COVID-19

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

Twenty-sixth report

WASHINGTON, DC

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CANADA

As of 17 September 2021, 38,017,179 doses of the COVID-19 vaccine of Pfizer-BioNTech, 13,455,047 doses of the Moderna vaccine, and 2,785,698 doses of the AstraZeneca and Covishield vaccine (AstraZeneca vaccine manufactured by the Serum Institute of India) had been administered.

A total of 16,134 individual reports of one or more adverse events (0.029% of doses administered) were received. Of these reports, 4,329 involved serious events (0.008% of doses administered).

Based on all reports, there were 43,040 reported adverse events following immunization (AEFI) (16,134 reports involved one or more events. The majority of events were non-serious, such as injection-site reactions, paresthesia, headache, pruritis, dyspnea, fatigue, nausea, etc.

Number of reports and reporting rate of adverse events (per 100,000 doses administered), by vaccine, to 17 September 2021

Vaccine	*Number of reports of non-serious AEFI*		*Number of reports of serious AEFI*		*Total number of reports of AEFI*	
	N	*Rate/100,000 doses administered*	*N*	*Rate/100,000 doses administered*	*N*	*Rate/100,000 doses administered*
Pfizer-BioNTech	6,122	16.10	2,827	7.44	8,949	23.54
Moderna	4,107	30.52	736	5.47	4,843	35.99
Covishield and AstraZeneca	1,538	55.21	610	21.90	2,148	77.11
Unknown	38	-	156	-	194	-
Total	11,805	21.55	4,329	7.90	16,134	29.46

Source: Public Health Agency of Canada. Canadian COVID-19 vaccine safety report. Ottawa: Public Health Agency of Canada; 24 September 2021. https://health-infobase.canada.ca/covid-19/vaccine-safety/. Data reproduced by PAHO/WHO.

Number of reports and reporting rate (per 100,000 doses administered) of adverse events, by vaccine, to 17 September 2021

Vaccine	*Pfizer-BioNTech*	*Moderna*	*Covishield and AstraZeneca*
Anaphylaxis	157 (0.41/100,000)	40 (0.30/100.000)	4 (0.14/100,000)
Thrombosis with thrombocytopenia syndrome (TTS)	16 (0.04/100,000)	4 (0.03/100,000)	61 (2.19/100,000)
Guillain-Barré syndrome	33 (0.09/100,000)	16 (0.12/100,000)	30 (1.08/100,000)
Capillary leak syndrome	-	-	2 (0.07/100,000)
Myocarditis/pericarditis	445 (1.17/100,000)	306 (2.27/100,000)	19 (0.68/100,000)
Bell's palsy/facial paralysis	340 (0.89/100,000)	110 (0.82/100,000)	43 (1.54/100,000)
Fatal events	191* post-vaccination deaths		

**Following a medical review of the 191 deaths, it was determined that 74 were not linked to administration of the COVID-19 vaccine,* while *42 are still under investigation; 6 (cases of TTS) are considered to be potentially attributable to the vaccination, and 69 could not be classified due to insufficient information.*

Source: Public Health Agency of Canada. Canadian COVID-19 vaccine safety report. Ottawa: Public Health Agency of Canada; 24 September 2021. https://health-infobase.canada.ca/covid-19/vaccine-safety/. Data reproduced by PAHO/WHO.

An analysis of 770 of the 774 cases of myocarditis/pericarditis, with indication of the vaccine administered, is shown below:

Number of cases of myocarditis/pericarditis, by vaccine administered, sex, and dose, to 17 September 2021						
Vaccine	***Total number of cases (rate per 100,000 doses administered)***	***By sex (median age)***		***Number of reports, by dose administered***		
		Number of women (median age)	***Number of men (median age)***	***1st***	***2nd***	***Not specified***
Pfizer-BioNTech*	445 (1.17)	159 (39 years)	282 (22 years)	188	202	55
Moderna**	306 (2.27)	79 (35 years)	223 (26 years)	63	209	34
Covishield and AstraZeneca	19 (0.68)	N/A	N/A	N/A	N/A	N/A

* In four 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. Ottawa: Public Health Agency of Canada; 24 September 2021. https://health-infobase.canada.ca/covid-19/vaccine-safety/. Data reproduced by PAHO/WHO.

