COVID-19

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

Thirty-eighth report

WASHINGTON, DC

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In partnership with Canada

CONTENTS

Following is a description of serious events of special interest detailed in the AEFI bulletins of the Region that have been published to date.

BRAZIL

As of 18 June 2022, except for the state of São Paulo, 363,960 events temporally related to COVID-19 vaccines administered in Brazil had been reported; of these, 19,684 (5.4%) were serious adverse events (SAEs). Reported SAEs temporally related to the Sinovac/Butantan and AstraZeneca/Fiocruz vaccines consisted mostly of respiratory, thoracic, and mediastinal disorders, with 2.77 events/100,000 doses administered for the Sinovac/Butantan vaccine and 1.61 events/100,000 doses administered for the AstraZeneca/Fiocruz vaccine. For the Pfizer/Wyeth and Janssen vaccines, most reported events consisted of nervous system disorders, with 0.54 events/100,000 doses administered for the Pfizer/Wyeth vaccine and 0.93 events/100,000 doses administered for the Janssen vaccine.

An analysis of adverse events following immunization (AEFI) potentially related to Guillain-Barré syndrome (GBS) was performed. Included in this analysis were reports made between 18 January 2021 and 28 May 2022, during which time 185,929 reports of AEFI related to COVID-19 vaccines were received, out of 328,791,453 total doses of COVID-19 vaccines administered. The search for cases identified 395 events potentially related to GBS, of which 244 cases (61.7%) occurred after administration of the AstraZeneca/Fiocruz vaccine. Events occurred more frequently after administration of the first dose (D1), with a rate of 0.21 events/100,000 doses administered. The following table details the number of events and rate of GBS-related reports per vaccine.

Vaccine	***Type of dose***							
	Number of GBS-related events				***Rate****			
	D1	***D2***	***REF***	***Total***	***D1***	***D2***	***REF***	***Total***
Sinovac/Butantan	26	23	-	49	0.06	0.07	-	**0.07**
AstraZeneca/Fiocruz	206	34	4	244	0.43	0.07	0.03	**0.23**
Janssen	16	-	1	17	0.40	-	1.68	**0.11**
Pfizer/Wyeth	51	15	19	85	0.10	0.03	0.04	**0.06**
Total	**299**	**72**	**24**	**395**	**0.21**	**0.06**	**0.03**	**0.12**

* Rate per 100,000 doses administered.

References: D1: Dose 1; D2: Dose 2; REF: Booster dose.

Data source: CGPNI/DEITD/SVS/MS.

Source: Brazil Ministry of Health, Secretariat of Health Surveillance. Special Epidemiological Bulletin No. 122. Doença pelo Novo Coronavírus – COVID-19. Available at: https://www.gov.br/saude/pt-br/centrais-de-conteudo/publicacoes/boletins/epidemiologicos/covid-19/2022/boletim-epidemiologico-no-122-boletim-coe-coronavirus/view.

CANADA

As of 19 August 2022, a total of 50,545 individual case reports had been received, of which 10,149 were considered serious. The following table details the number and rate of adverse events of special interest (AESI) reported, by vaccine.

Number of reports and reporting rate (per 100,000 doses administered) of main adverse events of special interest (AESI), by vaccine, in the general population, as of 19 August 2022

AESI	***Vaccine***					
	Pfizer-BioNTech		***Moderna***		***AstraZeneca/Covishield***	
	N*	***Rate***	***N****	***Rate***	***N****	***Rate***
Guillain-Barré syndrome	8	0.01	6	0.02	8	0.28
Thrombocytopenia	100	0.17	33	0.13	51	1.81
Myocarditis/pericarditis	668	1.12	422	1.70	15	0.53
Thrombosis with thrombocytopenia syndrome (TTS)	29	0.05	12	0.05	64	2.27
Bell's palsy/facial paralysis	120	0.20	37	0.15	13	0.46
Anaphylaxis	641	1.08	193	0.78	28	1.00

* N: number of reports.

Rate: per 100,000 doses administered.

Note: Information on the Janssen and Novavax vaccines was not included, due to the small number of reported cases.

