

COVID-19

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

Twenty-second report

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OPS



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CANADA

- As of 6 August 2021, 50,254,577 doses of COVID-19 vaccines (Pfizer-BioNTech, Moderna, AstraZeneca, and Covishield [AstraZeneca manufactured by the Serum Institute of India]) had been administered.
- There were a total of 12,023 individual reports of one or more adverse events (0.024% of doses administered). Of these, 3,078 were serious events (0.006% of doses administered).
- A breakdown of the reports is given below:

<i>Number and reporting rate (reports per 100,000 doses administered) of adverse event, by name of vaccine, as of 6 August 2021</i>						
<i>Vaccine</i>	<i>Number of reports of non-serious AEFI</i>		<i>Number of reports of serious AEFI</i>		<i>Total number of reports of AEFI</i>	
	<i>No.</i>	<i>Rate/100,000 doses administered</i>	<i>No.</i>	<i>Rate/100,000 doses administered</i>	<i>No.</i>	<i>Rate/100,000 doses administered</i>
Pfizer-BioNTech	4,683	13.58	2,005	5.81	6,688	19.39
Moderna	3,198	26.23	488	4.00	3,686	30.23
Covishield/AstraZeneca	1,037	37.40	455	16.41	1,492	53.81
Unknown	27	-	130	-	157	-
Total	8,945	17.80	3,078	6.12	12,023	23.92

- A total of 32,370 adverse events following immunization (AEFI) were reported, of which 12,023 were for one or more events. The most frequently reported non-serious adverse events were for injection-site reactions, paresthesia, headache, itching, difficulty breathing, fatigue, nausea, etc.

Number and reporting rate (reports per 100,000 doses administered) of adverse events, by name of vaccine, as of 6 August 2021

Vaccine	Pfizer-BioNTech	Moderna	Covishield/AstraZeneca
Anaphylaxis	126 (0.37/100,000)	29 (0.23/100,000)	-
Thrombosis with thrombocytopenia syndrome (TTS)	13 (0.04/100,000)	3 (0.02/100,000)	56 (2.02/100,000)
Guillain-Barré Syndrome (GBS)	22 (0.06/100,000)	9 (0.07/100,000)	27 (0.97/100,000)
Capillary leak syndrome	-	-	2 (0.07/100,000)
Myocarditis/pericarditis	223 (0.65/100,000)	184 (1.49/100,000)	14 (0.50/100,000)
Fatal events	169 post-vaccine deaths*		

*Following a medical review of the 169 deaths, it was determined that 69 were not linked to administration of the COVID-19 vaccine, while 33 are still being investigated; six deaths (cases of TTS) were deemed to be potentially attributable to vaccination, and in 61 cases the cause of death could not be determined due to insufficient information.

Analysis of the 421 cases of myocarditis/pericarditis is shown below:

Vaccine	Total number of cases (rate per 100,000 doses administered)	By sex/median age		Number of reports, by dose(s) administered		
		Number of women (median age)	Number of men (median age)	1st	2nd	Unknown
Pfizer-BioNTech*	223 (0.65)	88 (51 yrs)	132 (21 yrs)	122	75	26
Moderna**	184 (1.49)	45 (35 yrs)	135 (28 yrs)	44	124	16
Covishield/AstraZeneca	14 (0.50)	Not indicated	Not indicated	Not indicated	Not indicated	Not indicated

*In three cases the sex of the individual was not specified.

**In three cases the sex of the individual was not specified, and in one case, the sex was indicated as "other."

Source: Public Health Agency of Canada. Canadian COVID-19 vaccine safety report. Source: Public Health Agency of Canada. 13 August 2021. <https://health-infobase.canada.ca/covid-19/vaccine-safety/>. Data reproduced by PAHO/WHO.

UNITED STATES (data as of 11 August)

Following are data reported by the United States for selected events, as of 11 August:

Event	Vaccine	Doses administered	Cases/Incidence
Anaphylaxis	All vaccines	More than 357 million doses	Approx. 2 to 5 cases per million people vaccinated
Thrombosis with thrombocytopenia syndrome (TTS)	J&J/Janssen	More than 13 million	42 confirmed reports of people who received the vaccine and were later diagnosed with TTS
	Moderna	More than 339 million doses of mRNA vaccine	Two cases. mRNA vaccines do not pose any increased risk of TTS
Guillain-Barré Syndrome (GBS)	J&J/Janssen	More than 13 million doses	161 preliminary reports
Myocarditis/pericarditis	Moderna or Pfizer/BioNTech	328 million doses	1,306 reports, of which 762 have been confirmed
Deaths	All vaccines	More than 357 million doses of vaccines	VAERS registered 6,789 reports of deaths among people vaccinated (0.0019%)

Source: Centers for Disease Control and Prevention. COVID-19. A number of adverse reactions were reported after vaccination against COVID-19. Updated 17 August 2021. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>. Data reproduced by PAHO/WHO.

