COVID-19

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

Eighteenth report

WASHINGTON, DC

Updated: 30 June 2021

CONTENT

CANADA

- As of 18 June 2021, 31,400,466 doses of COVID-19 vaccines had been administered. Pfizer-BioNTech accounted for 72% of doses administered, Moderna for 18.6%, and AstraZeneca and Covishield (AstraZeneca manufactured by the Serum Institute of India) for 9.4%.
- A total of 7,926 individual reports of one or more adverse events (0.025% of doses administered) were received. Of these, 1,719 were considered serious events (0.005 % of doses administered), with anaphylaxis being the most frequently reported.
- Of total reports, there were 3,232 reports of non-serious events and 1,117 of serious events associated with the Pfizer-BioNTech vaccine. For the Moderna vaccine, there were 2,212 reports of non-serious events and 206 of serious events, while for Covishield/AstraZeneca, there were 742 non-serious and 323 serious events reported.
- A total of 20,759 adverse events following immunization (AEFI) were reported, with 7,926 reports involving one or more events. The most frequently reported adverse events were non-serious, such as injection-site reactions, paresthesia, itching, hives, headache, hypoesthesia, and nausea. There were 83 reported cases of anaphylaxis (70 for the Pfizer-BioNTech vaccine and 13 for the Moderna vaccine).
- As of 18 June, 52% of vaccine doses had been administered to women and 48% to men. The majority (80%) of reported adverse events were in women.
- As of 18 June, there were 58 reported cases of thrombosis with thrombocytopenia syndrome (TTS), of which 54 occurred following vaccination with the Covishield/AstraZeneca vaccine, three after administration of the Pfizer-BioNTech vaccine, and one after administration of the Moderna vaccine. In the 54 cases associated with the Covishield/AstraZeneca vaccine, symptoms occurred between one and 34 days after vaccination; 21 were in women (ages 44 to 88), 32 were in men (ages 34 to 73), and in one case the sex of the person was not specified.
- A total of 119 reported cases of adverse events resulted in post-vaccination deaths. Following a medical review, it was determined that 50 of these deaths were not linked to administration of the COVID-19 vaccine; 30 cases are still under investigation, 6 cases (involving thrombosis with thrombocytopenia syndrome) are considered to be potentially attributable to the vaccination, and in 33 cases the cause of death could not be determined due to insufficient information.
- As of 18 June, 65 cases of myocarditis/pericarditis had been reported, of which 50 occurred following administration of the Pfizer-BioNTech vaccine, 10 after administration of the Moderna vaccine, and 5

following administration of the Covishield/AstraZeneca vaccine. Of the 50 cases associated with the Pfizer-BioNTech vaccine, 28 involved women (ages 20 to 86) and 22 involved men (ages 17 to 76); 34 of the reported cases occurred after the first dose, 10 after the second dose, and in 6 cases there was no indication whether the occurrence followed the first or second dose. Onset of symptoms occurred between 5 hours and 94 days after administration of the vaccine. No clear association between myocarditis/pericarditis and COVID-19 vaccines has yet been established.

Source: https://health-infobase.canada.ca/covid-19/vaccine-safety/

COSTA RICA

- As of 21 June 2021, the Epidemiological Sub-Surveillance Directorate, of the Costa Rican Social Security Fund, reported that 2,331,030 doses of COVID-19 vaccines had been administered.
- As of 21 June, 4,173 AEFI had been reported for the Pfizer-BioNTech vaccine, involving 4,152 non-serious events and 21 serious events. For the AstraZeneca vaccine, there were 1,080 reports of non-serious events.
- There were two reports of serious cases of anaphylaxis associated with the Pfizer-BioNTech vaccine.

Source: Summary of reports of adverse events following immunization (AEFI), provided by the Directorate for the Regulation of Health Products of Interest. National Pharmacovigilance Center (CNFV). Ministry of Health of Costa Rica.

