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

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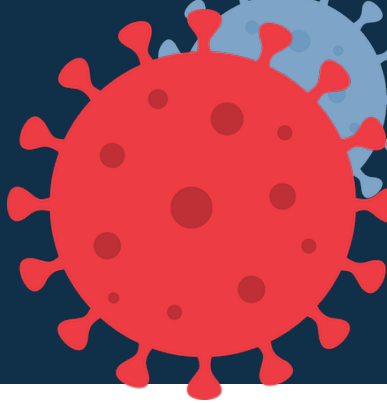
Potential New Vaccine for COVID-19



- 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

https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html

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

https://www.vaccines.gov/basics/safety/side_effects

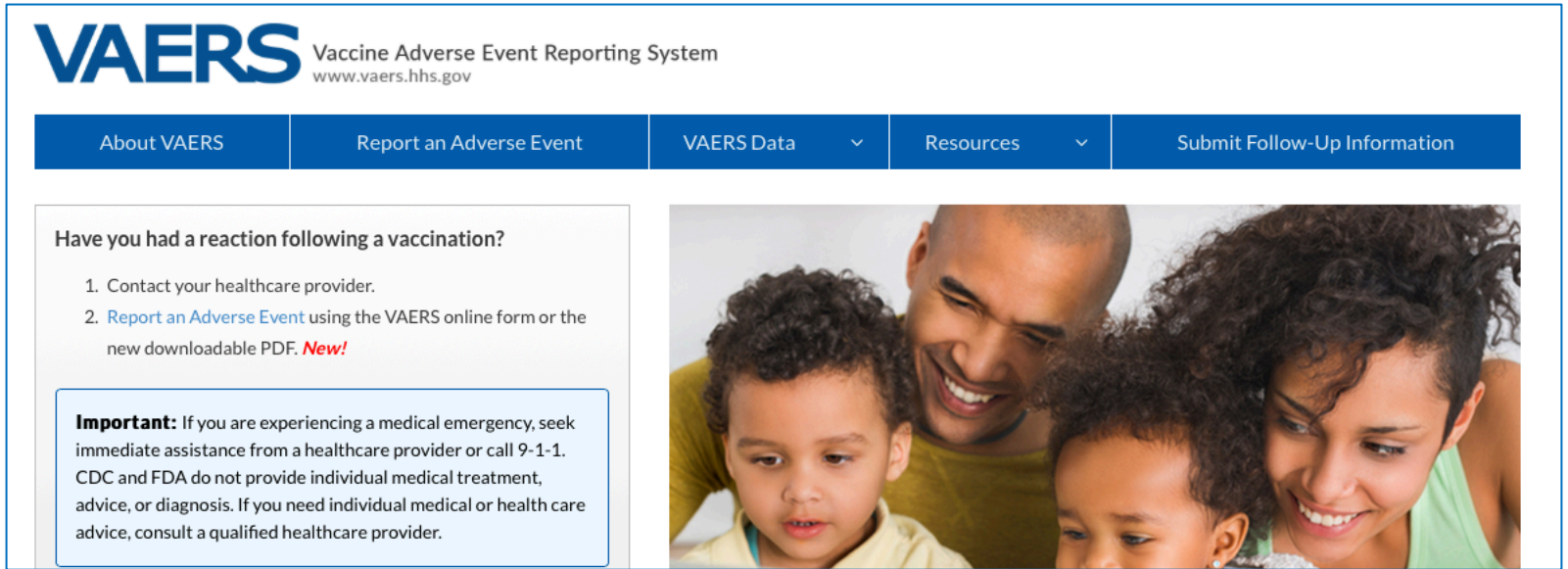
Vaccine Safety: Serious Adverse Events

- 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)

Spencer JP, Trondsen Pawlowski RH, Thomas S. Vaccine Adverse Events: Separating Myth from Reality. *Am Fam Physician*. 2017;95(12):786-794.