UNITED KINGDOM (data as of 11 August)

Following are data reported by the United Kingdom for selected events, as of 11 August:

	Vaccine		
	Pfizer-BioNTech	Moderna	AstraZeneca
Doses administered	36.5 million	2.0 million	48.6 million
Reports*	104,446	13,325	228,239
AEFI	293,779	41,274	813,622
Anaphylaxis	461 reports	30 reports	808 reports
Thrombosis with thrombocytopenia syndrome (TTS)	15 cases (6 women and 9 men)	2 cases (2 men)	412 reports (210 women and 200 men). Case-fatality rate of 18%.
Guillain-Barré Syndrome (GBS)	42	2	383
Capillary leak syndrome	-	-	11
Myocarditis/pericarditis	182/153	33/28	93/145
Bell's palsy	The number of reports is similar to the rate that would normally be expected in the general population		
Fatal events**	501	14	1,053

* There were 1,022 reported events for which the name of the vaccine was not specified.

** There were 28 reported cases of suspected AEFI in which the patient died shortly after vaccination, in which the name of the vaccine was not specified.

Source: Gov.UK. Medicines and Healthcare products Regulatory Agency. Research and analysis. Coronavirus vaccine – weekly summary of Yellow Card reporting. Updated 19 August 2021. Available at:

<https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting>. Data reproduced by PAHO/WHO.

Heterologous COVID-19 vaccination strategy

Regarding the use of heterologous vaccination regimens for COVID-19 vaccines, results of the heterologous ChAdOx1 nCoV-19 and mRNA1273 vaccination study, published 14 July 2021 in the New England Journal of Medicine, indicate that neutralizing antibody levels and T-cell-mediated immune response were higher when the first dose of a ChAdOx1-S-based [recombinant] vaccine was followed by a second dose of mRNA vaccine, such as Pfizer-BioNTech's BNT162b2 or Moderna's mRNA-1273, administered between 9 and 12 weeks later, compared with two doses of ChAdOx1-S [recombinant] vaccines. Moreover, the immune response proved to be similar to that obtained with two doses of mRNA vaccines, and superior to the response obtained from a first dose of mRNA vaccine followed by a dose of a ChAdOx1-S-based [recombinant] vaccine.

The study noted that, with administration of the ChAdOx1-S [recombinant] vaccine, followed by one dose of an mRNA vaccine, reactogenicity was higher but acceptable, compared to two doses of ChAdOx1-S [recombinant] vaccine, with more frequent reports of fever, headache, chills, and muscle aches.

Source: Heterologous ChAdOx1 nCoV-19 and mRNA-1273 Vaccination. The New England Journal of Medicine. Available at: <https://www.nejm.org/doi/full/10.1056/NEJMc2110716>.

Brazil's National Health Surveillance Agency issues alert on rare cases of post-vaccination Guillain-Barré Syndrome

On 28 July 2021, Brazil's National Health Surveillance Agency (ANVISA) indicated that it had received 34 reports of suspected cases of Guillain-Barré Syndrome (GBS) following vaccination, of which 27 were associated with the AstraZeneca vaccine, 3 with the Janssen vaccine, and 4 with the CoronaVac vaccine.

In view of these reports, ANVISA requested the inclusion of information on the possible risk of GBS in the product information for the AstraZeneca, Janssen, and CoronaVac vaccines. ANVISA also requested the addition of a warning that people vaccinated with one of these vaccines should seek immediate medical attention if they develop signs and symptoms related to GBS, such as double vision or difficulty moving the eyes, difficulty swallowing, speaking or chewing, coordination problems and unsteadiness, difficulty walking, a tingling sensation in hands and feet, weakness in the extremities, chest, or face, and problems with bladder control and/or bowel function. Healthcare professionals should be alert to the signs and symptoms of GBS, in order to ensure correct diagnosis, initiate care and appropriate supportive treatment, and to rule out other causes.

However, ANVISA continues to recommend the use of all Covid-19 vaccines authorized by the agency, in accordance with the indications described in the corresponding product information sheet, since, to date, the benefits of the vaccines outweigh the risks.

Source: <https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2021/alerta-sobre-casos-raros-de-sindrome-de-guillain-barre-pos-vacinacao>.

