

# Reporting a Suspected Vaccine Adverse Event



## Indian Health Service, National Pharmacy & Therapeutics Committee

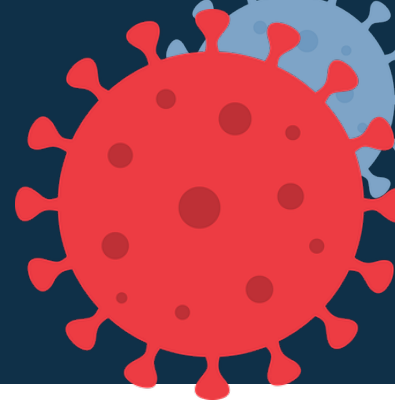
CAPT Matthew Clark, MD, FAAP, FACP, Chair

CAPT Ryan Schupbach, PharmD, BCPS, CACP, Vice Chair

CAPT Christopher Lamer, PharmD, MHS, BCPS, CDE, Director of Pharmacovigilance

October 2020

# Potential New Vaccine for COVID-19



- Operation Warp Speed (OWS)
  - Collaboration between the Federal Government and biopharmaceutical companies to develop medications, diagnostic tests, and vaccines.
  - Shortened timelines but safety and efficacy are the primary focus.
    - Vaccines must be at least 50% effective for FDA EUA or approval.
    - Vaccines must be safe and benefits of immunization must outweigh any risks of adverse events.
- Continued need for influenza immunization
- Continued need for scheduled immunizations

# Vaccine Safety: Common Adverse Events



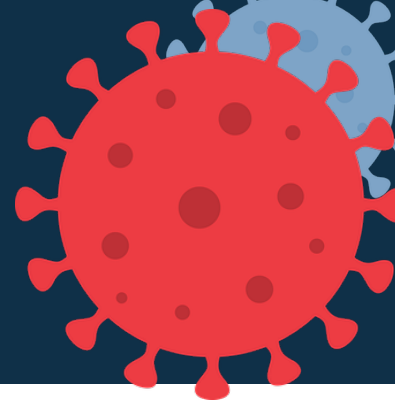
- Vaccines are considered to be safe and effective with most common adverse events being mild and are signs that the body is developing immunity:
  - Pain, swelling, or redness where the shot was given
  - Mild fever
  - Chills
  - Feeling tired
  - Headache
  - Muscle and joint aches

# Vaccine Safety: Serious Adverse Events



- More serious side effects are rare but can occur. Some examples are:
  - Anaphylaxis (0.65 cases/1 million vaccinations)
  - Thrombocytopenia from Rubella vaccine (1 case/40,000 vaccinations)
  - Orchitis from Mumps vaccine (0.3 cases/1 million vaccinations)
  - Intussusception from Rotavirus vaccine (1 case/100,000 vaccinations)
  - Guillain-Barre from flu vaccine (1 case/1.25 million vaccinations; association is stronger with flu infection than the vaccine)

# Reporting Vaccine Adverse Events



- Vaccine Adverse Events:
  - Document in the patients medical record using the Adverse Reaction Tracking system of RPMS EHR or equivalent.
  - Report to the vaccine Adverse Event Reporting System (VAERS).

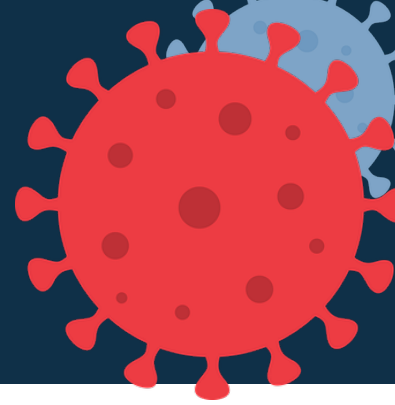
The screenshot shows the VAERS website homepage. At the top left is the VAERS logo with the text "Vaccine Adverse Event Reporting System" and the URL "www.vaers.hhs.gov". Below the logo is a navigation bar with five items: "About VAERS", "Report an Adverse Event", "VAERS Data" (with a dropdown arrow), "Resources" (with a dropdown arrow), and "Submit Follow-Up Information".

Below the navigation bar, there is a section titled "Have you had a reaction following a vaccination?". It contains two numbered steps: "1. Contact your healthcare provider." and "2. Report an Adverse Event using the VAERS online form or the new downloadable PDF. *New!*".

Below the steps is an "Important" box with the following text: "Important: If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider."

