# VAERS AWARE
# Practical Education for Healthcare Personnel

Ashley Grogg MSN-RN
The VAERS Project
Version 1
September 19th, 2022

The VAERS Project

# VAERS AWARE
# Practical Education for Healthcare Personnel

Ashley Grogg, MSN-RN
September 20, 2022

The purpose of this course is to provide the learner with relevant information on when and how to report to the Vaccine Adverse Event Reporting System (VAERS). This course is appropriate for all healthcare personnel.

After completing the course healthcare personnel can take pride in knowing they were part of creating a culture of safety, improving vaccine safety science, and an enduring faith in the methods in which adverse events are monitored.

### Learning Outcome
The learner will be able to describe what VAERS is, when and how to complete a report, and provide the patient with appropriate education and next steps.

### Learning Objectives
Upon completion of this course the learner will be able to:

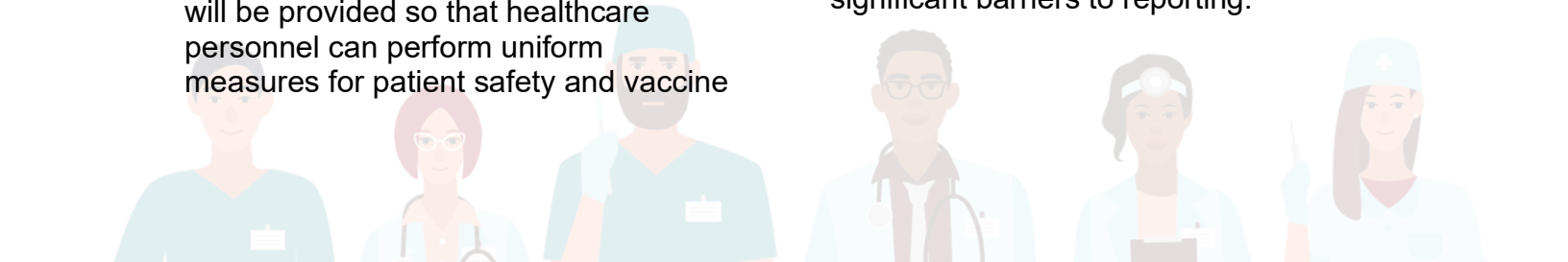
- define the purpose of VAERS
- define an Adverse Event
- discuss the importance of VAERS
- complete a VAERS report
- perform patient education on VAERS & reporting
- describe VAERS ESP

Please **STOP** and take the pretest found at VAERSproject.com prior to reading the educational materials below.

By completing the 5 minute VAERS pretest now and then a shorter posttest, learners will contribute to furthering the preliminary research initiated along with this education.

## Course Overview

This course material provides a thorough discussion on the Vaccine Adverse Event Reporting System (VAERS), its history, objectives, shortcomings, and barriers. Information will be provided so that healthcare personnel can perform uniform measures for patient safety and vaccine science. Clarification will be provided on what should be reported, how to make a report, along with a guide to provide patient education. Healthcare personnel will also be introduced to the VAERS Electronic Support for Public Health (ESP) as a potential solution to the most significant barriers to reporting.



# The VAERS Project

This educational material has been developed as part of the VAERS Project. The VAERS Project is a grassroots initiative driven by nurses in collaboration with a multidisciplinary team. The objective of VAERSproject.com is to provide widespread reliable education to healthcare personnel. The objective will produce an increase in correct reporting as well as a reduction in the taboos of discussing adverse events, adverse reactions, and injury with patients and peers.

The VAERS Project will continue to update data on VAERSproject.com and provide further resources as they become available. As part of the project, preliminary research was done to assess current knowledge of Healthcare Providers on VAERS. This research is ongoing. Results from the pretest and posttest of participants will continue to support and guide the VAERS Project. Results will periodically be updated on the website. Preliminary data validated the need for education. Most notable data points revealed by the research are as follows.

- Seventy-six percent (76%) of nurses who responded do not know where to file a VAERS report, despite sixty-eight percent (68%) of respondents claiming to have a working knowledge of VAERS in a previous question.
- Thirty percent (30%) of those who responded answered incorrectly when asked if healthcare providers were legally required to report certain AE.
- Thirty-five percent (35%) of nurses who responded have potentially cared for a patient who incurred a vaccine AR, and it was not reported or investigated.