UNITED STATES

- Nearly 312 million doses of COVID-19 vaccines were administered between 14 December 2020 and 21 June 2021.
- Anaphylaxis after administration of COVID-19 vaccines continues to be rare and has occurred in approximately 2 to 5 people per million vaccinated in the United States. When this occurs, it is approximately 30 minutes after vaccination, and can be immediately and effectively treated.
- As of 21 June, 12 million doses of the J&J/Janssen COVID-19 vaccine had been given, with 36 confirmed reports of people who received the J&J/Janssen COVID-19 vaccine and later developed thrombosis with thrombocytopenia syndrome (TTS). However, analysis of test results indicates that the benefits of the vaccine outweigh the known and potential risks. Women younger than 50 years old especially should be aware of the rare but increased risk of blood clots, accompanied by low platelet levels, following administration of the vaccine.
- As of 21 June, one confirmed case of thrombosis with thrombocytopenia syndrome following mRNA COVID-19 vaccination (Moderna) has been reported to VAERS after more than 306 million doses of mRNA COVID-19 vaccines administered in the United States. Based on available data, there is not an increased risk for TTS after mRNA COVID-19 vaccination.

- Myocarditis and pericarditis after COVID-19 vaccination are rare. As of 21 June, the Vaccine Adverse Event Reporting System (VAERS) had received 616 reports of myocarditis and pericarditis among people ages 30 and younger who received COVID-19 vaccine. Most cases have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna), particularly in male adolescents and young adults. After investigation, the number of cases was reduced to 393.
- As of 21 June, VAERS received 5,479 reports of deaths among vaccinated individuals (0.0017% of those vaccinated), though analysis failed to establish a link between these deaths and the vaccination. However, recent reports indicate that there may be a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS deaths. The U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) are continuing to investigate these adverse reactions, including deaths, reported to VAERS.

Source: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

PARAGUAY

- Paraguay's Expanded Immunization Program (PAI), through its AEFI Surveillance System, reports AEFI related to vaccination by the COVID-19 vaccines Sputnik V, Sinovac (CoronaVac), Sinopharm, AstraZeneca, Covaxin, and Hayat Vax* administered between 22 February 2021 and 18 June 2021.
- Between 22 March and 18 June 2021, 665,846 doses of COVID-19 vaccines were administered.
- A total of 1,489 AEFI were reported between the start of the COVID-19 vaccination program (22 February) and 11 May, representing 0.22% of total doses administered. Some 108 reported cases are still under investigation.
- Of the AEFI reported, 75.2% (1,120) involved women, while 24.7% (369) involved men. Reported cases of AEFI were mostly (957) among individuals under 40 years of age.
- The most frequently reported clinical manifestations of AEFI were myalgia (68%), fever (56%), headache (56%), injection-site pain (53%), and fatigue (46%). The majority of reports involved more than one clinical manifestation.
- Notably, the Coronavac vaccine had an AEFI reporting rate of 919.8 reports per 100,000 doses administered, while for Sinopharm, AstraZeneca, and Sputnik V, the rates were 510.7, 349.7, and 262.4, respectively. For the COVAXIN vaccine, the reporting rate was 64.7 reports per 100,000 doses administered.

* Vaccine was produced as the result of a joint project between Sinopharma CNBG and G42, of the United Arab Emirates, in Abu Dhabi.

Source:
http://pai.mspbs.gov.py/uploads/VIGIPAI2021/15%20Bolet%C3%ADn%20Epidemiol%C3%B3gico%20ESAVI.pdf

Possibility of contracting COVID-19 after being vaccinated

A small percentage of fully vaccinated people will still contract COVID-19 if they are exposed to the virus. These are known as "vaccine breakthrough cases." For the purpose of this surveillance, a vaccine breakthrough infection is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person ≥14 days after they have completed all recommended doses of a U.S. Food and Drug Administration (FDA)-authorized COVID-19 vaccine.