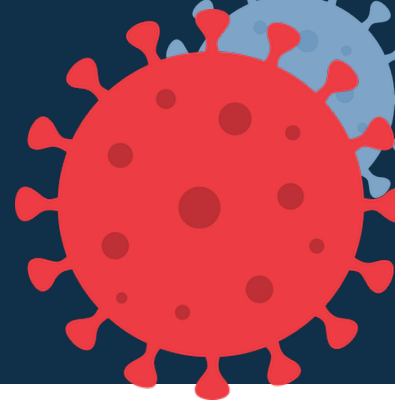
To the right of the text is a photograph of a smiling family consisting of a man, a woman, and two young children.

# Report Vaccine Adverse Events



- Why report vaccine adverse events?
  - It helps to improve patient safety through careful monitoring and pharmacovigilance.
  - It is required by IHS policy in Chapter 7 of the Indian Health Manual
    - Adverse reactions to vaccines will be reported online using Form VAERS-1, Vaccine Adverse Event Reporting System <https://vaers.hhs.gov/>. A copy of each report will be filed in the pharmacy with a copy sent to the P&T Committee.
  - Healthcare providers may be required by law to report under certain conditions.

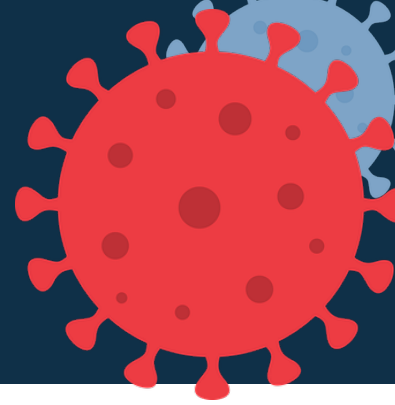
# When Reporting is Required by Law



- Any adverse event listed in the [VAERS Table of Reportable Events Following Vaccination](#) that occurs within the specified time period after vaccinations.
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.



# Reporting a Vaccine Adverse Event



1. Open a web browser and go to <https://vaers.hhs.gov>
2. Scroll down and select "Report an Adverse Event."

What is VAERS?

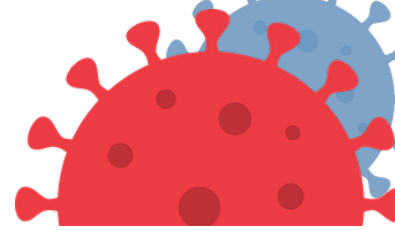
**REPORT AN ADVERSE EVENT**  
Review reporting requirements and submit reports.

**SEARCH VAERS DATA**  
Download VAERS Data and search the CDC WONDER database.

**REVIEW RESOURCES**  
Find materials, publications, learning tools, and other resources.

**SUBMIT FOLLOW-UP INFORMATION**  
Upload additional information VAERS reports.





- There are two options to submit an adverse event to VAERS:
  1. Using the online report.
  2. Uploading and submitting a PDF form. This option enables you to begin documentation, save it, and finish it at a later time.

### Two Ways to Submit an Online Report to VAERS



#### Option 1 - Report Online to VAERS (Preferred)

Submit a VAERS report online. The report must be completed online and submitted in one sitting and cannot be saved and returned to at a later time. Your information will be erased if you are inactive for 20 minutes; you will receive a warning after 15 minutes.



#### Option 2 - Report using a Writable PDF Form

Download the Writable PDF Form to a computer. Complete the VAERS report offline if you do not have time to complete it all at once. Return to this page to upload the completed Writable PDF form by clicking here.

If you need further assistance with reporting to VAERS, please email [info@VAERS.org](mailto:info@VAERS.org) or call 1-800-822-7967.

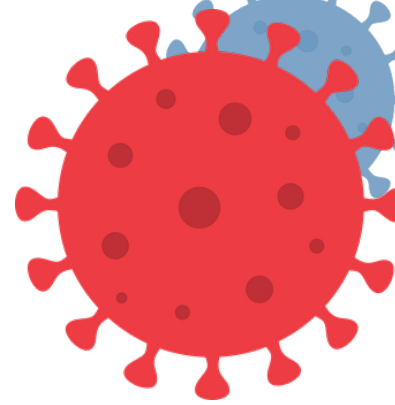
#### Checklist

##### What will I need to fill out the report?

- Patient information (age, date of birth, sex)
- Vaccine information (brand name, dosage)
- Date, time, and location administered
- Date and time when adverse event(s) started
- Symptoms and outcome of adverse event(s)
- Medical tests and laboratory results (if applicable)
- Physician's contact information (if applicable)

[Full checklist](#)

This presentation will review the first option (using the online report). Instructions for completing the PDF option can be found on the VAERS website.