COLOMBIA

On 29 September, Bulletin #5 of the COVID-19 Adverse Event Following Immunization (AEFI) Report was issued. According to the information it contained, a total of 38,002,826 doses of COVID-19 vaccine had been administered between 17 February and 15 September 2021, resulting in 17,859 reports of AEFI, of which 5.1% (914) were considered serious, with 72% of these (12,805) occurring in women. The age group with the highest number of reported AEFI consisted of individuals between the ages of 60 and 69, representing 18% of the total (3,208), followed by people between the ages of 30 and 39, accounting for 16.7% (2,974), and people between the ages of 20 and 29, representing 14.4% of the total (2,575). Among total AEFI reported nationally, 61.7% (11,015) were for individuals who had received the Pfizer vaccine, followed by 22.5% (4,019) for the Sinovac vaccine, 8.6% (1,528) for the AstraZeneca vaccine, 5% (893) for the Janssen vaccine, and 2.2% (395) for the Moderna vaccine.

Source: https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/ED/boletin5-farmacovigilancia-vacunas-sep2021.pdf

UNITED STATES (data to 22 September)

Following are data, to 22 September, reported by the United States for selected events:

Number of COVID-19 AEFI reported by the United States, by type of event, vaccine administered, and number of doses administered, to 22 September 2021

Event	Vaccine	Doses administered	Cases/Reporting frequency
Thrombosis with thrombocytopenia syndrome (TTS)	J&J/Janssen	More than 14.8 million	47 confirmed reports of people who received the vaccine and were later diagnosed with TTS
	Moderna	More than 372 million doses of mRNA vaccine	Two cases. There is currently no evidence of an increased risk of TTS following administration of the COVID-19 mRNA vaccine.
Guillain-Barré syndrome	J&J/Janssen	More than 14.8 million vaccines	210 preliminary reports identified
Myocarditis/pericarditis	Moderna or Pfizer-BioNTech	372 million doses	1,541 reports, of which 892 were confirmed (pending evaluation of their association with vaccination)
Deaths	All vaccines	More than 390 million doses of vaccine	8,164 reports of deaths in VAERS in people who had received a COVID-19 vaccine (0.0021%), which does not necessarily imply a causal relationship.

Source: Centers for Disease Control and Prevention. COVID-19. Selected Adverse Events Reported after COVID-19 Vaccination. Updated 27 September 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html. Data reproduced by PAHO/WHO.

PANAMA

On 29 September 2021, the Eighth Pharmacovigilance Report on Adverse Events Following Immunization with COVID-19 Vaccines was issued by Panama's Ministry of Health. According to the information, as of 31 August a total of 4,390,960 doses of COVID-19 vaccines had been administered in the country. During that period, Panama's National Center for Pharmacovigilance (CNFV) received 756 reports of AEFI associated with COVID-19 vaccinations, of which 93% (704) were for individuals who had received the Pfizer-BioNTech vaccine, while 6.8% were for those who had received the AstraZeneca vaccine. Among AEFI associated with the Pfizer-BioNTech vaccine, 7% were considered serious; of those associated with the AstraZeneca vaccine, 12% were considered serious.

Source: http://minsa.b-cdn.net/sites/default/files/alertas/7to_informe_de_fv_de_esavi_de_vacunas_contra_la_covid-19.pdf

U.S. Food and Drug Administration authorizes a booster dose of the Pfizer-BioNTech COVID-19 vaccine for certain populations

On 22 September 2021, the U.S. Food and Drug Administration (FDA) reported that it had amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine to allow the use of a single booster dose – to be given at least six months after completing the primary series of immunizations with the same vaccine – for the following individuals:

- People age 65 and older;
- People ages 18 to 64 at high risk of severe COVID-19; and
- People ages 18 to 64 whose institutional or occupational exposure to SARS-CoV-2 puts them at high risk for serious complications from COVID-19, including severe COVID-19.