U.S. Food and Drug Administration Authorizes Extending the Shelf-life of Janssen's COVID-19 Vaccine

On 28 July 2021, the U.S. Food and Drug Administration (FDA) authorized extension of the shelf-life of Janssen's COVID-19 vaccine, from 4.5 months to 6 months, when stored between 2°C and 8°C. In addition, the FDA indicated that the extension is applicable to lots that may have expired before the issuance of the authorized extension, provided that they have been stored at temperatures of between 2°C and 8°C.

Source: <https://www.fda.gov/media/134922/download>.

Reports of menstrual disorders and unexpected vaginal bleeding following administration of COVID-19 vaccines of Pfizer-BioNTech, Moderna, and AstraZeneca

The United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) is reviewing reports of menstrual disorders and unexpected vaginal bleeding following administration of COVID-19 vaccines. As of 11 August 2021, 31,414 reactions related to a variety of menstrual disorders had been reported. These include reports of periods with increased bleeding, and delayed or unexpected vaginal bleeding following administration, in women, of 45.5 million doses of the Pfizer-BioNTech, Moderna, and AstraZeneca COVID-19 vaccines. In principle, the number of reports is considered low, given the number of women who have received vaccinations to date, and the common nature of menstrual disorders. The events reported are transient, and there is no evidence to suggest that COVID-19 vaccines can affect fertility.

Source: <https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting>.

U.S. Food and Drug Administration (FDA) authorizes export of batches of the active ingredient in AstraZeneca's COVID-19 vaccine

On 6 August 2021, the U.S. Food and Drug Administration (FDA) announced it had authorized the export of batches of the active ingredient in AstraZeneca's COVID-19 vaccine, manufactured at Emergent's facility in Baltimore, Maryland. The AstraZeneca vaccine is not authorized for use in the U.S., but the FDA, after conducting a thorough review of facility records and quality test results by the manufacturer, authorized its export, in light of the global public health emergency caused by COVID-19.

Source: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-august-6-2021>.

The FDA authorizes additional doses of the mRNA COVID-19 vaccine for some immunocompromised individuals

On 12 August 2021, the U.S. Food and Drug Administration (FDA) announced that it was amending the emergency use authorizations for both the Pfizer-BioNTech and Moderna COVID-19 vaccines to allow for the use of an additional

dose in certain immunocompromised individuals, specifically, organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. Available data indicate that this group requires additional protection against COVID-19, as they are at increased risk of contracting and developing severe SARS-CoV-2 disease.

In addition, the FDA reported that the Advisory Committee on Immunization Practices, of the Centers for Disease Control and Prevention (CDC), will meet soon to discuss additional clinical recommendations regarding immunocompromised individuals.

Source: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised>.

Updated recommendations by the WHO Strategic Advisory Group of Experts on the use of ChAdOx1-S-based (recombinant) COVID-19 vaccines

On 30 July 2021, the World Health Organization (WHO) released interim recommendations by the Strategic Advisory Group of Experts (SAGE) on the use of AstraZeneca's ChAdOx1-S (recombinant) vaccines (AZD1222, Vaxzevria,™ SII COVISHIELD). These vaccines are considered fully equivalent, even when produced at different manufacturing sites and assigned different product names; the recommendations therefore apply to all ChAdOx1-S-based (recombinant) vaccines. In summary, the updated findings were as follows:

- Second-dose considerations in supply-constrained settings: Countries that have not achieved high vaccination coverage rates in priority groups, and that have a high incidence of COVID-19 cases, along with vaccine supply limitations, may consider a period of up to 16 weeks before administration of a second dose.
- Boosters: There is currently no evidence to indicate the need for additional doses, once an individual has received two doses.
- Interchangeability with other COVID-19 vaccines: It is recommended that, for the two-dose vaccination schedule, the ChAdOx1-S [recombinant] COVID-19 vaccine should be used. In situations where supply is interrupted, a heterologous immunization schedule may be considered, using a ChAdOx1-S-based (recombinant) vaccine for the first dose, and an mRNA vaccine (BNT162b2 or mRNA-1273) for the second dose.
- Precautions and contraindications: Cases of a very rare blood clotting disorder combined with a low platelet count, known as thrombosis with thrombocytopenia syndrome (TTS), has been reported, occurring between three and 30 days after vaccination with the ChAdOx1-S (recombinant) vaccine. A causal relationship between the vaccine and TTS is considered plausible, although the biological mechanism of this syndrome is still being investigated.

A number of cases of Guillain-Barré syndrome (GBS) have been reported after administration of the ChAdOx1-S (recombinant) vaccine; however, a causal relationship with the vaccine has been not been confirmed, though it has not been ruled out, and further studies are needed to assess a possible association.