Please note that the VAERS project aims to educate <u>all</u> healthcare personnel. Educating the interdisciplinary team will only assist in breaking down barriers to AE identification, treatment, and reporting, even though only 'healthcare providers' are legally required to make a VAERS report. "Healthcare Providers" as defined by the 1986 National Childhood Vaccine Injury Act (1986 NCVIA) "means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered."[14]

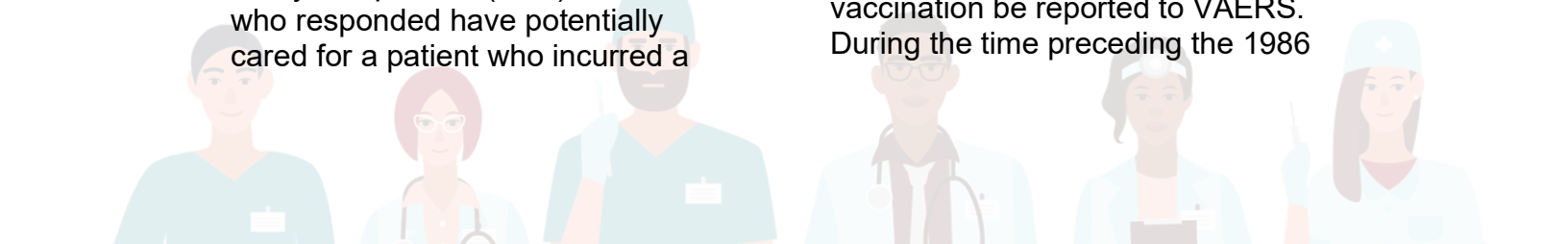
## What is VAERS?

### Understanding the basics:

VAERS is co-administrated by the Centers for Disease Control (CDC), the US Food and Drug Administration (FDA), and the Department of Health and Human Services (HHS) as "an early warning system monitoring for safety signals" related to vaccines after their release to the public.[1,2] It is a passive system and is dependent on patients, caregivers, and healthcare personnel to identify an adverse event (AE) and complete a report.[1,2]

### VAERS History

VAERS and the Vaccine Injury Compensation Program (VICP) was instituted in 1990 after the passage of the 1986 NCVIA. This Federal law requires that certain AEs occurring after vaccination be reported to VAERS. During the time preceding the 1986



NCVIA, vaccine manufacturers were facing large numbers of civil action due to vaccine injuries. As a result of their losses, the vaccine manufacturers met with government officials and reported that they would be unable to provide vaccinations for the national program if they continued to be held liable for injuries. Elected officials determined that vaccination shortages were a threat to the national vaccination program. To ensure the program continued, manufacturers and healthcare providers would no longer be liable for "side effects that were unavoidable."[3] Removal of liability was recognized as a conflict to ensure vaccine safety and the Department of Health and Human Services (HHS) was charged with ensuring the safety of vaccines thus creating VAERS. The removal of civil recourse for injury also resulted in the development of the VICP under subtitle 2 of the 1986 NCVIA. Under VICP petitions for compensation may be filed by those injured or by the family members of the injured or deceased. More information will be provided on VICP later in the course.

## VAERS Objectives

The primary objectives of VAERS are listed on the HSS website. The following are the primary objectives.[1]

- The detection of new, unusual, or rare vaccine adverse events.
- To monitor increases in known adverse events and identify potential patient risk factors for types of adverse events.
- Assess the safety of newly licensed vaccines.
- Recognize persistent safe-use problems and administration errors.
- To provide a national safety monitoring system that extends to the entire general population for response to public health emergencies, such as large-scale pandemic influenza vaccination programs.
- To determine and address possible reporting clusters such as those that may be localized temporally or geographically, or specific adverse event reporting related to certain products, batches, or lots.

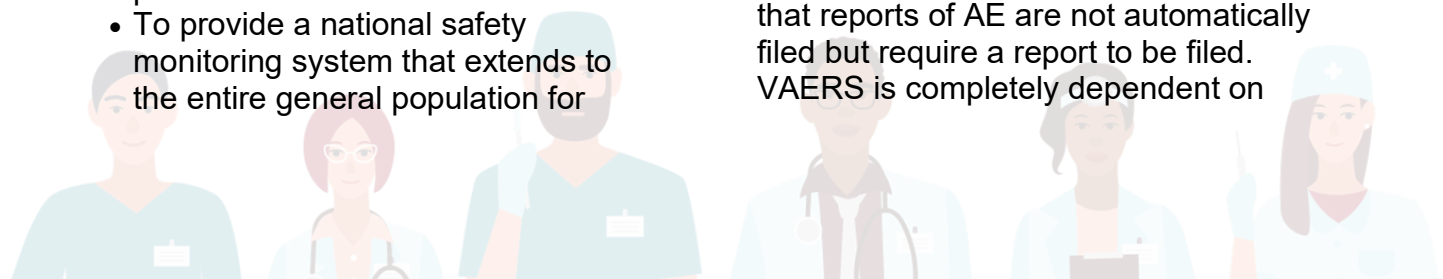
## Limitations

The objectives of VAERS are exceptionally important to ensure safety of vaccines administered to all children, pregnant women, and some adults across the nation. The program's potential strength of rapid detection of safety signals across the country is overshadowed and limited by the program's shortcomings.

VAERS receives heavy criticism for accepting reports from anyone including patients, caregivers, and other lay persons. Naysayers see this as an open door for inaccurate and unrelated reports to skew data. Others dismiss these statements due to the overall lack of knowledge of healthcare providers and lay persons surrounding the program.