The FDA examined the data submitted by the vaccine manufacturer, along with information presented at the 17 September meeting of the Vaccine and Related Biological Products Advisory Committee (VRBPAC), and determined that, based on the totality of available scientific evidence, a booster dose of the Pfizer-BioNTech COVID-19 vaccine may be effective in preventing COVID-19. It also determined that the known and potential benefits of a booster dose outweigh the known and potential risks in the populations designated by the FDA. The booster dose is authorized for administration to these individuals at least six months following completion of their primary series, and may be given at any point after that time.

Source: https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations

CDC Statement on recommendation of the Advisory Committee on Immunization Practices (ACIP)

On 24 September, after approval by the U.S. Food and Drug Administration (FDA) for use of the Pfizer vaccine booster shot, the Director of the Centers for Disease Control and Prevention (CDC) endorsed the recommendation of the Advisory Committee on Immunization Practices (ACIP) for a booster shot of the Pfizer-BioNTech COVID-19 vaccine in certain populations, and also recommended a booster dose for those in high risk occupational and institutional settings.

The CDC recommends that:

- People 65 years old and older and residents in long-term care settings should receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their primary series with the same vaccine;
- People ages 50 to 64 with underlying medical conditions should receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their primary series with the same vaccine;

- People ages 18 to 49 with underlying medical conditions may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their primary series with the same vaccine, based on their individual benefits and risks; and
- People ages 18 to 64 who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their primary series with the same vaccine, based on their individual benefits and risks.

With the Delta variant's dominance as the circulating strain, and cases of COVID-19 increasing significantly across the United States, a booster shot will help strengthen protection against severe disease in those populations that are at high risk for exposure to COVID-19 or the complications from severe disease.

The CDC will continue to monitor the safety and effectiveness of COVID-19 vaccines to ensure appropriate recommendations to keep all Americans safe. It will also evaluate with similar urgency available data in the coming weeks to swiftly make additional recommendations for other populations or for people who received the Moderna or Johnson & Johnson vaccine.

Source: https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html

Colombia's National Institute for Drug and Food Surveillance (INVIMA) approves administration of Moderna's COVID-19 vaccine for people ages 12 to 17

Colombia's National Institute of Drug and Food Surveillance (INVIMA) approved the request to modify the Emergency Use Authorization for the Moderna COVID-19 vaccine to include its use in people over 12 years of age, to be administered intramuscularly in a series of 2 doses (0.5 ml each).

The authorization was based on safety data gathered in the ongoing phase 2-3 randomized, placebo-controlled clinical trial being conducted in the United States, involving 3,726 individuals ages 12 to 17, in which the safety, immunogenicity, and efficacy of the vaccine were evaluated.

Source: https://www.invima.gov.co/en/web/guest/personas-a-partir-de-los-12-anos-podran-recibir-la-vacuna-desarrollada-por-la-farmaceutica-moderna-contra-el-covid-19?redirect=%2Fen%2Fnoticias

Ali K, Berman G, Zhou H et al. Evaluation of mRNA-1273 SARS-CoV-2 Vaccine in Adolescents. N Engl J Med. doi: 10.1056/NEJMoa2109522, https://doi.org/10.1056/NEJMoa2109522

Facial nerve palsy following administration of COVID-19 mRNA vaccines: analysis of a self-reporting database

On 4 September, a study investigating cases of facial nerve palsy (or Bell's palsy) following administration of messenger RNA vaccines (BNT162b2 and mRNA-1273) was published, based on data from the U.S. vaccine adverse event reporting system (VAERS) database. A disproportionality analysis, adjusted for age and sex, was performed for the reports contained in VAERS for people over 18 years of age who were vaccinated between January 2010 and April 2021. Data from 2010 were used for comparison with the influenza vaccine.

The analysis indicated that adverse events following immunization (AEFI) involving facial nerve palsy, following administration of COVID-19 mRNA vaccines, had significantly high reporting rates for both BNT162b2 (reporting odds ratio [ROR] 1.84; 95% confidence interval [CI] 1.65–2.06) and mRNA-1273 (ROR 1.54; 95% CI 1.39–1.70). The data represent 405 cases for BNT162b2 and 512 for mRNA-1273. These levels were comparable to levels following influenza vaccination, reported before the COVID-19 pandemic (ROR 2.04; 95% CI 1.76–2.36), involving a total of 462 influenza vaccine cases.

