COVID-19

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

Sixteenth report

WASHINGTON, DC
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INDEX

CANADA

- As of 29 May 2021, 22,806,404 doses of COVID-19 vaccines had been administered. Pfizer-BioNTech accounted for 71% of doses administered, Moderna for 19%, and AstraZeneca and Covishield (AstraZeneca manufactured by the Serum Institute of India) for 10%.
- There were a total of 6,408 individual reports of one or more adverse events (0.028% of doses administered). Of these, 1,262 were considered serious events (0.006% of doses administered), with anaphylaxis being the most frequently reported.
- Of total reports, there were 2,695 reports of non-serious events and 810 of serious events associated with the Pfizer-BioNTech vaccine. For the Moderna vaccine, there were 1,884 reports of non-serious events and 158 of severe events, while for Covishield/AstraZeneca, 558 non-serious events and 240 serious events were reported.
- A total of 186,276 adverse events following immunization (AEFI) were reported (including 6,408 reports of one or more events), of which the majority were for non-serious events, such as injection-site reactions, paresthesia, pruritus, hives, headache, hypoesthesia, and nausea. A total of 69 cases of anaphylaxis were reported (57 for the Pfizer-BioNTech vaccine and 12 for the Moderna vaccine).
- As at 29 May, 53% of doses of vaccine had been administered to women and 47% to men. The majority of reported adverse events were in women (81.5% of total doses administered).
- As of 29 May, there were 42 reports of thrombosis with thrombocytopenia syndrome (TTS) following vaccination with Covishield/AstraZeneca. There was also one reported case of TTS with the Pfizer-BioNTech vaccine and one with the Moderna vaccine. Symptoms occurred between 3 and 34 days after vaccination; 17 were in women (ages 40 to 72), 26 were in men (ages 34 to 81), and in one case the sex of the person was not specified.
- A total of 94 reported cases of adverse events resulted in post-vaccination deaths. Following a medical review, it was determined that 36 of these deaths were not linked to administration of the COVID-19 vaccine; 45 deaths are still under investigation, while

five deaths (involving TTS) are considered to be potentially attributable to the vaccination, and eight could not be classified due to insufficient information.

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

HONG KONG

- As of 16 May 2021, 1.96 million doses of COVID-19 vaccines had been administered, of which Comirnaty accounted for 1,081,900 doses and CoronaVac for 873,200 doses.
- As of 16 May, there had been 2,890 reports of AEFI (0.15% of doses administered).
- A total of 20 reported cases of adverse events resulted in post-vaccination deaths (0.001% of doses administered), of which 13 were associated with the CoronaVac vaccine and 7 with the Comirnaty vaccine. An analysis of these cases indicated that 15 were not associated with vaccination, while 5 were classified as being inconsistent with vaccination as the cause of death.
- As of 16 May, there were 65 suspected cases of Bell's palsy, of which 34 were associated with the CoronaVac vaccine (0.0039% of doses administered, equivalent to 3.9 cases per 100,000 doses administered), while 31 cases were associated with the Comirnaty vaccine (0.0029% of doses administered, or 2.9 cases per 100,000 doses administered).

Source: https://www.drugoffice.gov.hk/eps/do/en/doc/Safety_Monitoring_of_COVID-19_Vaccines_in_Hong_Kong.pdf

Data from other authorities were updated in Bulletin No. 15.

Consolidated information on AEFI, serious AEFI, and deaths following administration of COVID-19 vaccines administered in the Region of the Americas

Vaccine	Number of doses administered	Number of AEFI	Number of serious AEFI	Number of deaths	AEFI per 100,000 doses administered	Serious AEFI per 100,000 doses administered
AstraZeneca	35,736,254	8,428	1,139	117	23.6	3.2
CanSino	3,624,525	1,049	46	-	28.9	1.3
Gamaleya	6,185,743	25,782	18	1	416.8	0.3
Janssen	11,141,493	35,491	2,641	428	318.5	23.7
Moderna	129,951,637	123,356	9,390	2,269	94.9	7.2
Pfizer/BioNTech	201,657,753	118,992	11,567	2,279	59.0	5.74
Sinopharma	3,164,637	6,991	66	3	220.9	2.09
Sinovac	52,096,765	5,486	841	304	10.5	1.6
Totals	*443,558,807*	325,575	25,708	5,401	*73.4*	*5.8*

