The analysis compared the GBS reporting rate in adults after COVID-19 vaccination (determined using the Brighton criteria) with the GBS reporting rate after influenza vaccination, and with the GBS reporting rate after vaccination with all other vaccines.

A machine learning model was used to identify factors associated with a worse outcome, defined as emergency room or doctor visits, hospitalizations, and deaths.

Results showed that the GBS reporting rate after COVID-19 vaccination was 4.97/1 million, significantly higher than after influenza vaccination, with a value of 0.02/1 million, and 0.02/1 million for other vaccines ($p<0.0001$). However, the reporting rate was within the historical range of GBS incidence in the general population.

In self-controlled, case-centered analyses, there was a significant difference in the reporting rate of GBS after COVID-19 vaccination between the risk period and control period ($p < 0.0001$). There was an estimated 0.7–1.7 per million excess reports of GBS within 6 weeks of COVID-19 vaccination.

Female gender and age between 18 and 44 are associated with worse outcomes. No association was found between the onset interval of GBS and its prognosis.

The authors conclude that although the reporting rate of GBS after COVID-19 vaccination was not statistically different from that of the general population, the increased reporting of GBS within the first 6 weeks after COVID-19 vaccination, more so than with other vaccinations, suggests that some cases of GBS are temporally associated with COVID-19 vaccination. However, there is a reduction in the reporting rate of GBS after other vaccines, compared to reporting rates pre-COVID-19, highlighting limitations inherent in any passive surveillance system.

These findings warrant continuous analysis of GBS after COVID-19 vaccination. Further improvement of the machine learning model is needed for clinical use.

Source: Jaffry M, Mostafa F, Mandava K, Rosario S, Jagarlamudi Y, Jaffry K, Kornitzer J, Jedidi K, Khan H, Souayah N. No significant increase in Guillain-Barré syndrome after COVID-19 vaccination in adults: A vaccine adverse event reporting system study. Vaccine. 2022 Sep 22; 40(40):5791–5797. doi: 10.1016/j.vaccine.2022.08.038. Epub 2022 Aug 22. PMID: 36055875; PMCID: PMC 9393 181.

Peripartum outcomes associated with COVID-19 vaccination during pregnancy. A systematic review and meta-analysis.

A systematic review with meta-analysis was published on 3 October to evaluate the association between COVID-19 vaccination during pregnancy and peripartum outcomes.

Study selection included retrospective trials and observational studies comparing individuals who received at least one COVID-19 vaccination during pregnancy with those who did not, and reporting the neonatal outcomes. Two independent investigators extracted relevant data from each study. Odds ratios (ORs) were calculated using a random-effects model. This study followed the Preferred Reporting Items for Systematic Reviews and Meta-analysis guidelines.

The primary outcomes were the neonatal outcomes, including preterm birth, small for gestational age, low Apgar score, NICU admission, and IFD. The secondary outcomes were maternal outcomes, including maternal SARS-CoV-2 infection, cesarean delivery, postpartum hemorrhage, and chorioamnionitis.

Nine observational studies involving 81 349 vaccinated (mean age, 32-35 years) and 255 346 unvaccinated individuals during pregnancy (mean age, 29.5-33 years) were included. COVID-19 vaccination during pregnancy was associated with lower risk of NICU admission (OR: 0.88; 95% CI, 0.80-0.97) and IFD (OR: 0.73; 95% CI, 0.57-0.94), whereas there was no statistically significant association with preterm birth (OR: 0.89; 95% CI, 0.76-1.04), small for gestational age (OR: 0.99; 95% CI, 0.94-1.04), and low Apgar score (OR: 0.94; 95% CI, 0.87-1.02).

COVID-19 vaccination during pregnancy was associated with a lower risk of maternal SARS-CoV-2 infection (OR: 0.46; 95% CI, 0.22-0.93), whereas it was not associated with increased risk of cesarean delivery (OR: 1.05; 95% CI, 0.93-1.20), or postpartum hemorrhage (OR: 0.95; 95% CI, 0.83-1.07).

The authors conclude that COVID-19 vaccination during pregnancy was not associated with an increase in the risk of peripartum outcomes, and was associated with a decreased risk of NICU admission, IFD,

and maternal SARS-CoV-2 infection. Thus, COVID-19 vaccination should be encouraged for pregnant individuals.

Source: Watanabe A, Yasuhara J, Iwagami M, et al. Peripartum Outcomes Associated With COVID-19 Vaccination During Pregnancy: A Systematic Review and Meta-analysis. JAMA Pediatr. Published Online 3 October 2022. doi:10.1001/jamapediatrics.2022.3456.