Source: Public Health Agency of Canada. Canadian COVID-19 vaccine safety report. Ottawa: Public Health Agency of Canada. 2 September 2022. https://health-infobase.canada.ca/covid-19/vaccine-safety/. Data reproduced by PAHO/WHO.

UNITED STATES

Following is updated information from the U.S. Centers for Disease Control and Prevention (CDC) regarding cases of myocarditis and pericarditis following COVID-19 vaccination:

As of 8 September, 1,022 preliminary reports in VAERS of people under 18 years of age were being reviewed for possible cases of myocarditis and pericarditis. Of these, 260 cases are still under review. Of the preliminary reports, 672 cases met the CDC case definition for myocarditis and are detailed below, by age group:

- ages 5 to 11: 22 reports out of 21,196,313 doses administered*
- ages 12 to 15: 348 reports out of 24,377,482 doses administered*
- ages 16 to 17: 302 reports out of 13,362,076 doses administered*

*Doses administered with unspecified COVID-19 vaccines.

Centers for Disease Control and Prevention (CDC). Selected Adverse Events Reported after COVID-19 Vaccination. Updated 12 September 2022. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.

Note: The website is periodically updated, thus the data may differ at the time this bulletin is published.

LATEST AEFI BULLETINS PUBLISHED IN THE REGION

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2 PUBLICATIONS ON POTENTIAL SAFETY SIGNALS IDENTIFIED WITH THE USE OF COVID-19 VACCINES

Evaluation of acute adverse events after COVID-19 vaccination during pregnancy

On 14 July 2022, a retrospective observational matched-cohort study was published, which aimed to evaluate acute adverse events after COVID-19 vaccination during pregnancy. The study involved pregnant women between the ages of 16 and 49and analyzed health data from electronic records at eight U.S. Vaccine Safety Datalink sites.

The study period ran from 15 December 2020 to 1 July 2021. The authors evaluated the incidences of 25 medically attended acute adverse events (known reactogenic adverse events and clinically serious outcomes, such as cerebral venous sinus thrombosis, encephalitis, or myelitis, Guillain-Barré syndrome, myocarditis or pericarditis, or pulmonary embolism), among vaccinated women compared with the unvaccinated matched controls. For the primary analyses, events that occurred within 21 days after vaccination with any COVID-19 vaccine were analyzed. In secondary analyses, events that occurred within 42 days after the second dose of an mRNA vaccine (Pfizer-BioNTech BNT162b2 or Moderna mRNA-1273) were included. The authors identified 45,232 pregnant women who had received one or two doses of a COVID-19 vaccine immediately preceding or during pregnancy (78,026 vaccine doses): 32,794 (72.5%) had received two doses of mRNA vaccine, 5,652 (12.5%) had received only the first dose of mRNA vaccine, 4,912 (10.9%) had received only the second dose of an mRNA vaccine, and 1,874 (4.1%) had received a single dose of the Ad26.COV2 (Johnson & Johnson-Janssen) vaccine. The women who received only a second dose of vaccine had received the first dose >28 day before becoming pregnant.

The results showed that the frequencies of all medically attended acute adverse events were less than one percent. Among those vaccinated, the most common events were fever, with an adjusted rate ratio as compared with unvaccinated controls of 2.85 (95% CI, 1.76 to 4.61), malaise or fatigue 2.24 (95% CI, 1.71 to 2.93), local reactions 1.89 (95% CI, 1.33 to 2.68), and lymphadenopathy or lymphadenitis 2.16 (95% CI, 1.42 to 3.28). No serious acute adverse events that were evaluated occurred more frequently in vaccinated women after each dose than among unvaccinated controls.

The authors concluded that acute adverse events following COVID-19 vaccination during pregnancy were uncommon, and these vaccines were not associated with an increased risk of the clinically serious adverse events that were evaluated. The present data add to the growing literature supporting the safety of COVID-19 vaccination during pregnancy.

Source: Malini DeSilva et al. N Engl J Med 2022; 387:187–189. DOI: 10.1056/NEJMoa2007764.