- A total of 497,844,928 doses of COVID-10 vaccine were administered in 49 countries and territories. Countries that have not reported adverse events or that have not given a breakdown of vaccines administered are not included. The numbers of doses administered shown in the table are those for which there was information on the vaccine used and for which adverse events were reported.
- Reported rates are calculated with a maximum range of variation of one week (doses administered vs. events). These figures are subject to adjustment.
- The sources for doses administered are country reports, and are given in PAHO's Regional vaccination dashboard.
- The sources for reported events are: (1) public reports; (2) data that have been adjusted after contact with the countries; and (3) VigiBase (Uppsala Monitoring Center).

COVID-19 Vaccine Pharmacovigilance Dashboard

In May 2021, PAHO incorporated the Vaccine Pharmacovigilance Dashboard (developed to support regulatory efforts and the monitoring of vaccine safety) in the available resources related to COVID-19 vaccines.

This dashboard is presented in Spanish and English, and consists of the following components or sections:

- Number of vaccines in the various phases of clinical evaluation, as well as vaccines included in the WHO Emergency Use Listing (EUL) and authorized by countries or regions;
- Information on each of the authorized vaccines, including: authorization, manufacture, general characteristics, dosage and administration schedule, indications and contraindications, storage and logistics, clinical studies and efficacy, pre- and post-authorization safety, monitoring, and references. This information is presented in layers, allowing for sequential access to the content developed.
- Resources: including the Regional vaccination dashboard and the WHO coronavirus dashboard; collection of manuals, guides, and documents on COVID-19 vaccines; regulation and related topics; available training; as well as consolidated regional and global information bulletins on adverse events following vaccination (AEFI) against COVID-19 and other updates issued to date;
- Updated news and evidence;
- Methods used in the pharmacovigilance dashboard for COVID-19 vaccines;
- Glossary of terms.

The COVID-19 Vaccine Pharmacovigilance Dashboard is available at:
https://covid-19pharmacovigilance.paho.org/

Sources:
https://www.paho.org/en/news/9-5-2021-covid-19-vaccine-pharmacovigilance-dashboard
https://www.paho.org/en/covid-19-vaccines

Study on effectiveness of vaccination against SARS-CoV-2 in Uruguay in 2021: preliminary results

Uruguay's Ministry of Public Health is conducting a study on the effectiveness and safety of a SARS-CoV-2 vaccine, led by an interdisciplinary team. Its objective is to monitor the effectiveness of vaccination against SARS-CoV-2 in preventing infection, severe disease, and mortality from SARS-CoV-2. As of 1 June of this year, in Uruguay, 51.8% of the population had been vaccinated with at least one dose of COVID-19 vaccine, and 29.2% of the total population had received both doses according to the defined schedule.

Preliminary results from this study indicate that there was a 66.0% reduction in COVID-19 cases among health care workers at 14 days following the last dose of the CoronaVac vaccine, and a 78.2% reduction at the same point for the Pfizer vaccine. In the general population, there was a 64.5% reduction in COVID-19 cases for people between the ages of 18 and 49 who received the CoronaVac vaccine, and a 61.5% reduction in people ages 50 to 69 who received the same vaccine. The reduction in COVID-19 cases for the group that received the Pfizer vaccine was 79.7% in people ages 80 and older. The reduction in intensive-care hospitalizations (ICH) for COVID-19 was 94.9% for people ages 18 to 49 and 92.2% for people ages 50 to 69 who received the CoronaVac vaccine, and a reduction of 96.7 in ICH for COVID-19 in people ages 80 and older who received the Pfizer vaccine. In terms of mortality from COVID-19, there was a 95.3% reduction in deaths among people ages 18 to 49 who received the CoronaVac vaccine, and a reduction of 95.2% in those ages 50 to 69 who received the same vaccine. In the case of the Pfizer vaccine, there was a 94% reduction in deaths among people ages 80 and older.