Criticism around dilution of data may also be raised due to the encouragement of providers to report any health issue or concern that arises after vaccination. However, this is a vital part of the program. Within the larger population, symptoms or signs of rare or unexpected adverse events may only be detected as a result of this type of reporting.

VAERS is a passive system meaning that reports of AE are not automatically filed but require a report to be filed. VAERS is completely dependent on



individuals recognizing an AE. A hesitancy to complete reports due to misconceptions, lack of knowledge, and time constraints may all impede the program. A preliminary survey completed by the VAERS project revealed that some medical professionals have been discouraged from reporting to VAERS. Further, VAERS data is subject to provider or reporter bias including both under and over reporting.

Unfortunately, reports submitted are often incomplete, contain inaccurate information, and may be coincidental or unverifiable.[4,5] Statistics found in VAERS data cannot be relied upon as evidence of safety concerns until they are investigated. The program is not set up to complete follow-up reviews on all reports to validate information, which is a serious limitation for both validation or exclusion of a correlation between a vaccination and an AE. However, if a reaction is classified as serious, VAERS may request medical records.

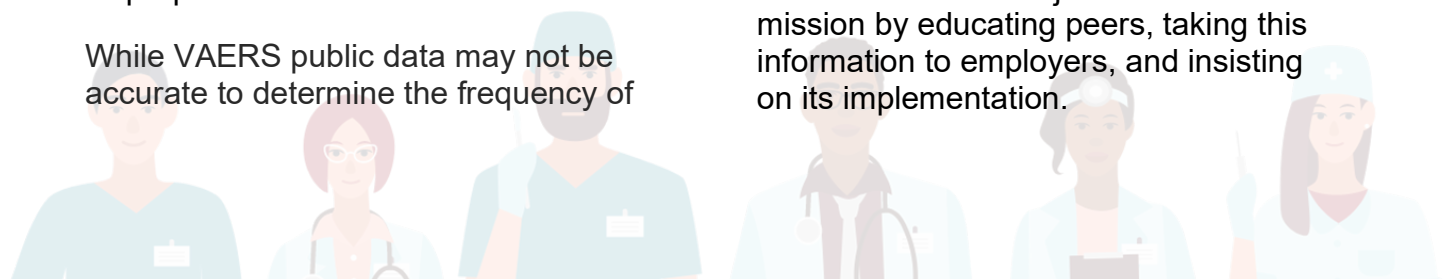
Despite these limitations, VAERS has been successful in identifying safety signals after licensing of a vaccination. For example, between 2006-2012 a signal was noted for the rotavirus vaccination. After further investigation it was confirmed that the rotavirus vaccine had an increased risk for intussusception clustering within 3-6 days post vaccination.[6] Though this side effect occurred within days after vaccination it still took 6 years of data and reporting to recognize, thus demonstrating the importance of VAERS and the need to ensure all healthcare personnel are educated on its proper use.

While VAERS public data may not be accurate to determine the frequency of an AE within the general population,[4,5] healthcare personnel should not take their first-hand experiences for granted. Medicine is practiced and refined, but never perfected.The scientific process relies on the practitioner's ability to critically think, hypothesize, test different theories, analyze, and then validate or disprove a theory. Conversations surrounding patterns of adverse events must take place. Practitioners should share these concerns with VAERS and other practitioners to determine if further inquiry is warranted.

## Barriers to reporting

The greatest barrier to VAERS reporting is the lack of knowledge surrounding the basics of who, what, why, when, where, and how to report. After reviewing this course, learners should feel more confident in accurately completing a report. Once learners understand the process, the next step to overcoming the overarching lack of knowledge is to educate peers. VAERS reporting is imperative to patient safety and the professional responsibility of all healthcare personnel. Therefore, VAERS education must be easily accessible to all healthcare professionals.

Healthcare personnel are an integral part of vaccine safety science. In order to provide a successful contribution, they must be VAERS aware. Learners can do their part by reporting and ensuring that their employer is providing this education to all employees. Healthcare personnel must band together to overcome the shortcomings of VAERS and ensure best practices are instituted across all areas of healthcare. Learners can aid Project VAERS in this mission by educating peers, taking this information to employers, and insisting on its implementation.



# The VAERS Project

Closing the knowledge gap is one barrier this course addresses, but like many other issues in healthcare, this is multifactorial. Some providers may be intimidated by VAERS reporting due to the undeveloped skill of efficient and effective report submission. VAERS reporting may be perceived as "optional" documentation due to the absence of formal and continuing education opportunities provided by employers, professional organizations, or the government entities overseeing the system. Trends of high patient volumes and increasing patient acuity or complexity may result in otherwise willing providers to view reporting as overwhelming and unnecessary in addition to standard charting responsibilities. The lack of value placed on VAERS may exacerbate the educational barrier, leading to speculation, doubt, and false suspicion of VAERS and its importance within the healthcare system. Preliminary results from the VAERS Project survey revealed 14% of the Indiana Nurses responding reported they were discouraged from completing a VAERS report. Aspects of this limitation should be further researched. Healthcare personnel must understand and champion proper VAERS reporting to ensure a culture of patient safety.