Safety of primary and heterologous booster schedules with ChAdOx1-S and BNT162b2 or mRNA-1273 vaccines: nationwide cohort study

A nationwide cohort study was published in Denmark on 13 July 2022. The aim of this study was to assess the risk of adverse events associated with heterologous primary vaccine schedules with the Oxford-AstraZeneca ChAdOx1-S vaccine followed by mRNA vaccines (Pfizer-BioNTech BNT162b2 or Moderna mRNA-1273) as compared with homologous mRNA vaccine schedules. The population studied consisted of adults aged 18 to 65 years with no history of previous infection. The study was conducted from 1 January 2021 to 26 March 2022.

Data were prospectively obtained at the individual level from different Danish national health registers, and cross-linked using the unique personal civil registration number, which is assigned to all citizens. Information on vaccines administered was collected from the Danish Vaccination register. Individuals who had received a heterologous primary vaccine (n=137,495) or a homologous scheme (n=2,688,142) were identified, as well as those who had received a heterologous booster (n=129,770) or a homologous booster (n=2,197,213).

The main outcome measures were the incidence of hospital contacts for cardiovascular and hemostatic adverse events within 28 days after the second or third vaccine dose, comparing heterologous versus homologous vaccine schedules.

The adjusted incidence rate ratios of adverse cardiovascular and hemostatic events within 28 days for the heterologous compared with the homologous vaccine schedules were as follows:

Adverse Events	**Adjusted incidence rate ratios Heterologous schedule**	**Adjusted incidence rate ratios Homologous schedule**
Ischemic cardiac events	1.22 (95% CI 0.79 to 1.91)	1.00 (0.58 to 1.72)
Cerebrovascular events	0.74 (0.40 to 1.34)	0.72 (0.37 to 1.42)
Arterial thromboembolisms	1.12 (0.13 to 9.58)	4.74 (0.94 to 24.01)
Venous thromboembolisms	0.79 (0.45 to 1.38)	1.09 (0.60 to 1.98)
Myocarditis/pericarditis	0.84 (0.18 to 3.96)	1.04 (0.60 to 4.55)
Thrombocytopenia and coagulative disorders	0.97 (0.45 to 2. 10)	0.89 (0.21 to 3.77)

Other bleeding events	1.39 (1.01 to 1.91)	1.02 (0.70 to 1.47)

The authors concluded that heterologous primary and booster COVID-19 vaccination schedules were not associated with increased risk of serious adverse events compared with homologous mRNA vaccine schedules. The authors state that these results are reassuring, but that, given the rarity of some of the adverse events, associations cannot be excluded.

Source: Andersson et al. Safety of heterologous primary and booster schedules with ChAdOx1-S and BNT162b2 or mRNA-1273 vaccines: nationwide cohort study. BMJ 2022;378:e070483.

Assessing case fatality on cases of thrombosis with concurrent thrombocytopenia following COVID-19 vaccine AstraZeneca (Vaxzevria) in the UK: a review of spontaneously reported data

On 4 August 2022, a study was published analyzing clinical and demographic information on thrombosis with thrombocytopenia syndrome (TTS) events, that included calculating the case fatality of reported cases of TTS by age and sex, using spontaneously reported data from the UK's Yellow Card spontaneous reporting system of suspected adverse drug reactions.

The reported TTS events were extracted between 12 May 2021 and 25 May 2022. Cumulative numbers of TTS cases and deaths were recorded for each weekly interval, overall and stratified by age, sex, and vaccine dose.

As of 25 May 2022, 443 cases (81 fatal, 18.28%) had been reported in the UK. Events more frequently occurred following the first vaccine dose. No trends were observed for case fatality overall, or by age or sex.

The authors concluded that the case fatality of TTS events reported to the Medicines and Health Products Regulatory Agency following administration of Vaxzevria has been approximately 17%–18% since May 2021. There were no statistical differences in fatality based on age or sex. Most reports were of the first vaccine dose; none have been reported following a third dose to date, although Vaxzevria was not recommended for a third dose of COVID-19 vaccine in the UK. TTS remains very rare, and the benefits of vaccination outweigh the risks.

Source: Lane S, Shakir S. 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 Sep;45(9):1003–1008. Doi: 10.1007/s40264–022-01217–9. Epub 2022 Aug 4. Erratum in: Drug Saf. 2022 Sep 3; PMID: 35927605; PMCID: PMC 9362462.