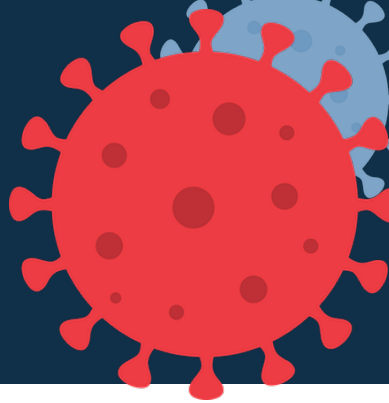
Reporting Vaccine Adverse Events

- 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).



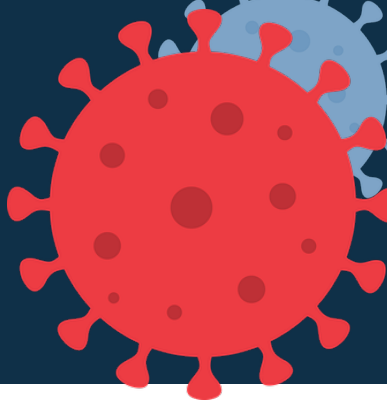
https://vaers.hhs.gov

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.

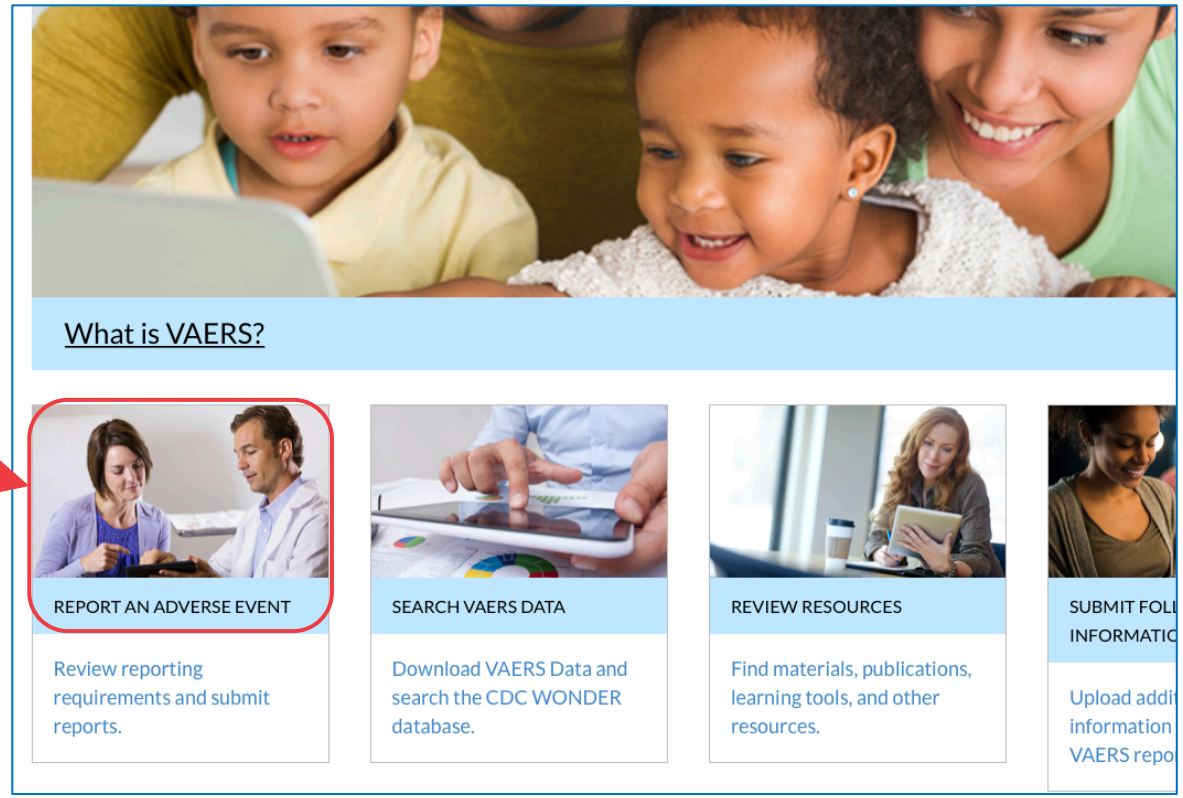
When Reporting is Required by Law



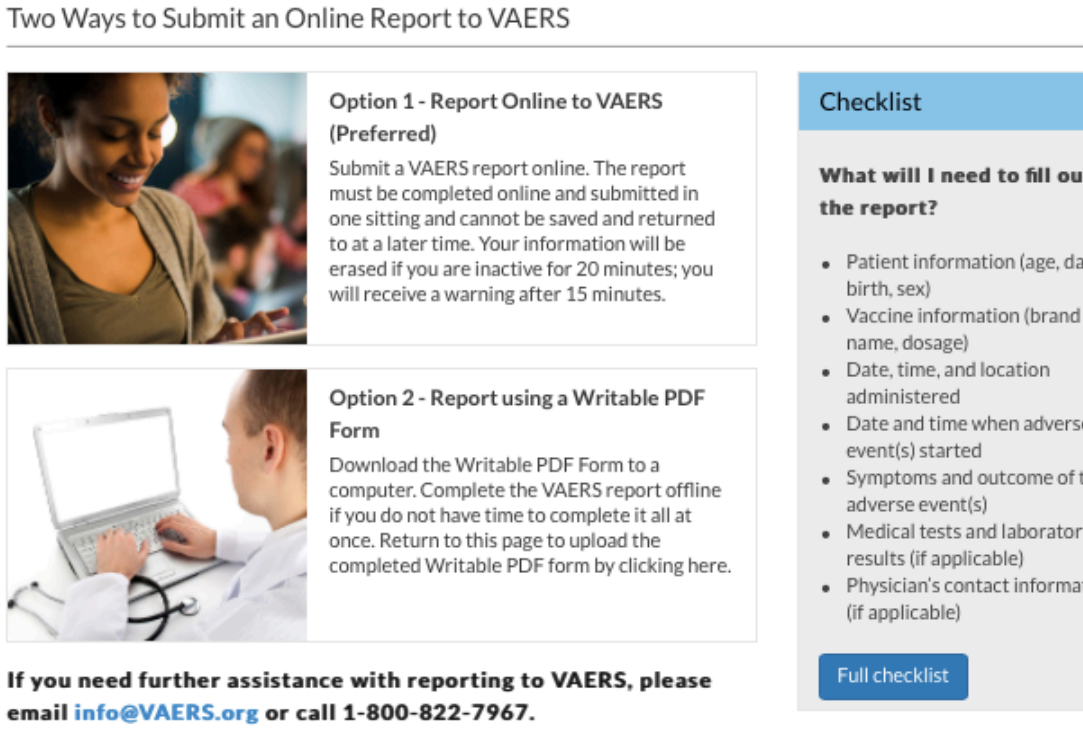
- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations.
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.

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.”