The tools provided in this course will assist in reducing the time it takes to complete a VAERS report. As with all charting, having the information at hand hastens the process. The goal of this education is to assist healthcare personnel in completing a report in 5-10 minutes. Achieving this goal while maintaining quality will aid in keeping pace with normal workflow, avoid losing work, and contribute to patient and vaccine safety.

Eventually, VAERS reporting will be done with a few clicks in the Electronic Medical Record (EMR), but until then learners will have the tools to ease the process. There will be more information provided about VAERS Electronic Support for Public Health (ESP) at the end of this course. VAERS ESP will have a profound impact on VAERS reporting by allowing it to be nearly instantaneous in some cases, requiring less work from the healthcare provider.

### What happens after a safety signal is detected?

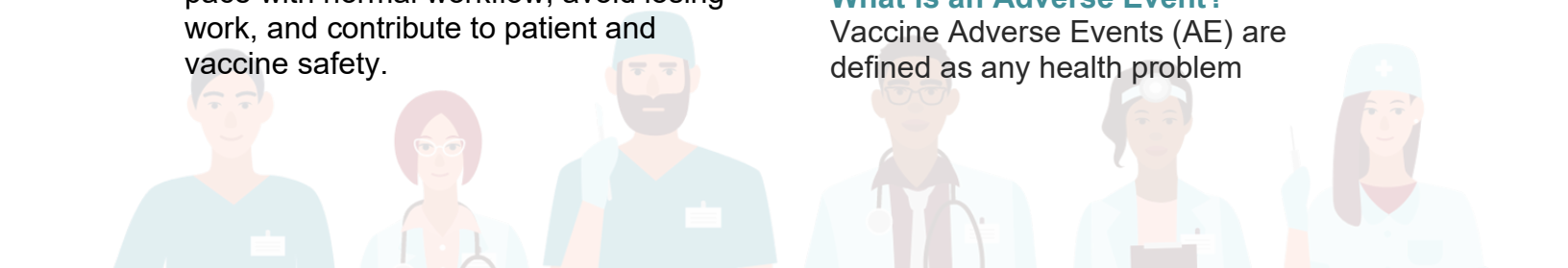
Once a safety signal, or hypothesis of risk, is detected in VAERS it can be further investigated in a network of other systems such as the Vaccine Safety Datalink (VSD) or Clinical Immunization Safety Assessment (CISA) Project administered by the CDC or via the FDA Biologics Effectiveness and Safety (BEST) system.[4,7,8] Unlike VAERS, these programs are conducted with a limited population. However, they are not dependent on spontaneous reports. Scientists and physicians can work together to research potential connections between safety signals and vaccinations. Each of these programs play a role in ensuring safety, but VAERS is the only system to monitor the entire population.

VAERS reporting is imperative to patient safety and is the professional responsibility of all healthcare personnel. Therefore, VAERS education must be easily accessible to all healthcare professionals.

## What to report?

### What is an Adverse Event?

Vaccine Adverse Events (AE) are defined as any health problem



happening at the time of or after a vaccination. AE may or may not be caused by the vaccination. They can be coincidental in timing.[9]

AE can be broken down into three classifications:[10]

1. Vaccine Adverse Reactions (VAR) are defined as being directly related to the vaccine, may be mild, moderate, or severe, and often called a side effect.
2. *Unrelated Health Problem* following vaccination, which would have occurred even if the individual did not receive the vaccination.
3. Health Problems with Unknown Cause, where there is not enough information to confirm or refute the vaccine as a cause.

The CDC & FDA request that any AE occurring after the administration of a vaccine be reported to VAERS.[10,11,12,13] As a reminder, the purpose of the VAERS database is to aggregate data regarding AE from across the entire US population. Submission of a report is not confirming that an AE can be attributed to a vaccine. This data may reveal rare, previously undetectable, or unexpected signals or safety concerns that warrant investigation to determine if they are related to a vaccine.[8,13]

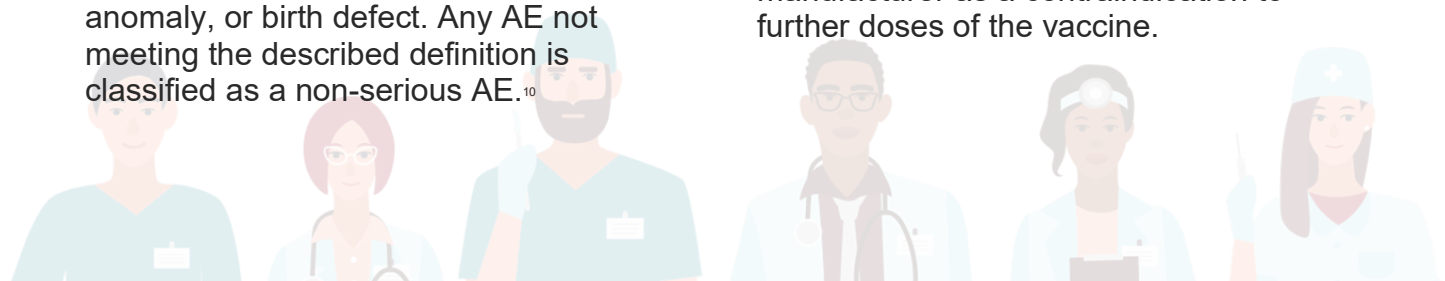
After an AE is reported, VAERS scientists break them down into two classifications: serious or non-serious. Serious AEs are given their definition from the Code of Federal Regulations and include events that result in death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly, or birth defect. Any AE not meeting the described definition is classified as a non-serious AE.[10]