Effectiveness of BNT162b2 vaccine against Omicron in children 5 to 11 years of age

A nationwide cohort study was published in Singapore on 11 August 2022. The study's objective was to evaluate the incidences of SARS-CoV-2 infection and hospitalization among children aged 5 to 11 years, according to vaccination status, and to estimate the effectiveness of partial (≥1 day after the first dose of vaccine and up to 6 days after the second dose) and full (≥7 days after the second dose) vaccination with the BNT162b2 vaccine against the Omicron variant. This study was conducted from 21 January 2022 to 8 April 2022, when the Omicron variant was spreading rapidly in the country.

The information analyzed was based on official data of 255,936 children aged 5 to 11 years, reported to and maintained by the Ministry of Health of Singapore. The authors assessed the incidences of all reported SARS-CoV-2 infections (positive on PCR, rapid antigen testing, or both), PCR-confirmed SARS-CoV-2 infections, and COVID-19-related hospitalizations among unvaccinated, partially vaccinated, and fully vaccinated children. Poisson regression was used to estimate vaccine effectiveness from the incidence rate ratio of outcomes.

Among unvaccinated children, the crude incidence rates of all reported SARS-CoV-2 infections, PCR-confirmed SARS-CoV-2 infections, and COVID-19-related hospitalizations were 3,303.5, 473.8, and 30.0 per million person-days, respectively.

Among partially vaccinated children, vaccine effectiveness was 13.6% (95% CI, 11.7 to 15.5) against all SARS-CoV-2 infections, 24.3% (95% CI, 19.5 to 28.9) against PCR-confirmed SARS-CoV-2 infection, and 42.3% (95% CI, 24.9 to 55.7) against COVID-19-related hospitalization.

In fully vaccinated children, vaccine effectiveness was 36.8% (95% CI, 35.3 to 38.2) against all COVID-19 infections, 65.3% (95% CI, 62.0 to 68.3) against PCR-confirmed SARS-CoV-2 infection, and 82.7% (95% CI, 74.8 to 88.2), against COVID-19-related hospitalization.

The authors concluded that during a period in which the Omicron variant was predominant, vaccination with BNT162b2 reduced the risks of SARS-CoV-2 infection and COVID-19-related hospitalization among children aged 5 to 11 years.

Source: Sharon H.X. Tan et al. Effectiveness of BNT162b2 Vaccine against Omicron in Children 5 to 11 Years of Age. N Engl J Med 2022; 387:525–532 DOI:10.1056/NEJMoa2203209.

DECISIONS OF REGIONAL AND INTERNATIONAL REGULATORY AUTHORITIES

The International Coalition of Medicines Regulatory Authorities (ICMRA) and the WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) agree on key principles for adapting vaccines to SARS-COV-2 variants.

Among the agreements of the meeting, held on 1 July, is the suggestion that bivalent mRNA vaccines incorporating a variant strain of Omicron could be initially recommended for use as boosters. Adapted vaccines that include other variants, for example the Beta variant, could be considered as boosters, if data from clinical trials demonstrate an adequate level of neutralization against Omicron and other variants of concern. Effectiveness studies with adapted vaccines should be planned to determine the level of protection conferred against infection, hospitalization, and death under real-life conditions.

Additional information available at: https://www.ema.europa.eu/en/news/global-regulators-agree-key-principles-adapting-vaccines-tackle-virus-variants.

The European Center for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) are recommending expanding the age group for second booster doses of COVID-19 mRNA vaccines.

On 11 July, the ECDC and EMA recommended expanding the age group for second booster doses of COVID-19 mRNA vaccines to include people between the ages of 60 and 79, and people at risk of developing severe disease. In April 2022, both agencies recommended that people over 80 years of age be considered for a second booster.

Additional information available at: https://www.ema.europa.eu/en/news/ecdc-ema-update-recommendations-additional-booster-doses-mrna-covid-19-vaccines.

The U.S. Food and Drug Administration (FDA) Authorizes Novavax COVID-19 Vaccine

On 13 July 2022, the FDA authorized emergency use of Novavax's COVID-19 vaccine in individuals 18 years and older. In the fact sheet for this vaccine, the FDA included a warning about the risk of myocarditis and pericarditis, due to cases reported in pivotal clinical trials for FDA clearance. These events were included in the surveillance plan during deployment of this vaccine in the United States.