- After clicking the online report icon, a new page will open.
- Begin filling out the report with as much info as possible.
  - Please note that items marked with an asterix (“\*”) are mandatory.

**VAERS** Vaccine Adverse Event Reporting System  
www.vaers.hhs.gov

About VAERS | Report an Adverse Event | VAERS Data | Resources | Submit Follow-Up Information

Completion Status | Report an Adverse Event - Patient Information | Instructions | en Español

Patient Information  
 Reporter Information  
 Facility Information  
 Vaccine Information  
 Additional Information

**Note:** Fields marked with an \* are essential and should be completed.

**Item 1**

Patient first name:  Patient last name:

Street address:

City:  State:  County:

Zip code:  Phone:  Email:

**Item 2** **Item 3**

\* Date of birth ( mm/dd/yyyy or  mm/yyyy)

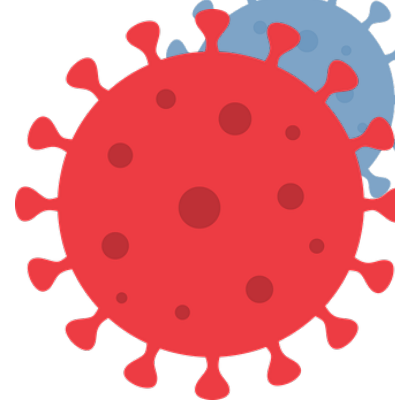
\* Sex:  Male  Female  Unknown

**Item 4**

\* Date of vaccination ( mm/dd/yyyy or  mm/yyyy)

Time:   AM  PM

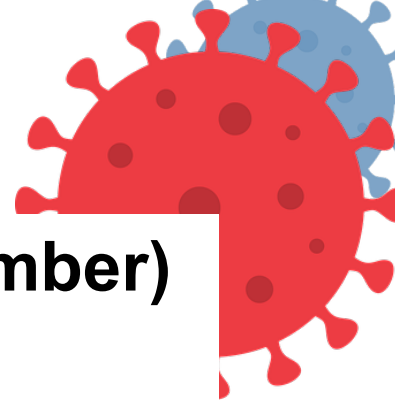
[Click to preview VAERS form](#)



- When you get to the bottom of the screen, click the next button to move on to the next page.

**Warning:** Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

Next

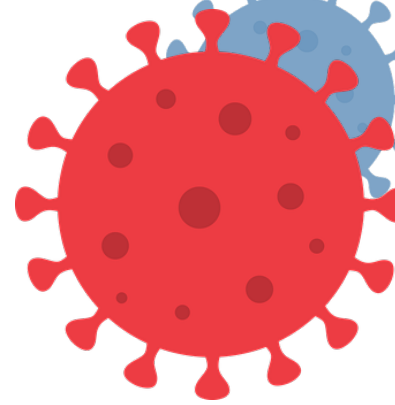


- **When you get to item #26 (immunization project report number) it is very important that you enter the letters “IHS.”**
- This enables the CDC to identify American Indian/Alaska Native patients treated at Federal, Tribal, and Urban programs and to evaluate vaccine safety among our patient population.

Item 26 ⓘ

Immunization project report number: **(Health Dept use only)**

- Federal, Tribal, and Urban programs are all encouraged to put “IHS” into this field to help better evaluate adverse events experienced in our patient population.



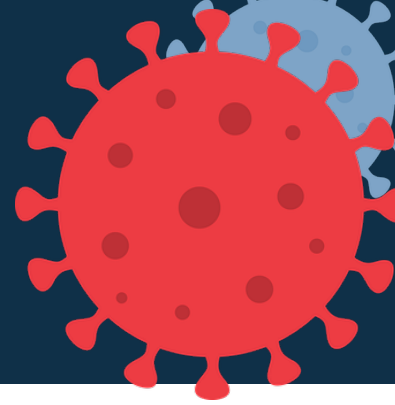
- After you have completed the form, click the “Submit” button in the bottom right to send your report to VAERS and complete the reporting process.

**Warning:** Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

Prev

Submit

# Summary



- Severe adverse events associated with vaccines are rare, but may occur.
- When adverse events occur, they should be documented in the patient's medical record and many should be reported to VAERS.
  - **Include “IHS” for item #26 on the VAERS.**
- Continue to promote routine vaccinations including the flu vaccine.