## Legal Reporting Requirements

Conscientious healthcare providers may find it disconcerting to hear they are legally required to file VAERS reports, especially if they had not heard this before. Reviewing “RECORDING AND REPORTING OF INFORMATION” section 2125 of the 1986 NCVIA requires that healthcare providers report AE as described in the Vaccine Injury table or AE that are listed by the manufacturer as a contraindication to receiving further doses of the vaccination. The definition of “Healthcare Providers” as defined by the 1986 NCVIA “means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.[14]

In basic layman’s terms, a healthcare provider, for the purpose of reporting, includes any individual or entity who provides or administers vaccinations listed in the Vaccine Injury Table. Note that the requirement is not placed on the shoulders of an individual alone, but also on the organization. The failure or refusal to complete a VAERS report by one healthcare provider does not negate the legal responsibility of another. Each individual or entity holds an independent duty to report.

Again, required reporting includes any AE listed in the VAERS Table of Reportable Events Following Vaccination[15] that occurs within the specified time period after vaccinations or an AE listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.



Vaccinations included in the Table of Reportable Events Following Vaccination[15] at the date of this publication include: Chickenpox (Varicella), Diphtheria, Tetanus, and Pertussis, Haemophilus influenzae Type b (Hib), Hepatitis A & B, Human Papillomavirus (HPV), Influenza (Flu), Measles, Mumps, Rubella (MMR), Measles, Mumps, Rubella, Varicella (MMRV), Meningococcal Vaccines, Pneumococcal, Rotavirus, and any new vaccine recommended by the CDC for routine use in children.[15]

Table injuries and times vary from vaccine to vaccine and are subject to change. At the date of this publication table injuries include: anaphylaxis or anaphylactic shock, brachial neuritis, chronic arthritis, Guillain-Barré Syndrome, intussusception, encephalopathy, encephalitis, paralytic polio, shoulder injury, thrombocytopenic purpura, vaccine strain measles, vaccine strain polio, or vaccine strain varicella, vasovagal syncope, acute complications or sequelae, and any events described in the manufacturer's package insert as a contraindication to additional doses of the vaccine.[15] Review the Table of Reportable Events Following Vaccination for vaccine specific instructions. Contraindications of each vaccination must be obtained from the package insert. Please note, package inserts are different from Vaccine Information Statements distributed to patients. The package insert is found in the box with the vials. Providers may also find them by visiting the CDC website. Link available in the resources.

## Emergency Use Authorization

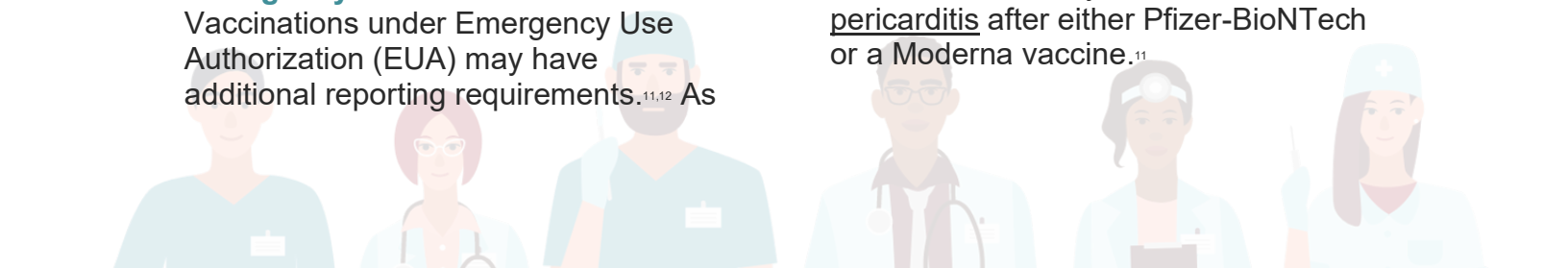
Vaccinations under Emergency Use Authorization (EUA) may have additional reporting requirements.[11,12] As time progresses these requirements may change. Prudent healthcare providers should check requirements often. It is best to submit any AE to ensure there is not a failure to report.