Surveillance of these cases is essential to guide public health decisions, as they will be indicative of whether the vaccine is less effective in certain population groups, or immunity is declining over time, requiring boosters.

If cases occur in a higher proportion in people vaccinated at the same time, or in the same geographic space, it could be considered indicative that there may have been problems in the production, shipment, handling, and/or administration of a particular vaccine lot – information that will be helpful in decision-making.

Identification of the genetic strain involved in the cases presented will also be of paramount importance in determining whether there might be a reduction in the vaccine's effectiveness against a particular variant. The U.S. Centers for Disease Control and Prevention (CDC) has developed a protocol to investigate cases of COVID-19 infection in vaccinated individuals, using appropriate tools, including case investigation forms, and providing information to laboratories and to state and local health departments.

Source: https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html

Report from England notes that the Pfizer-BioNTech and Oxford-AstraZeneca vaccines are highly effective in preventing hospitalizations from infection by the Delta variant of COVID-19.

An analysis by Public Health England (PHE) suggests that the Pfizer-BioNTech vaccine is 96% effective, after two doses, in preventing hospitalization from infection by the Delta variant of SARS-CoV-2. For the Oxford-AstraZeneca vaccine, efficacy, after two doses, in preventing hospitalization is 92%. These results are comparable to the effectiveness of these two vaccines against the Alpha variant.

The analysis included 14,019 cases of the Delta variant – 166 of whom were hospitalized. PHE has previously published analysis showing that one dose is 17% less effective at preventing symptomatic illness from the Delta variant, compared to Alpha, but there is only a small difference after two doses.
Source: https://www.gov.uk/government/news/vaccines-highly-effective-against-hospitalisation-from-delta-variant

3- CLARIFICATIONS/CONCLUSIONS ON THE EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS

At present there are no additional updates to the most recent report, regarding conclusive analyses of AEFI.

Commercial name for the Moderna COVID-19 vaccine

The European Medicines Agency (EMA) posted on its website that Moderna's mRNA (modified nucleoside) COVID-19 vaccine is to be known as Spikevax. This vaccine is indicated in individuals ages 18 and older.

Additional information on the authorization of this vaccine in Europe is available at:
https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna

Guillain-Barré syndrome (GBS) and AstraZeneca's COVID-19 vaccine

Researchers in England and India have reported an unusual form of Guillain-Barré syndrome (GBS) that occurred between 10 and 22 days after administration of AstraZeneca's COVID-19 vaccine. Four cases, all men, occurred in Nottingham, England. There were also seven cases, six women and one man, in Kerala, India, characterized by the presence of severe bilateral facial paresis.

The researchers indicate that facial weakness is not atypical in GBS, which usually begins in the lower extremities and rises over time, causing loss of reflexes. However, facial weakness is not usually a predominant finding, compared with severe appendicular weakness and respiratory dysfunction. In addition, the researchers point out that the incidence of GBS in the general population is approximately 6 to 40 cases per million per year. They note a 1.4- to 10-fold increase in the incidence of the disorder.

Based on these findings, the researchers suggest that doctors be alert to recognizing GBS in patients who have received the AstraZeneca COVID-19 vaccine, with its distinctive, unusually severe clinical manifestations, which may require mechanical ventilation.

Sources:

Ann Neurol. June 2021. DOI: 10.1002/ana.26144

MedPage Today. Unusual Variant of Guillain-Barré Syndrome Linked to COVID Vaccines, June 22, 2021

Bell's palsy in cases of post-vaccination COVID-19 infection

Between 1 January and 28 February 2021, a case-control study was conducted in Israel to evaluate the possible association of Pfizer-BioNTech's COVID-19 vaccine with an increased risk of peripheral facial nerve palsy. The study involved 37 patients with acute onset facial nerve palsy, and a matched control group. The study reports that it found no association between recent vaccination and the risk of facial nerve palsy. Additionally, it indicated that there was no significant increase in the number of admissions for facial nerve palsy compared to previous years.