On 12 September 2022, the FDA extended the authorized emergency use of Novavax's COVID-19 vaccine for individuals of 12 years and older.

Additional information available at: https://www.fda.gov/media/159897/download.

Health Canada Authorized Use of Moderna's Pediatric Spikevax Vaccine

On 14 July 2022, Health Canada authorized use of the Moderna Spikevax COVID-19 vaccine in children 6 months to 5 years of age, making it the first vaccine licensed in Canada for this age group. The immunization schedule in children in this age range is two doses of 25 micrograms each (pediatric formulation), with an interval of four weeks. This is half the dose authorized for children 6 to 11 years of age, and one quarter of the dose authorized for people 12 years of age and older.

https://www.canada.ca/en/health-canada/news/2022/07/health-canada-authorizes-use-of-moderna-covid-19-vaccine-in-children-6-months-to-5-years-of-age.html.

The EMA's Committee for Medicinal Products for Human Use (CHMP) recommends expanding the age group in which the Spikevax COVID-19 vaccine can be used as a booster, as well as extending the vaccine's shelf life.

On 22 July 2022, the CHMP recommended expanding the use of Moderna's Spikevax COVID-19 vaccine as a booster to include adolescents between the ages of 12 and 17. The committee also endorsed updating the product information to state that stability has been demonstrated for 12 months when Spikevax is stored at -20°C ± 5°C.

Additional information available at: https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-18-21-july-2022.

Chile's Institute of Public Health (ISP) authorizes age range extension starting from 6 months for Pfizer, Sinovac, and Moderna COVID-19 vaccines.

On 23 August 2022, the ISP approved extending the age to 6 months for the Pfizer, Sinovac, and Moderna COVID-19 vaccines. These vaccines had been previously authorized for emergency use beginning at 2 years of age in the case of Moderna, 3 years for Sinovac, and 5 for Pfizer.

Additional information available at: https://www.ispch.gob.cl/noticia/isp-amplia-rango-etario-desde-los-seis-meses-de-edad-para-vacunas-contra-covid-19/.

COVID-19 vaccines Safety Update from the EMA's Pharmacovigilance Risk Assessment Committee (PRAC)

Following is a summary of the safety updates of 3 August and 8 September 2022 issued by the EMA's PRAC for the following vaccines:

Vaccine	Adverse event	Description
Comirnaty	• **Myocarditis/pericarditis**	The risk appears to be similar after the second and third doses of Comirnaty.
	• **Corneal graft rejection**	The available evidence does not support a causal association with administration of Comirnaty.
Nuvaxovid	• **Myocarditis/pericarditis**	After assessing the cases reported in Australia and the five cases reported as of 31 May 2022, with approximately 200,000 doses administered in the European Union, the agencies concluded that cases of myocarditis and pericarditis can occur following administration of this vaccine.
	• **Anaphylaxis** (frequency unknown)	A number of reported cases of anaphylaxis.
	• Paresthesia and hypoesthesia (frequency unknown)	189 cases of paresthesia and 67 cases of hypoesthesia worldwide, with more than 1.5 million doses distributed as of 31 May 2022.
Spikevax	• **Extensive inflammation of the vaccinated limb** (frequency unknown)	More than 3,200 cases in the European Union as of 2 May 2022. In general, it requires no treatment, and resolves after a few days.
	• **Myocarditis/pericarditis**	The risk appears to be similar after the second and third doses of Spikevax.
	• **Corneal graft rejection**	The available evidence does not support a causal association with administration of Spikevax.
Vaxzevria	• **Tinnitus** (persistent ringing in the ears) (frequency uncommon)	Less than one case per 100 people vaccinated.
	• Paresthesia and hypoesthesia (frequency unknown)	An estimated one case per approximately 100 people vaccinated.
	• **Corneal graft rejection**	The available evidence does not support a causal association with administration of Vaxzevria.

For the other vaccines authorized in the European Union (Valneva and Jcovden, previously the Janssen vaccine), PRAC did not issue updated recommendations. Additional information available at: https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccines-safety-update-14-july-2022_en.pdf.
https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccines-safety-update-8-september-2022_en.pdf .

SAGE/WHO updates interim statement on COVID-19 vaccination for children.