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Chile's Institute of Public Health (ISP) approves bivalent vaccines from Pfizer and Moderna laboratories for emergency use

On 29 September, the ISP authorized emergency use of bivalent COVID-19 vaccines from Pfizer and Moderna, based on the original (Wuhan) strain of COVID-19 and the Omicron BA.1 variant.

These bivalent COVID-19 vaccines were licensed for use starting at age 12 for the Pfizer vaccine and age 18 for the Moderna vaccine.

Additional information available from: https://www.ispch.gob.cl/noticia/isp-aprueba-uso-de-emergencia-de-vacunas-bivalentes-de-laboratorios-pfizer-y-moderna/.

The European Medicines Agency (EMA) recommends approval of Comirnaty and Spikevax COVID-19 vaccines for children from 6 months of age

On 19 October, the EMA's Committee for Medicinal Products for Human Use recommended extending the use of Pfizer-BioNTech's Comirnaty and Moderna's Spikevax vaccines based on the original strain of SARS-CoV-2, to include children 6 months to 4 years of age for Comirnaty, and children 6 months to 5 years of age for Spikevax.

Comirnaty and Spikevax are already licensed for use in people aged from 5 and 6 years, respectively.

Additional information available from: https://www.ema.europa.eu/en/news/ema-recommends-approval-comirnaty-spikevax-covid-19-vaccines-children-6-months-age.

EMA recommends approval of second adapted Spikevax vaccine

On 19 October, the EMA's Human Medicines Committee recommended authorizing the bivalent COVID-19 vaccine, based on the original SARS-CoV-2 strain and Omicron BA.4/BA.5, for use in individuals age 12 years and older who have already received a primary vaccination course against COVID-19.

This is the second adapted Spikevax vaccine that the EMA has recommended for approval. An adapted Spikevax vaccine targeting Omicron BA.1 and the original SARS-CoV-2 strain was authorized in September 2022.

Additional information available from: https://www.ema.europa.eu/en/news/ema-recommends-approval-second-adapted-spikevax-vaccine.

EMA recommends approval of VidPrevtyn Beta as a COVID 19 booster vaccine in adults

On 10 November 2022, the EMA's Committee for Medicinal Products for Human Use concluded that sufficiently robust data on the quality, safety, and immunogenicity of the VidPrevtyn Beta COVID-19 vaccine are now available to recommend its authorization as a booster in adults previously vaccinated with an mRNA or adenoviral vector COVID-19 vaccine.

VidPrevtyn Beta, developed by Sanofi Pasteur, contains a version of the spike protein found on the surface of the Beta variant of the SARS-CoV-2 virus, obtained through recombinant DNA technology, with the adjuvant AsO3.

Additional information available from: https://www.ema.europa.eu/en/news/ema-recommends-approval-vidprevtyn-beta-covid-19-booster-vaccine.

EMA's Emergency Task Force concludes that adapted mRNA bivalent vaccines against SARS-CoV-2 may be used for primary vaccination

On 6 December, the EMA reported that the emergency task force reviewed laboratory (non-clinical) studies and data on the immune response following natural infection with Omicron BA.4-5 in unvaccinated people who had not been previously infected with SARS-CoV-2. The data suggest that primary vaccination with these adapted bivalent vaccines should give rise to a broad immune response in people who have not yet been exposed to, or vaccinated against, SARS-CoV-2.

The ETF further noted that the safety profile of the adapted vaccines when used as boosters is comparable to that of the original mRNA vaccines, for which the safety profile is well established.

The ETF therefore considered that the bivalent original/Omicron BA.4-5 vaccines may be used in previously unvaccinated children and adults.

Additional information available from: https://www.ema.europa.eu/en/news/etf-concludes-bivalent-original-omicron-ba4-5-mrna-vaccines-may-be-used-primary-vaccination.

U.S. Food and Drug Administration (FDA) gives updated emergency use authorizations for Moderna and Pfizer-BioNTech bivalent vaccines to extend indicated age range

On 8 December 2022, the FDA updated authorizations of the Moderna and Pfizer-BioNTech bivalent vaccines to include children 6 months of age and older for both vaccines. On 12 October, the FDA extended the authorized age range of bivalent COVID-19 vaccines (original strain/Omicron BA.4 and BA.5) for administration at least two months after completion of primary or booster vaccination, starting at 6 years of age for Moderna's bivalent vaccine and 5 years of age for Pfizer-BioNTech's bivalent vaccine.

Additional information available from: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-bivalent-covid-19-vaccines.