At the same time, researchers from the United States assessed the risk of peripheral facial nerve palsy in relation to COVID-19 infection, and to administration of the Pfizer-BioNTech COVID-19 vaccine. They reviewed the records of

41 health care organizations dating from 1 January to 31 December 2020. After matching patients diagnosed with COVID-19 with vaccinated individuals (n = 63,551), they reported that there was an increased relative risk of 6.8 (95% CI = 3.5-13 206.0, p <0.001) of a facial paralysis diagnosis in individuals with COVID-19, compared to vaccinated individuals.

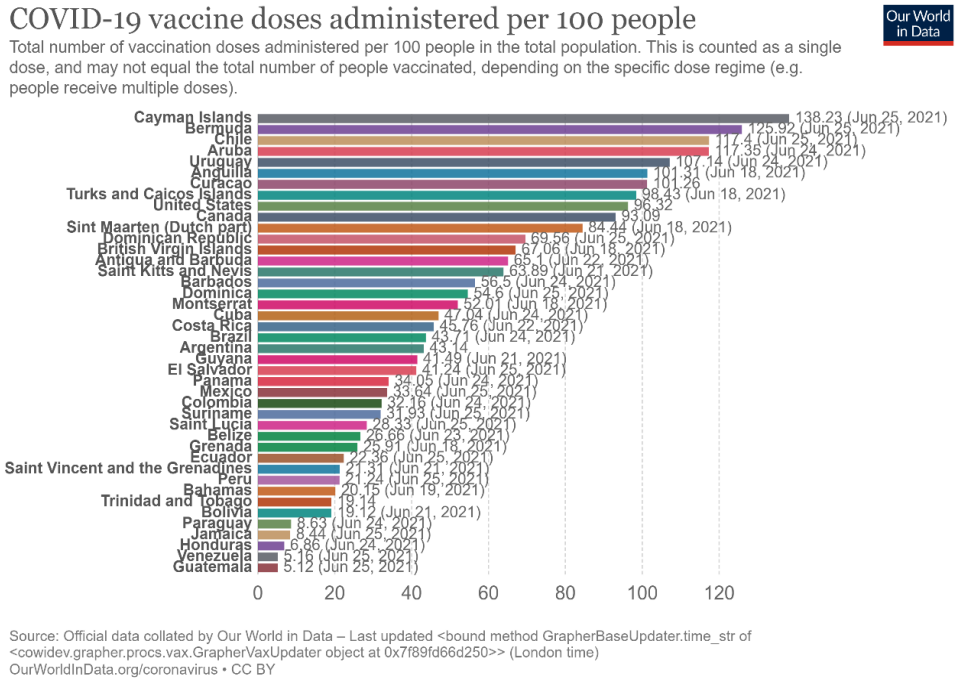
Sources:

JAMA. Otolaryngol Head Neck Surg. 24 June 2021 doi:10.1001/jamaoto.2021.1259

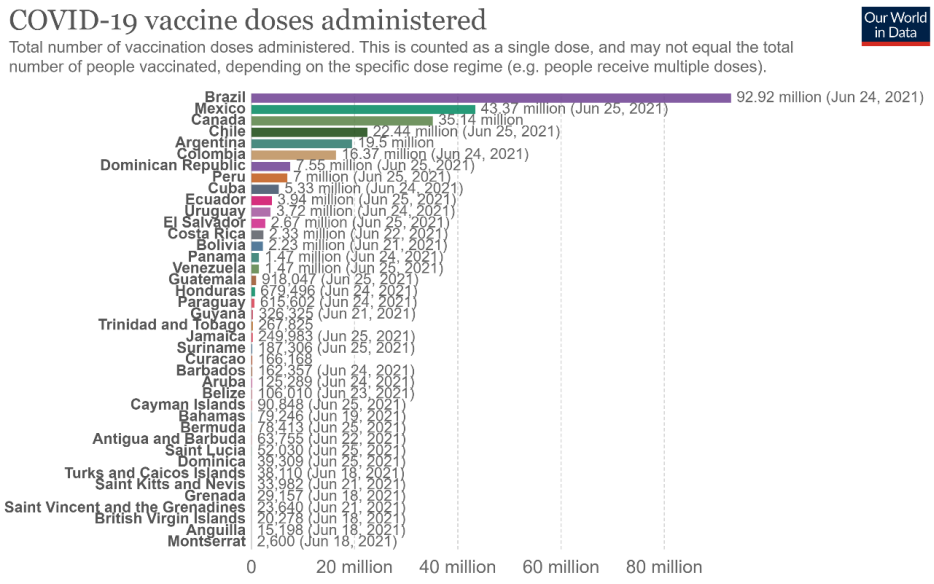
JAMA. Otolaryngol Head Neck Surg. 24 June 2021 doi:10.1001/jamaoto.2021.1266