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

Preliminary recommendations of the WHO Strategic Advisory Group of Experts on heterologous immunization schemes, fractional doses, and booster doses of COVID-19 vaccines

On 10 August 2021, the World Health Organization published preliminary recommendations, issued by the Strategic Advisory Group of Experts on Immunization (SAGE), and the Working Group on COVID-19 Vaccines, regarding the use of heterologous vaccination schedules, fractional dosing, and booster doses. The following is a summary of the SAGE report.

Heterologous vaccination schedules, also known as mix-and-match schedules, consist of administering the second dose with a vaccine different from that used for the first dose, for which SAGE provides the following recommendations:

- For COVID-19 vaccines listed for emergency use by WHO with a 2-dose primary series schedule, WHO recommends that the same vaccine product be used for both doses.
- If different COVID-19 vaccine products are inadvertently administered in the two doses, no additional doses of either vaccine are recommended.
- At present, mix-and-match schedules constitute off-label use of the vaccines, and as such should only be used if the benefits outweigh the risks, such as in situations of interrupted vaccine supply.
- The first results on short-term vaccine effectiveness (VE) against infection following a heterologous schedule are now available from Denmark. They show an effectiveness of 88% (95% CI 83-92%) when combining the ChAdOx1-based vaccine with an mRNA vaccine, similar to the VE achieved using two doses of an mRNA vaccine. However, this study was performed when the Alpha variant was dominant.
- Currently, a large number of trials of various combinations and immunization schedules are being conducted, and these recommendations will be updated as data become available.

Dose fractionation: In the face of a limited global supply of COVID-19 vaccines, SAGE is reviewing available information related to dose fractionation from clinical trials conducted in the development of COVID-19 vaccines, and indicates the following:

- SAGE recommendations for COVID-19 vaccines on the WHO emergency use listing are based on evidence from phase 3 clinical trials, which used full doses. Additional trials would therefore be needed in order to make recommendations related to the use of different doses.
- There are some preliminary data for fractional doses derived from the phase 3 clinical trial of the ChAdOx-1 S (recombinant) vaccine, and from a phase 2 trial of the mRNA-1273 vaccine.

- There are no known studies using reduced doses for inactivated virus vaccines, such as Sinovac's CoronaVac, and the COVID-19 vaccine BIBP, nor for the BNT162b2 or Ad26.COV2.S vaccines.
- SAGE recognizes the potential public health benefits of dose fractionation strategies to increase vaccine supply and accelerate vaccination coverage, as well as to reduce reactogenicity. However, the group believes that there is currently insufficient evidence to recommend the use of fractional doses.

Booster doses of COVID-19 vaccines:

- The introduction of booster doses should be based on evidence showing that they are necessary. The duration of vaccine-induced protection depends on many variables, such as type of vaccine, primary vaccination schedule, age, underlying medical conditions of the individual, risk of exposure, and circulation of specific variants.
- The decision to recommend a booster dose should take into account national strategic and programmatic aspects, in addition to clinical and epidemiological data.
- In the context of current global vaccine supply constraints, the ongoing priority is to increase global vaccination coverage with the primary series of vaccinations (i.e., for current EUL vaccines, one or two doses).
- The introduction of booster doses should be based on firm evidence, and should be targeted to the population groups most in need.
- To date, the evidence remains limited and inconclusive regarding any widespread need for booster doses following a primary series of vaccinations.

Sources:

[https://www.who.int/news/item/10-08-2021-interim-statement-on-dose-sparing-strategies-for-covid-19-vaccines-\(fractionated-vaccine-doses\)](https://www.who.int/news/item/10-08-2021-interim-statement-on-dose-sparing-strategies-for-covid-19-vaccines-(fractionated-vaccine-doses)).

<https://www.who.int/news/item/10-08-2021-interim-statement-on-heterologous-priming-for-covid-19-vaccines>.

<https://www.who.int/news/item/10-08-2021-interim-statement-on-covid-19-vaccine-booster-doses>.

Allergic reactions after vaccination with COVID-19 vaccines

Cases of allergic reactions have been reported following administration of the various COVID-19 vaccines, ranging from mild skin reactions to anaphylaxis. The following table indicates the main ingredients present in the formulations, by type of vaccine, that could be related to allergic reactions. Additionally, it is important to consider that the impurities contained in the natural latex used in preparing the cap of the vaccine container or the prefilled syringe can cause reactions of hives and anaphylaxis. Therefore, the use of synthetic latex is recommended for development of the vaccine container's closure system.