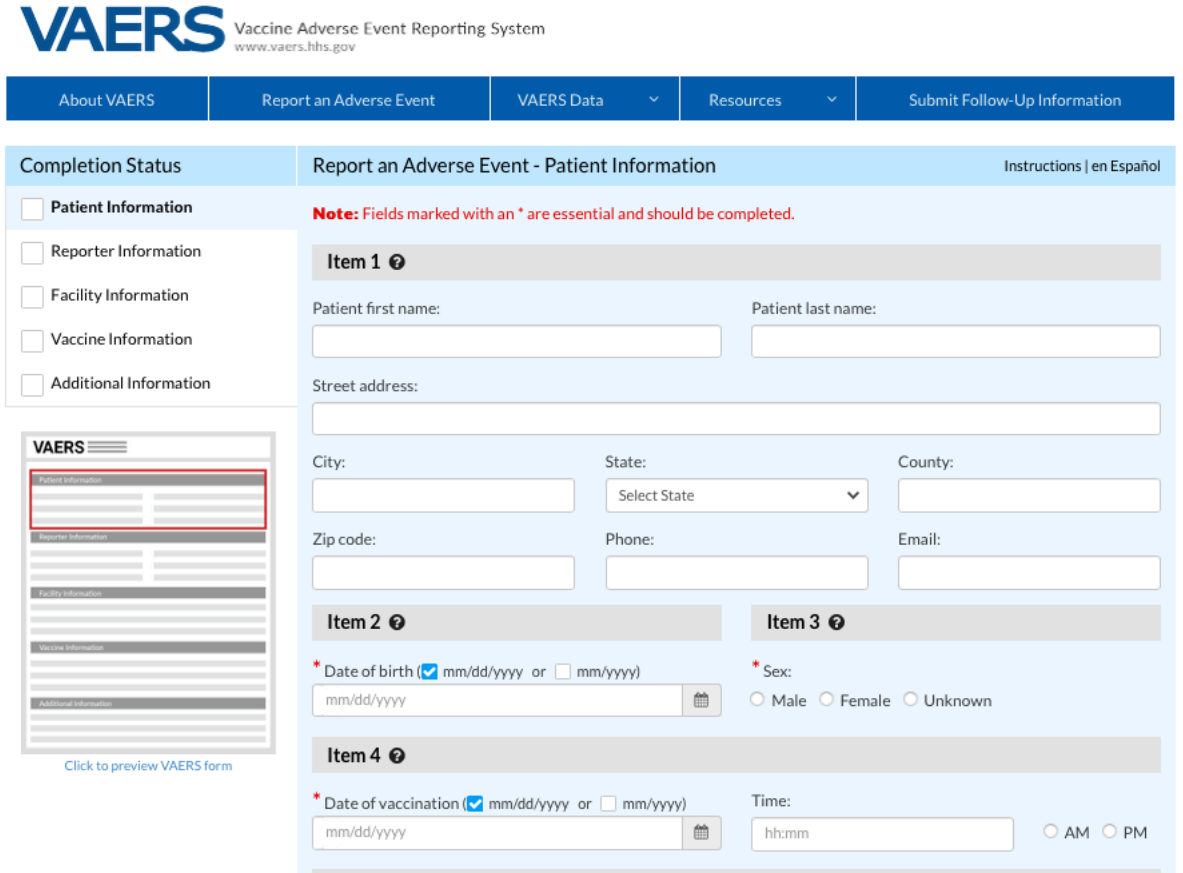


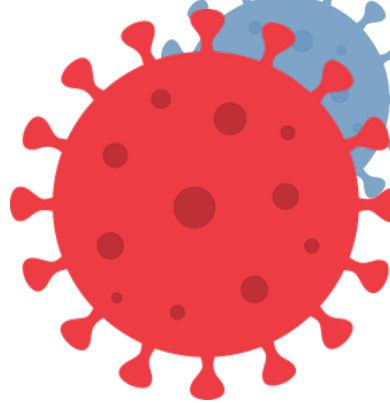
- There are two options to submit an adverse event to VAERS:
  1. Using the online report.
  2. Uploading and submitting a PDF form. This option enables you to begin documentation, save it, and finish it at a later time.



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.





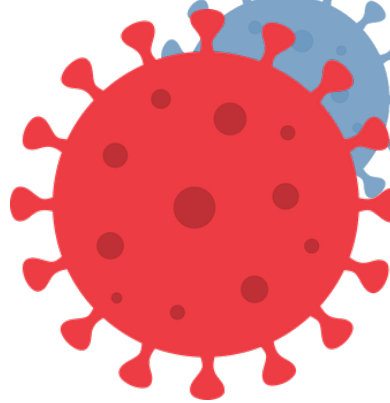
- When you get to the bottom of the screen, click the next button to move on to the next page.

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.

- 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.

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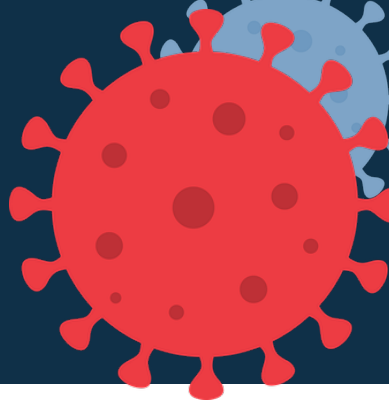
Prev

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.