Use of the COVID-19 vaccine in the Region of the Americas as of 24 June 2021

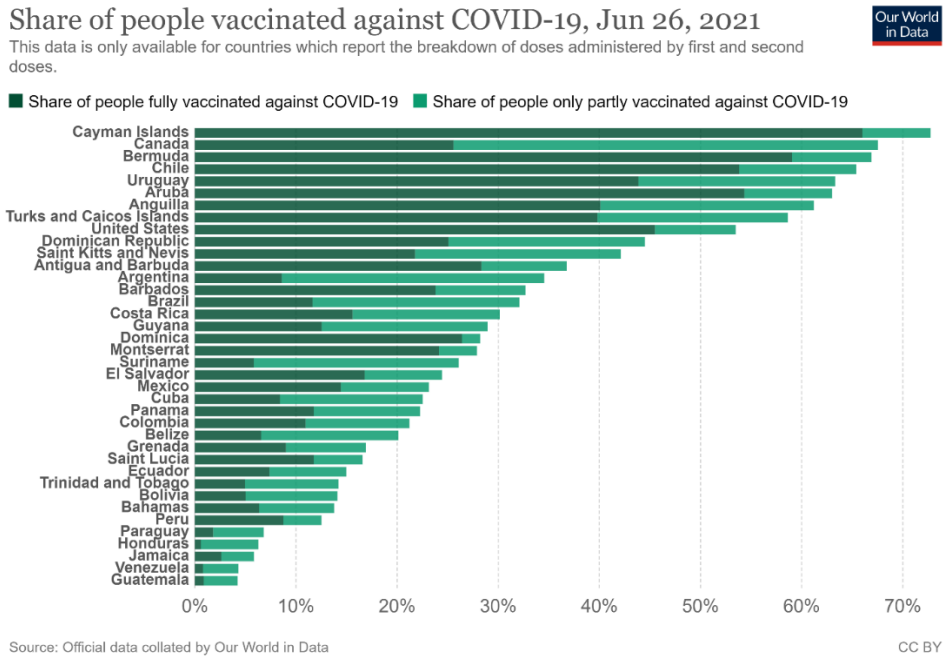
Following are consolidated data on doses administered per 100 people in the overall population, by country, total doses administered, and percentage of the population partially or totally vaccinated as of 24 June 2021. The count represents single doses, and may not match the number of people vaccinated, depending on the specific dosing regimen (since some people receive multiple doses). In the second figure, the United States, with 322.12 million doses administered as of 24 May 2021, is not included.



Source: https://ourworldindata.org/covid-vaccinations



Source: https://ourworldindata.org/covid-vaccinations



Source: https://ourworldindata.org/covid-vaccinations

Note: This document includes material published by third parties and compiled by PAHO. PAHO has taken reasonable precautions to verify the information contained in the document. However, this material is being distributed without warranty of any kind. The reader is responsible for the interpretation and use of this information and in no event shall PAHO be held liable for any damages arising from its use.