The authors' conclusion was that the results suggest that the incidence of facial nerve palsy as a non-serious AEFI may be lower than, or equivalent to, that of influenza vaccines. This information might be of value in the context of promoting worldwide vaccination, but needs to be validated in future observational studies.

Source: K. Sato, T. Mano, Y. Niimi et al. Facial nerve palsy following the administration of COVID-19 mRNA vaccines: analysis of a self-reporting database. International Journal of Infectious Diseases 111 (2021) 310–312. https://doi.org/10.1016/j.ijid.2021.08.071

Study on the risk of SARS-CoV-2 infection and subsequent hospital admission and death at different time intervals since the first dose of COVID-19 vaccine administration

On 26 June, an observational study, with no control group, was published evaluating the effectiveness of COVID-19 vaccines in Italy. The study included data from more than 7 million people vaccinated with at least one dose of COVID-19 vaccine. As a reference, 0 to 14 days after the first dose was used, analyzing the risk of SARS-CoV-2 infection after administration of the vaccine.

Fourteen days after vaccination, the risk of infection decreased, with the adjusted risk of infection declining gradually until the period 42–49 days after the first dose, with a reduction of up to 78% (incidence rate ratios [IRR]: 0.22; 95% CI: 0.21–0.24). Similarly, the risk of hospitalization and death decreased gradually until the period 35-42 days after the first dose, when the estimated risk reduction was 89% (IRR: 0.11; 95% CI: 0.09–0.15) for hospitalization and 93% (IRR: 0.07; 95% CI: 0.04–0.11) for death. The authors conclude that these results support ongoing vaccination campaigns. However, they emphasize the need for complete two-dose vaccine schedules.

Source: Mateo-Urdiales A., Spila Alegiani S., Fabiani M. et al. Risk of SARS-CoV-2 infection and subsequent hospital admission and death at different time intervals since first dose of COVID-19 vaccine administration, Italy, 27 December 2020 to mid-April 2021. Euro Surveill. 2021;26(25):p ii=2100507. https://doi.org/10.2807/1560-7917.ES.2021.26.25.2100507

Maternal and child outcomes reported by breastfeeding women following administration of messenger RNA COVID-19 vaccination

On 31 August, a cross-sectional observational study was published on breastfeeding women residing in the United States who received either of the two messenger RNA vaccines (Pfizer or Moderna) and who were enrolled in the Mommy's Milk Human Milk Research Biorepository at the University of California, San Diego. The data from 14 December 2020 to 1 February 2021 were analyzed; during that period, 180 women who received two doses of one of the two mRNA vaccines were recruited. Women receiving the Pfizer and those receiving the Moderna reported, in similar proportions, one or more symptoms following vaccination. However, following the second dose of vaccine, women who received the Moderna vaccine were significantly more likely to report symptoms.

Following the first dose of either vaccine, a small proportion of women reported a reduction in milk supply and significantly more women reported a reduction in milk supply following the second dose of Moderna. Few infant events were reported for either vaccine following either dose, and no serious adverse events were reported. The authors concluded that the data are reassuring regarding the safety of vaccination in breastfeeding women and their breastfed children with either of the COVID-19 mRNA vaccines.

Source: Kerri Bertrand, Gordon Honerkamp-Smith, and Christina D. Chambers. Maternal and Child Outcomes Reported by Breastfeeding Women Following Messenger RNA COVID-19 Vaccination. BREASTFEEDING MEDICINE Volume 16, Number 9, 2021. Mary Ann Liebert, Inc. DOI: 10.1089/bfm.2021.0169.

CLARIFICATIONS/CONCLUSIONS ON EVENTS PRESENTED IN PREVIOUS COMMUNICATIONS

WHO authorizes extension of the shelf-life of Pfizer-BioNTech's Comirnaty vaccine

On 20 September 2021, the World Health Organization (WHO) authorized an extension of the shelf-life of unopened vials of the Pfizer-BioNTech Comirnaty vaccine from 6 to 9 months, provided they have been stored at between -90°C and -60°C. Unopened vials stored between -25°C and -15°C continue to be authorized for use for a single period of up to two weeks and, for unopened thawed vaccine stored between 2°C and 8°C, from 5 to 31 days, within the authorized shelf-life of 9 months.