## COVID-19 Vaccinations

At present, the COVID-19 vaccines under EUA have several special considerations required by the FDA under provider agreements. They are provided below exactly as on the VAERS website:

- Administration errors, whether or not associated with an AE
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death
- Serious AEs including:
  - Death
  - A life-threatening AE
  - Inpatient hospitalization or prolongation of existing hospitalization
  - Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - Congenital anomaly/birth defect
  - An important medical event that, based on appropriate medical judgment, may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above[13]

Unfortunately, information for COVID reporting requirements provided on the VAERS website and the CDC website are not consistent. Additional reporting items as found on the CDC website include cases of myocarditis or pericarditis after either Pfizer-BioNTech or a Moderna vaccine.[11]



# The VAERS Project

### Monkeypox Vaccinations

Providers administering Monkeypox vaccines JYNNEOS or ACAM2000 under EUA are required to report to VAERS.[11] AE to be reported are provided below exactly as on the VAERS website:

- Vaccine administration errors, whether or not associated with an AE
- Serious AE (irrespective of attribution to vaccination)
  - Death
  - A life-threatening AE
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - A congenital anomaly/birth defect
  - An important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of cardiac events, including myocarditis and pericarditis
- Cases of thromboembolic events and neurovascular events[11]

As with all other vaccines, monkeypox vaccine administrators are also encouraged to report any clinically significant AEs, whether or not they think the vaccination caused the AE.

### Requested Reporting

Healthcare providers are requested to report administration errors as well as any other clinically significant AE that occurs after vaccination. This is a wide-open request, and for good reason. As mentioned previously, the purpose of VAERS is to aggregate data regarding AEs from across the entire US population. The submission of a report is not confirming an AE can be attributed to a vaccine. Rather, this data may reveal rare, previously undetectable, unexpected signals, or safety concerns that warrant investigation to determine if they are related to a vaccine.[9,13] If diligent providers had not heeded this request, the connection between intussusception and the rotavirus vaccination may not have been made. The knowledge of side effects may impact the risk-benefit analysis for some families and recommendations for small groups of susceptible patients. Once this subset of patients is identified, their health care provider can inform them with additional education, follow-up care, and early treatment for impacted patients.

## How to make a report

### Making a VAERS Report

VAERS reports can be made by visiting **vaers.hhs.gov** then selecting “Report an Adverse Event.” Reporters can choose between the online submission form or downloading the PDF version. Reports should be made as soon as an AE is identified and information needed can be obtained. It may be helpful to keep copies of PDF report forms or quick reference guides readily available so practitioners can easily access and begin collecting information with the patient at the time of initial finding.

A VAERS report contains 5 sections which includes information on the patient, reporter, facility, vaccine, and any additional information that might be helpful to VAERS staff. The forms do not have to be completed in their entirety. However, it is helpful to add as

much information as possible in order to validate reports. It is important to note that the online submission form times out after 20 minutes on the same page. When completing an online form it will be important to have details ready to input to avoid losing work.

## Essential Facts

Required information is marked on each version of the forms. The online form prohibits advancing unless a reporter has completed all required fields. The PDF version has a list of required fields highlighted in yellow at the top of the form as well as on the individual questions. Reporters must be able to provide patient details such as date of birth, sex, date and time of vaccination, along with the date and time the AE started, and age of the patient at vaccination. The date of birth requests "months" and this is to be used for children under the age of two. If a reporter is unsure about exact dates or times of vaccination or AE, the instructions from the VAERS PDF form encourage using the best guess or leaving the space blank. It is strongly encouraged to add as much information as possible. Reporters may use month and year for the date and AM or PM for the time rather than leaving the entire section blank.

Required information about the vaccination includes which vaccinations were given on the same date. It is important to include as much information as possible on the vaccine type, brand, manufacturer, lot number, route, body site, and dose number in the series if applicable.

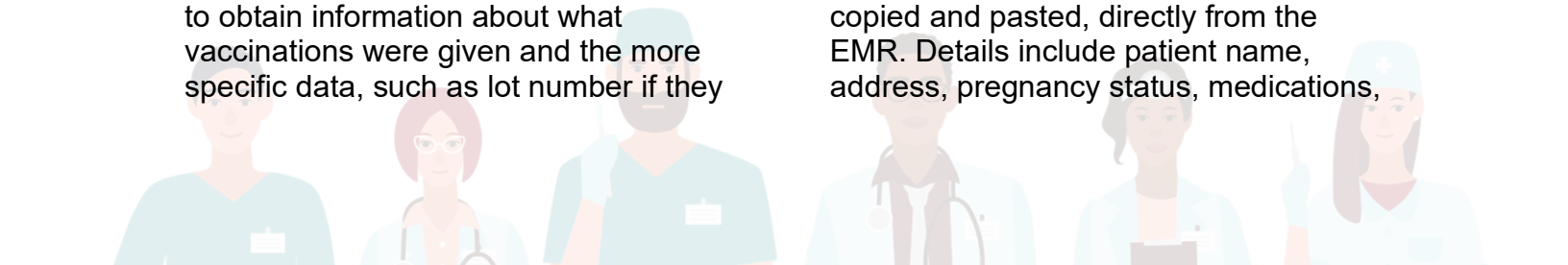
Reporters may be concerned about how to obtain information about what vaccinations were given and the more specific data, such as lot number if they were not provided at that facility where the AE was recognized. Ideally, patients would be provided with this information. However that is not required at this time. Many healthcare professionals are not aware that most states have vaccination registries that are connected to healthcare provider networks. Reporters may be able to access these systems through electronic medical records (EMR), like Epic. Employer specific information may be gathered from administration or IT. If unable to access state registries, reporters may be able to obtain vaccination information by contacting the facility where the vaccine was administered or working with the local health department. Of course these options may be more time consuming.