Type of vaccine	Potentially allergenic ingredient	Function	Other products containing the ingredient	Type of allergic reaction
mRNA	Polyethylene glycol [PEG] Tromethamine* (trometamol or tris)	surfactant buffer	Over-the-counter medications (cough syrup, laxatives); prescription drugs, medical bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, solutions for the care of contact lenses, ultrasound gel. Contrast media, oral and parenteral medications.	Anaphylaxis
Viral vector	Polysorbate (80 or 20)	surfactant	Medications (vitamin oils, tablets, and anticancer agents), cosmetics	Non-immunological anaphylaxis, Delayed hypersensitivity (local reactions)
Subunits/inactivated	Aluminum (hydroxide or phosphate)	adjuvant	present in different adsorbed vaccines	Delayed hypersensitivity (local reactions)

*Present in Moderna's mRNA vaccine.

Sources:

<https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#t4>.

<https://www.vaccinesafety.edu/components-Allergens.htm>.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3890451/>

Vaccines and allergic reactions: The past, the current COVID-19 pandemic, and future perspectives. European Journal of Allergy and Clinical Immunology.

WHO alert on falsified Covishield COVID-19 vaccine

On 16 August 2021, the World Health Organization published alert No. 5/2021 on its website, related to the falsified COVID-19 Covishield vaccine, identified in Africa and Asia, between July and August 2021. The manufacturer of Covishield, the Serum Institute of India Pvt. Ltd., has confirmed that the lots listed below are falsified.

This alert states that samples of Covishield, Lot 4121Z040, of 10 doses (5 ml), with a falsified expiry date of 10.08.2021, were found in Uganda. In India, samples from an undeclared Covishield batch of 4 doses (2 ml) was found, a dosage not produced by the Serum Institute of India Pvt. Ltd. Below are images of these falsified vaccines.

Falsified COVISHIELD, Batch 4121Z040. Identified in UGANDA



Falsified COVISHIELD 2ml (4 doses). Identified in INDIA



Source: <https://www.who.int/news/item/16-08-2021-medical-product-alert-n-5-2021-falsified-covishield-vaccine>.

Adverse Events of Special Interest (AESI) and related risks: facial palsy/Bell's palsy/peripheral facial nerve palsy

Definition: Peripheral facial nerve palsy is the partial (paresis) or complete (paralysis) loss of function of some or all the structures innervated by the facial nerve (cranial nerve VII). It is also classified by the temporal course of its development, depending on whether it is acute (minutes to days), subacute (days to weeks) or chronic (months or more).

Diseases: This can be seen in the context of many conditions, including infections such as otitis media with or without cholesteatoma, rubella, Lyme borreliosis, herpes virus reactivation, influenza, and HIV infection. It can also be associated with traumatic injuries, malignancy, and autoimmune disorders, as well as in the context of hormonal changes during pregnancy (1).

Approximately half of all cases of acute peripheral facial nerve palsy are idiopathic, for which no specific cause can be found. In the remaining half of cases, a specific cause can be determined, including infection (viral, bacterial,

mycoplasma, mycobacteria, spirochetes, tick-borne zoonoses), cancer, neurological/neuromuscular junction, autoimmune/endocrine disorders, trauma, drug toxicity, hereditary disorders; diabetes, prediabetes; hypertension; migraine; and psychological factors (1).

Medications: There are no medications associated with peripheral facial nerve palsy.

Vaccines: The only proven association of Bell's palsy with a vaccine is with influenza vaccine administered intranasally with E. coli heat labile toxin (Nasalflu®, Berna Biotech) (2). The MMR vaccine has been temporarily associated with the onset of facial paralysis (3).

Sources:

- (1) Barbara Rath, Jane Gidudu, Helen Anyoti, Brigid Bollweg, Patrick Caubel, Yeoung-Hwang Chen, et al. Facial nerve palsy including Bell's palsy: Case definitions and guidelines for collection, analysis, and presentation of immunization safety data, *Vaccine*, Volume 35, Issue 15, 2017, Pages 1972–1983, ISSN 0264–410X. <https://doi.org/10.1016/j.vaccine.2016.05.023>.
- (2) SPEAC - Work Package: WP2 Standards and tools V1.0 – February 15th, 2021 Authors: Barbara Law Nature: Report | Diss. level: Public https://brightoncollaboration.us/wp-content/uploads/2021/03/SPEAC_D2.5.2.1_Facial-Nerve-Palsy-Case-Definition-Companion-Guide_V1.0_format12067-1.pdf.
- (3) Brazil. Ministry of Health. Manual de vigilância epidemiológica de eventos adverses pós-vacinação [electronic resource], 2020. http://bvsmms.saude.gov.br/bvs/publicacoes/manual_vigilancia_epidemiologica_eventos_vacinacao_4ed.pdf.

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