The three-month extension in the shelf-life of this vaccine applies to vials manufactured after 10 September 2021, the date on which the European Medicines Agency (EMA) approved the change, and can be applied retroactively to vaccine vials manufactured before this date, provided that the approved storage conditions of -90° C to -60°C have been met.

Source: https://extranet.who.int/pqweb/vaccines/who-recommendation-covid-19-mrna-vaccine-nucleoside-modified-comirnaty

WHO authorizes new production site for Pfizer-BioNTech's Comirnaty vaccine

On 22 September 2021, WHO authorized a new site for production of Pfizer-BioNTech's Comirnaty vaccine, at Delpharm Saint-Remy's factory located at Rue de l'Isle, 28380 Saint-Remy-sur-Avre, France. There will now be six additional authorized sites for the final phase of production for this vaccine.

Source: https://extranet.who.int/pqweb/vaccines/who-recommendation-covid-19-mrna-vaccine-nucleoside-modified-comirnaty

Chile's Institute of Public Health issues an information notice on the safety of Pfizer-BioNTech's COVID-19 vaccine following reports of myocarditis and pericarditis

On 23 September 2021, Chile's Public Health Institute (ISP) issued an information notice on the safety of the Pfizer-BioNTech COVID-19 vaccine, after cases of myocarditis and pericarditis following administration of the vaccine were reported. The ISP notes that, in Chile, since 16 December 2020, more than 6.8 million doses of this vaccine have been administered, and it has received a total of 11 reports of myocarditis and/or pericarditis, of which 10 were serious cases. Of the total reported cases, seven occurred in men and four in women; the mean age was 22 years, with median age of 19 years (14–32 years). These cases are being evaluated by Chile's Committee of Experts on Vaccine Pharmacovigilance, which concluded that four of the cases are “consistent with vaccination.”

In this information notice, directed at the community, the ISP indicated that, after administration of the Pfizer-BioNTech COVID-19 vaccine, there is a very low probability that myocarditis and/or pericarditis will occur, mostly in young men after the second dose, in the 14 days after vaccination. The ISP alerts people to the need to seek medical attention immediately if, in the days following vaccination, they experience shortness of breath, heart palpitations sometimes accompanied by an irregular heartbeat, feel faint, or have chest pain.

The ISP also notes that the benefit of the Pfizer-BioNTech COVID-19 vaccine in preventing COVID-19 hospitalizations and deaths outweighs the risks described.

Source: https://www.ispch.cl/wp-content/uploads/2021/09/Scan24-09-2021-151552.pdf

Selection of two regional centers for the development and production of mRNA vaccines in Latin America

On 21 September 2021, PAHO announced the selection of two regional centers for the development and production of mRNA vaccines in Latin America, in a bid to tackle COVID-19 and future infectious-disease challenges. The selection is the result of an April 2021 WHO call for expressions of interest by manufacturers and research institutions.

The selected centers are the following: Brazil's Bio-Manguinhos Institute of Technology on Immunobiologicals, at the Oswaldo Cruz Foundation (FIOCRUZ), has a long tradition in vaccine manufacturing and has made promising advances in the development of an innovative mRNA vaccine against COVID-19; and the private-sector biopharmaceutical company Sinergium Biotech, in Argentina, will be partnering with pharmaceutical mAbxience, which belongs to the same group, to develop and manufacture active vaccine ingredients. The two companies have extensive experience in the area.

Source: https://www.paho.org/en/news/21-9-2021-paho-selects-centers-argentina-brazil-develop-covid-19-mrna-vaccines

The National Institute of Drug and Food Surveillance (INVIMA) participates in “Solidarity Trial of COVID-19 vaccine candidates”

On 13 September 2021, Colombia's National Institute of Drug and Food Surveillance (INVIMA) announced approval of the clinical research protocol for the “Solidarity Trial of COVID-19 vaccine candidates,” a study sponsored by WHO.