Finally, reporters will add details about the AE and the patient disposition. The more information that can be added to the narrative about the AE is helpful for investigation of adverse events. Patient disposition includes type of treatment, follow up, and permanent injury if applicable. Much of this can be gathered from the patient's history and physical (H&P) or the visit summary. Obviously, reviewing the report forms with a patient is ideal, but isn't always practical.

## Requested, but not required.

All information on the report is important however it is not all required. Detailed reporting allows VAERS scientists and doctors to better investigate safety signals. It is strongly encouraged to complete the forms in their entirety.

Requested information includes more detail about the patient. The additional information can often be found, or even copied and pasted, directly from the EMR. Details include patient name, address, pregnancy status, medications,



allergies, other illnesses up to one month prior to vaccination, and chronic health conditions. It is important to note that VAERS keeps all identifying information confidential. It is **not** a violation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule for healthcare personnel to provide this information.[16]

The VAERS report also asks for information about the individual reporting the adverse event including the name, relationship to the patient, address, and contact information. This information is used to send a confirmation letter. VAERS only contacts the reporter if required information is missing from the report or for more information regarding a serious AE. Contact will only occur via a letter or email based on the reporter's preference. VAERS will not contact reporters via phone.[12]

If the reporter is not the provider treating the patient for an AE, the treating provider's information should also be included in case additional information is required. The next section covers the facility of vaccine administration including the name, address, fax, phone, and type of facility. These types of questions can help identify administration or geographic concerns.

Information about lab tests or diagnostics used to treat the patient for the AE should be provided, along with a statement stating whether or not the patient has recovered from the AE or is requiring further care. The last section asks for additional information including other vaccinations given within 1 month prior to the date of vaccination, previous adverse events, and the patient's race. Additional questions only apply if the patient is being treated by the U.S. Military or the Department of Defense. Military questions include service status and if vaccination was provided at a Department of Defense site.

The list of information for a report may seem daunting. However, it can be quickly obtained using the patient record. If issues arise while completing a VAERS report, they can be contacted via a toll-free information line available Monday through Friday 8:30 AM to 8:00 PM Eastern Standard Time by calling 1-800-822-7967, or via email at info@vaers.org. The PDF report also has detailed instructions for each question on the last two pages of the file.[17]

Finally, if more information becomes available or the patient has a change in condition, reporters can follow up with VAERS after the initial report. To add more information, reporters can contact VAERS via e-mail at info@vaers.org. In the communication, reporters should notify VAERS that they would like to add additional information to a case and include a VAERS ID or E-number for reference. Only one is needed. This is why maintaining a record of the confirmation number in the patient's permanent record is vital. Once access is granted to the Upload Tool, reporters may upload up to 3 documents per session including files like *.doc, .pdf, .jpeg, etc*. Once files are uploaded, the reporter will receive a confirmation at the end of submission. If a reporter needs to add more information, they may contact VAERS to request additional access to the Upload Tool.[18]

The VAERS Project

# Patient Education on VAERS

Completing thorough patient education by a novice reporter may prove to be intimidating. Although VAERS & AE reporting are complex topics, it does not have to be difficult. Follow this simple outline to get started.

## What should I tell patients about VAERS?

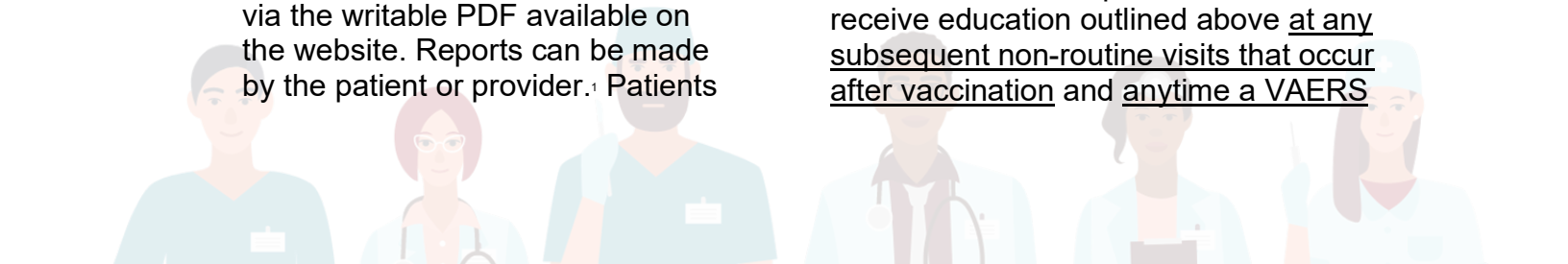
Start with a basic overview including the definition. Add facts about the purpose, what to report, and how to report.