In the update published on 11 August 2022, SAGE/WHO highlighted the need for aligned and coordinated action to achieve the global COVID-19 vaccination targets. The decision to vaccinate children and adolescents must account for prioritization to fully protect the highest risk subgroups through primary vaccination series, and booster doses; this includes children with comorbidities and severe immunocompromising conditions.

Benefit-risk assessments clearly support the benefit of vaccinating all age groups, including children and adolescents, to reduce the number of infections, hospitalizations, deaths, and "long COVID-19"; but the direct benefit of vaccinating healthy children and adolescents is less pronounced, due to the lower incidence of severe COVID-19 and deaths in younger people. Vaccination may decrease the transmission of SARS-CoV-2 from children and adolescents to older adults; however, during the current Omicron dominant period, vaccine impact on transmission is only modest and short-lived.

Countries should consider the individual and population benefits of immunizing children and adolescents in their specific epidemiological and social contexts when developing their COVID-19 immunization policies and programs. In addition, it is of paramount importance that children continue to receive recommended pediatric vaccines against other infectious diseases.

Additional information available at: https://www.who.int/news/item/11-08-2022-interim-statement-on-covid-19-vaccination-for-children.

SAGE/WHO Good practice statement on the use of second booster doses for COVID 19 vaccines

In the statement released on 18 August 2022, SAGE/WHO recommended that countries consider implementing a second booster dose in the following population groups to reduce the risk of serious illness, death, and disruption to health services:

- Older persons (age-specific cut-off should be defined by countries based on local COVID-19 epidemiology);
- persons with moderately and severely immunocompromising conditions;
- adults with comorbidities that put them at higher risk of severe disease;
- pregnant women; and
- health workers.

A second booster dose should be offered 4 to 6 months after the first booster and should not be delayed in anticipation of future variant-containing COVID-19 vaccines.

Given the known risk of severe illness in older adults and other priority groups infected with influenza virus or SARS-CoV-2, WHO recommends that countries consider co-administration of COVID-19 vaccines and seasonal influenza vaccines, where feasible, depending on seasonality.

Additional information available at: http://apps.who.int/iris/bitstream/handle/10665/361714/WHO-2019-nCoV-Vaccines-SAGE-Boosters-2022.1-eng.pdf.

WHO SAGE updated recommendations for use of Moderna and Pfizer-BioNTech vaccines

Following is a summary of updates on recommended use published on 18 August 2022:

Moderna mRNA-1273 and Pfizer–BioNTech BNT162b2 vaccines	
Indication	This was expanded to include individuals starting at 6 months of age.
Interchangeability with other vaccines and platforms:	It is recommended that either homologous or heterologous immunization schedules be used.
Booster dose	A booster dose (third dose) is recommended 4 to 6 months after the second dose of the primary schedule.

	The second booster dose (fourth dose) is recommended for high-risk groups, to be given 4 to 6 months after the first booster.
Co-administration with other vaccines	This includes the recommendation on co-administration of these vaccines with any live or inactivated vaccines in adults and adolescents.

Additional information available at: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1.

https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-mRNA-1273-2021.3.

WHO SAGE issues interim recommendations for use of the Valneva VLA2001 against COVID-19

On 18 August 2022, WHO SAGE published interim recommendations for use of the Valneva VLA2001 COVID-19 vaccine, as summarized below.

Use recommendations	
Name	Valneva (VLA2001)
Platform	Whole-virion inactivated with adjuvant
Adjuvant	CpG 1018 in combination with aluminum hydroxide
Indication	Individuals age 18 to 50
Immunization schedule: **Primary series**	2 doses (0.5 mL/dose) with an interval of 28 days Immunocompromised individuals: one-third dose 1–3 months after the second dose
Booster	One dose of 0.5 mL 4–6 months after completing the primary series
Effectiveness	The immunogenicity of VLA2001 was assessed in a phase 1/2 trial involving participants aged 18–55 years, and a phase 3 COV-COMPARE trial with 2,975 participants The immunogenicity of VLA2001 was similar to that of AstraZeneca's ChAdOx1-S vaccine.
Safety	Reported side effects included injection-site tenderness (>60%) and pain (>40%), fatigue (>50%), headache (>30%), muscle pain (>30%), and nausea/vomiting (>10%) that resolve within two days of vaccination.
Interchangeability of vaccines	Valneva as a heterologous booster: Not recommended after the primary series of BNT162b2 vaccine (Pfizer BioNTech). Can be used after the primary series with the ChAdOx1-S vaccine; there are no data on its use after the primary series with inactivated vaccines, and it is not currently recommended.