Colombia is one among the group of countries that will participate in this large-scale, randomized, controlled international clinical trial, whose goal is to coordinate a rapid, efficient, and reliable evaluation of SARS-CoV-2 vaccines now in development. Initially, Colombia will participate in evaluating two types of vaccines: the MVC-COV1901, a protein subunit COVID-19 vaccine developed by the Medigen Vaccine Biologics Corporation; and the INO-4800 vaccine, developed by Inovio Pharmaceuticals, which uses a deoxyribonucleic acid (DNA) technology, linked to an electroporation device called CELLECTRA™.

This study has an adaptive design, and it is therefore expected that other types of vaccines will be involved in its development, with the participation of approximately 120,000 volunteers 16 years or older worldwide, who live in places with a high incidence of the SARS-CoV-2 virus, or who, due to their circumstances, are at significant risk of exposure. The trial will last 15 months.

Source: https://www.invima.gov.co/en/web/guest/invima-autoriza-el-estudio-clinico-solidaridad-para-vacunas-contra-covid-19-en-colombia?redirect=%2Fen%2Fnoticias]

Adverse Events of Special Interest (AESI) and related risks: anaphylaxis

Definition: Anaphylaxis is an acute hypersensitivity reaction with multi-organ system involvement that can rapidly progress to a severe life-threatening reaction. It can occur following exposure to allergens from a variety of sources including food, airborne allergens, insect venom, drugs, and immunizations. Anaphylaxis is triggered by the binding of allergen-specific immunoglobulin E (IgE).

Risk and disease factors: Anaphylaxis can occur after exposure to allergens from a variety of sources, including food, aeroallergens, insect venom, drugs, or vaccines. Risk factors include age, sex, geography, comorbidity (severe asthma, lung disease, mastocytosis, thyroid disease, coronary artery disease, ischemic dilated cardiomyopathy). Other factors include food, atopy, and hymenoptera venom in high-exposure areas. Frequency of occurrence depends on lifestyle and on consumption of foods such as celery, cow's milk, chicken eggs, peaches, peanuts, seeds (e.g., sesame), shellfish, nuts, wheat, and buckwheat; a further cause can be insect venom (venom of bees and wasps, red ants, horseflies).

Drugs: These include analgesics, nonsteroidal anti-inflammatory drugs, or NSAIDs (dipyrone, ketoprofen, diclofenac, ibuprofen, ketorolac), antibiotics (penicillin and beta-lactam antibiotics such as ampicillin, amoxicillin, cephalexin, cefuroxime, ceftriaxone), neuromuscular blocking agents used in surgical and anesthetic procedures, biologics, chemotherapeutics, contrast media, proton pump inhibitors, acyclovir, antihypertensive drugs (beta-adrenergic blockers), calcium channel blockers, ACE inhibitors, angiotensin receptor blockers, direct renin inhibitors), polyethylene glycol (PEG), sedatives, hypnotics, and recreational drugs, which can mask symptoms and make the condition difficult to detect.

Vaccines: Post-vaccination anaphylaxis is serious, and is associated with vaccines against MMR, varicella zoster virus (VZV), influenza, hepatitis B, tetanus toxoid, and meningitis. There is a causal relationship with human papillomavirus (HPV) vaccines. Anaphylaxis, as an adverse event of special interest, has been reported – in clinical trials and by countries – for different vaccines, among the events considered serious.

Sources:

Pan American Health Organization. PAHO/HSS/MT/COVID-19/21-0006. Consultation Document for Case Definitions Adverse Events of Special Interest and Adverse Events Following Immunization during COVID-19 Vaccine Introduction. https://iris.paho.org/handle/10665.2/53772

Jens Ruggeberg, Michael Gold, José-Maria Bayas, Michael Blum, Jan Bonhoeffer, Sheila Friedlander, et al. Anaphylaxis: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data, Vaccine, Volume 25, Issue 31, 2007, Pages 5675-5684, ISSN 0264-410X. https://doi.org/10.1016/j.vaccine.2007.02.064

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