These figures are preliminary, and are not from a peer-reviewed publication; they should therefore be interpreted with caution. The research team is developing multivariate statistical analyses to incorporate information on demographics and at-risk groups.

Source: https://bit.ly/3gkSsoO

Effectiveness of a single dose of Sputnik V COVID-19 vaccine (not yet peer-reviewed)

The Ministry of Health of the Province of Buenos Aires, Argentina, monitored the effectiveness of a first dose of the Sputnik V vaccine in people between ages 60 and 79, from 29 December 2020 to 21 March 2021. The main objective was to compare the proportion of confirmed infections, hospitalizations, and deaths from COVID-19 in 186,581 people, of whom 40,387 were vaccinated with one dose of Sputnik V, and 146,194 were unvaccinated, between 21 days

and 40 days after vaccination or initiation of monitoring. People with a prior history of SARS-CoV-2 infection were excluded.

The results of this study indicate that, among people ages 60 to 79, a single dose of the Sputnik V vaccine was 78.6% effective in preventing cases of COVID-19, 84.7% effective in preventing deaths, and 87.6% effective in reducing hospitalizations.

This study was sent to an international scientific journal for peer review and publication.

Source:

https://www.gba.gob.ar/saludprovincia/noticias/sputnik_v_tiene_una_efectividad_con_una_sola_dosis_de_786_para_evitar_casos

ANVISA authorizes clinical studies of the ButanVac vaccine

The vaccine was developed in the laboratories of the Icahn School of Medicine at Mount Sinai Hospital (New York), based on the Newcastle disease virus that expresses the SARS-CoV-2 spike S protein in its membrane and is produced in eggs.

In late March 2021, the Butantan Institute submitted the information required for authorization of phase 1 and 2 studies for the vaccine. Phase 1 and 2 clinical studies of ButanVac will be conducted in three stages (A, B, and C). Stage A, which will involve 400 volunteers, is currently being authorized. In total, phases 1 and 2 plan to enlist 6,000 volunteers ages 18 and older. The vaccine is administered in two doses, with 28 days between doses.

Sources:

https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2021/anvisa-autoriza-pesquisa-clinica-da-vacina-butanvac

Sun W, McCroskery S, Liu W-C, et al. A Newcastle Disease Virus (NDV) Expressing a Membrane-Anchored Spike as a Cost-Effective Inactivated SARS-CoV-2 Vaccine. Vaccines. 2020; 8(4):771. https://doi.org/10.3390/vaccines8040771

Brighton Collaboration updates interim case definition of thrombosis and thrombocytopenia syndrome

The Brighton Collaboration released an update to its provisional case definition of thrombosis and thrombocytopenia syndrome (TTS). The update recognizes the possibility that patients with this condition could be part of a spectrum that may include thrombocytopenia alone, as well as patients suffering from thrombosis without thrombocytopenia.

Because heparin can cause heparin-induced thrombosis and thrombocytopenia syndrome (HITTS) which is clinically similar to TTS, the updated definition of TTS includes how to address exposure to heparin in identifying cases, and its stratification based on whether the administration of heparin occurred within 100 days after the onset of symptoms, while also taking into account that exposure to heparin could have occurred before or after administration of the vaccine.

Source: https://brightoncollaboration.us/thrombosis-with-thrombocytopenia-syndrome-interim-case-definition/

Best practices in using the decisions of regulatory authorities from other jurisdictions in regulating medical products

WHO published the document *Good reliance practices in the regulation of medical products: high-level principles and considerations*, which aims to highlight the importance of international cooperation to ensure the efficacy, safety, and quality of medical products for local use, and to make better use of resources and expertise, avoid duplication, and focus efforts on the regulatory processes most in need of this cooperation.