Health Canada authorizes Pfizer-BioNTech Comirnaty Omicron BA.4/BA.5 bivalent booster vaccine for children 5 to 11 years of age

On 9 December 2022, Health Canada reported that it had authorized the first bivalent COVID-19 booster for children ages 5 to 11. Health Canada previously authorized Pfizer-BioNTech's bivalent (Original strain/Omicron BA.4 and BA.5) Comirnaty vaccine for use in individuals 12 years of age and older in October 2022.

Additional information available from: https://www.canada.ca/en/health-canada/news/2022/12/health-canada-authorizes-the-pfizer-biontech-omicron-ba4ba5-bivalent-adapted-covid-19-booster-for-children-5-to-11-years-of-age.html.

Highlights from the 3–6 October SAGE meeting on COVID-19 vaccines:

- Achieving high and equitable rates of primary series vaccination with ancestral strain vaccines remain the highest public health priority.
- Four variant-containing bivalent mRNA vaccines, which include either BA.1 or BA. 4-5 in combination with the ancestral virus have been authorized for use as booster doses.
- Booster vaccination 4-6 months after the last dose provides improved protection against currently circulating SARS-CoV-2, using either the monovalent ancestral virus vaccines or bivalent variant-containing vaccines.

Additional information available from: https://cdn.who.int/media/docs/default-source/immunization/sage/2022/october/highlights_sage_oct_2022.pdf?sfvrsn=69f947c4_5c2bd9f68 1.

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WHO/SAGE good practice statement on the use of variant-containing COVID-19 vaccines

The SAGE/WHO statement, published on 17 October, contains the following recommendations:

- Until supporting evidence or regulatory approval becomes available, variant-containing vaccines should not be used as the primary series.
- Currently available data are insufficient to support a recommendation for preferring variant-containing vaccines as boosters over boosters with ancestral virus-based vaccines.
- WHO recommends that any COVID-19 vaccine included in the WHO Emergency Use Listing (EUL) or authorized bivalent variant-containing mRNA vaccine be used as booster vaccinations.
- Evidence suggests that boosters using a COVID-19 vaccine platform different from that used for the primary series (heterologous booster) provide superior immunogenicity compared to homologous boosters.

For heterologous boosters, countries may consider the following recommendations:

  - **Inactivated WHO/EUL vaccines for initial doses:** Use viral vector or WHO/EUL mRNA vaccines.
  - **WHO EUL viral vector vaccines as initial doses**: WHO EUL mRNA vaccines.
  - **WHO EUL mRNA vaccines for initial doses:** WHO EUL viral vector vaccines.

Additional information available from: https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccines-SAGE-Variants-2022.1.

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommends adding heavy menstrual bleeding to the Comirnaty and Spikevax vaccine product information

At its meeting on 24-27 October, the PRAC finalized its assessment of this safety signal after reviewing the available data, including cases reported during clinical trials, cases spontaneously reported in Eudravigilance, and findings from the medical literature. The Committee concluded that there is at least a reasonable possibility that the occurrence of heavy menstrual bleeding is causally associated with COVID-19 mRNA vaccines, and therefore recommended updating the product information to include this as a side effect of unknown frequency.

It was noted that the reviewed data involved mostly cases that appeared to be non-serious and temporary in nature, and that there is no evidence to suggest that the menstrual disorders experienced by some people have any impact on reproduction and fertility.

Additional information available from: https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-24-27-october-2022.

Inclusion of vaccines in the WHO Emergency Use Listing (EUL)

In October and November 2022, WHO added Pfizer-BioNTech's adapted COVID-19 vaccines to the EUL. Key characteristics of these vaccines are summarized below:

COVID-19 vaccine (EUL)	International non-proprietary name	EUL holder	EUL authorization date	Responsible NRA*	Indication	Pharmaceutical form
COMIRNATY Original/Omicron BA.1	tozinameran riltozinameran	BioNTech Manufacturing GmbH	19 October 2022	European Medicines Agency (EMA)	Booster in people aged 12 years and older	Sterile dispersion for injection (ready to use)
COMIRNATY Original/Omicron BA.4-5	tozinameran famtozinameran	BioNTech Manufacturing GmbH	11 November 2022	European Medicines Agency (EMA)	Booster in people aged 12 years and older	Sterile dispersion for injection (ready to use)

*The NRA that first authorized the vaccine and that is responsible for supervision of the vaccine.

Additional information available from: https://extranet.who.int/pqweb/vaccines/comirnaty-originalomicron-ba1 and https://extranet.who.int/pqweb/vaccines/comirnaty-originalomicron-ba4-5.

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