Additional information available at: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Valneva-VLA2001.

The U.S. FDA and Europe's EMA authorize Moderna and Pfizer-BioNTech adapted COVID-19 vaccines

On 31 August and 12 September of this year, the FDA and EMA, respectively, authorized the bivalent COVID-19 vaccines from Moderna and Pfizer-BioNTech. Following is a summary of their characteristics.

Vaccine of	Moderna		Pfizer-BioNTech	
Name	Spikevax bivalent (original strain/Omicron BA.1)	Spikevax bivalent (original strain/Omicron BA.4/BA.5)	Comirnaty bivalent (original strain/Omicron BA.1)	Comirnaty bivalent (original strain/Omicron BA.4/BA.5)
Authorization	EMA	FDA	EMA	EMA and FDA
Indication	Booster doses for people ages 12 years and older	Booster doses for people ages 18 years and older	Booster doses for people ages 12 years and older	Booster doses for people ages 12 years and older
Dosage	One dose within 3 months of completing the primary series or the booster with a COVID-19 vaccine	One dose within 3 months of completing the primary series or the booster with a COVID-19 vaccine	One dose within 3 months of completing the primary series or the booster with a COVID-19 vaccine	One dose within 3 months of completing the primary series or the booster with a COVID-19 vaccine
Concentration	25 µg elasomeran (original strain) and 25 µg imelasomeran (Omicron BA.1) per dose (0.5 mL)	25 µg elasomeran (original strain) and 25 µg Omicron BA.4/BA.5 per dose (0.5 mL)	15 µg tozinameran (original strain) and 15 µg riltozinameran (Omicron BA.1) per dose (0.3 mL)	15 µg tozinameran (original strain) and 15 µg famtozinameran (Omicron BA.4/BA.5) per dose (0.3 mL)

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

https://www.ema.europa.eu/en/news/first-adapted-covid-19-booster-vaccines-recommended-approval-eu

https://www.ema.europa.eu/en/news/adapted-vaccine-targeting-ba4-ba5-omicron-variants-original-sars-cov-2-recommended-approval

China's National Medical Products Administration authorizes CanSino's inhaled COVID-19 vaccine

On 5 September 2022, China's National Medical Products Administration authorized the recombinant COVID-19 inhalable vaccine Convidecia Air™ for use as a booster dose.

This vaccine was developed using the same adenoviral vector technology platform as the intramuscular Ad5-nCoV Convidecia™ vaccine and is administered using a nebulizer for oral inhalation.

Additional information available at: http://english.nmpa.gov.cn

Invitation to a practical exercises in case series causality assessment course from the Uppsala Monitoring Center (UMC)

The instructor-led online course "Practical Exercises in Case Series Causality Assessment" from the Uppsala Monitoring Centre (UMC) will be held from 24 October to 11 November.

This free, 20-hour course (given in Spanish and English) is aimed for the staff of national and regional pharmacovigilance centers with access to a VigiLyze (VL) account who have previously completed the following eight online UMC courses:

1. PV management systems and terminologies (4 hours)
2. VigiLyze Introductory course (1.5 hours) - *available to VigiLyze users only*
3. Introduction to signal detection (30 minutes)
4. Causality assessment of single case safety reports (30 mins to 1 hour)
5. Practical exercises in individual case causality assessment (3 hours)
6. Causality assessment of case series (30 mins to 1 hour)
7. Signal assessment (30 mins)
8. Statistical reasoning and algorithms in pharmacovigilance (30 mins to 1 hour)

To participate in this course you must complete the online registration form before 10 October 2022. Maximum capacity is 20 people.

English version will take place from October 3 until October 21, 2022.

Additional information available at:

Spanish version: https://learning.who-umc.org/visitor_catalog_class/show/49455.

English version: https://learning.who-umc.org/visitor_catalog_class/show/37752?link_id=gpZ9FzJNkS

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