This document includes guidelines on using the decisions of regulatory authorities from other jurisdictions in cases of public health emergencies, and examines the processes of authorization, lot releases, and surveillance. Subsequently, a practical guide will be published, with a compilation of cases and examples of applying the high-level principles and considerations promoted in this document.

Source: https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf

Technology transfer of the mRNA-based COVID-19 vaccine

Given the need to increase countries' availability of COVID-19 vaccines, WHO and its partners are seeking to expand production capacity and thereby contribute to the success of the global vaccination campaign at the national, regional, and global levels. Through this new initiative, WHO will help to establish centers for technology transfer, and training for small and medium-sized public and private manufacturers of medical products (medicines, vaccines, and pharmaceuticals), preferably in low- and middle-income countries. Initially, this initiative will prioritize mRNA vaccine technology. The technology is highly flexible and allows a relatively rapid adaptation of the vaccine to variants, if necessary; they can be produced by manufacturers of medicines and active medical ingredients, in addition to vaccines. In future, they hope to extend this call to other technologies, as appropriate.

Source: https://bit.ly/3wQ7biv

Authorization of Pfizer-BioNTech's Comirnaty vaccine in the 12- to 16-year-old age group

In May 2021, Chile's Institute of Public Health (ISP), together with a group of experts of the National Immunization Program (NIP) and the Ministry of Health's National Advisory Committee on Vaccines and Immunizations (CAVEI) approved use of the Pfizer-BioNTech COVID-19 vaccine in a new age group, namely, 12- to 16-year-olds. This vaccine had been approved in Chile by the ISP on 16 December 2020 for emergency use.

Source: https://www.ispch.cl/noticia/isp-aprueba-inoculacion-con-vacuna-pfizer-biontech-en-rango-etario-de-12-a-16-anos/

On 11 June 2021 the National Health Surveillance Agency (ANVISA) reported that it had authorized Pfizer-BioNTech's Comirnaty vaccine for use in children ages 12 and older. The authorization occurred after reviewing studies submitted by the manufacturing laboratory on the vaccine's safety and efficacy in this age group. The Comirnaty vaccine had initially been licensed for ages 16 and older.

Source: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2021/anvisa-autoriza-vacina-da-pfizer-para-criancas-com-mais-de-12-anos

Recommendations of the European Centre for Disease Prevention and Control on vaccinating adolescents against COVID-19

The European Centre for Disease Prevention and Control (ECDC) issued recommendations related to the vaccination of adolescents against COVID-19, including:

- Vaccinating adolescents at high risk of contracting severe COVID should be a priority, as with those at high risk in other age groups.
- Given the lower individual benefit/risk ratio of vaccination in adolescents, compared with older age groups, the epidemiological circumstances and the extent of vaccine coverage in the older age groups should be considered before including adolescents.
- It is important to continue monitoring the spread of viral variants among younger people, and to assess the actual incidence of the disease in younger age groups, including consideration of the sequelae of COVID-19.

Sources:

https://www.ecdc.europa.eu/sites/default/files/images/Teenagers_Vaccination-infographic-1-6-21.png

https://www.ecdc.europa.eu/en/publications-data/interim-public-health-considerations-covid-19-vaccination-adolescents-eueea

Global BioHub for pathogen storage, sharing, and analysis

The World Health Organization (WHO) and Switzerland have signed a memorandum of understanding to launch the first BioHub facility, as part of the WHO BioHub System, which was announced in November 2020. This facility, headquartered in Spiez, Switzerland, will be a center for safely receiving, sequencing, storing, and preparing biological materials for distribution to other laboratories, in order to continue risk assessments and maintain global pathogen preparedness.

Source: https://www.who.int/news/item/24-05-2021-who-and-switzerland-launch-global-biohub-for-pathogen-storage-sharing-and-analysis