1. VAERS is a passive national vaccine adverse event reporting system. Patients, caregivers, and providers should use VAERS to report any adverse event following vaccination. Scientists and physicians will review the data and monitor for safety signals.[1]
2. VAERS is a vital part of vaccine safety science. Even though vaccines go through rigorous clinical studies, there are some adverse events that are only detectable after introduction into the general population. VAERS is also the only system in place that can detect rare bad batches of vaccines that may be more likely to cause an AE or injury. The detection of batch specific issues can result in pulling the batch or improving manufacturing or handling conditions which will decrease the risk to patients and improve safety across the nation.[1]
3. Any health event occurring after vaccination is to be reported to VAERS online via vaers.hhs.gov or via the writable PDF available on the website. Reports can be made by the patient or provider.[1] Patients should ask for a copy of the report including a confirmation number.
4. If the patient is not provided with a copy of the report and would like one they can obtain it through the CDC VAERS WONDER website if they have a confirmation number. Patients may also contact VAERS at (800) 822-7967 or info@vaers.org. Patients desiring more information than what is available on CDC WONDER may be able to contact the FDA or submit a Freedom of Information Act (FOIA) request.[2]
5. Only one report should be made per AE. Patients should follow up with the treating provider or vaccination site to verify if a report has been or will be made. If more than one report is made by accident, VAERS staff will pair them and only one of the reports will be visible in the public data. Patients and providers may submit more information even after a report is made.[4]

## When should you provide education on VAERS?

Education on VAERS should be provided to every patient *prior* to vaccination. The Vaccine Information Statement (VIS) is legally required to be distributed with many vaccines.[19] The VIS contains a small section on VAERS reporting under number five (5) titled "What if there is a serious problem." Patients may not understand what a "serious problem" is. Further, the CDC requests that AEs be reported. These instructions are inconsistent and should be explained to the patient or caregiver.

In addition to providing education at the time of vaccination, patients should receive education outlined above at any subsequent non-routine visits that occur after vaccination and anytime a VAERS



report is completed. If the healthcare professional has completed a VAERS report on behalf of the patient, they should be provided with the confirmation number, a copy of the report, and given follow-up care information.

Healthcare personnel should facilitate early treatment and follow up to mitigate the risk of long-term impacts on the patients health. If the individual completing the VAERS report is not the primary care physician (PCP) or pediatrician, the individual completing the report should notify the PCP or pediatrician with the patient's permission. Some states may have laws that already require this step be taken. The patient should also be educated on the importance of adding the AE and VAERS report information to their permanent record with their other providers.

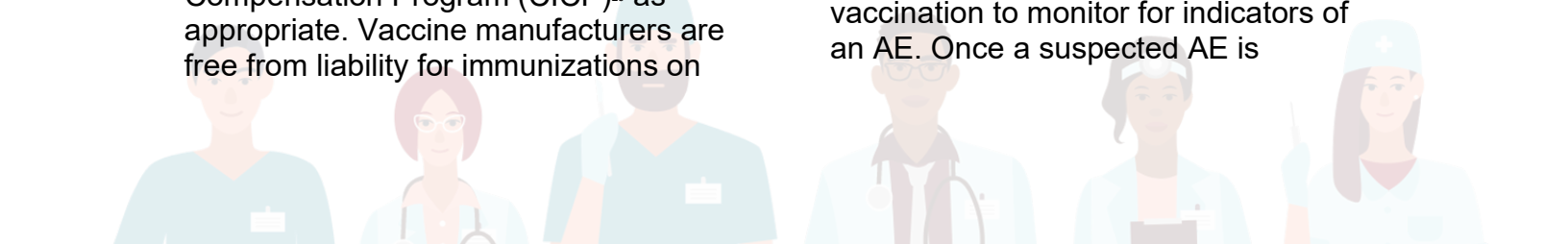
When providing education to patients, be clear on the terminology. A **vaccine adverse EVENT (VAE)** is any health condition that arises after vaccination. This term is synonymous with AE. A **vaccine adverse REACTION (VAR)** can be directly attributed to the vaccine. It is important to note that both of these circumstances should be reported to VAERS.[10] Either way, it is not the responsibility of the reporter to prove causation or even correlation with the vaccination. VAERS is simply to detect safety signals, which can be investigated by scientists.

Patients who have experienced a serious vaccine adverse reaction should be provided with information on the Vaccine Injury Compensation Program (VICP)[3] or the Countermeasure Injury Compensation Program (CICP)[20] as appropriate. Vaccine manufacturers are free from liability for immunizations on the childhood schedule. Timely education on VICP/CICP is imperative. VICP claims must be filed as early as 2 years after injury or death and CICP claims must be filed within one year of vaccine administration. Injuries as a result of qualifying vaccines may be reimbursable through the VICP.[3] However, vaccinations under emergency use authorizations do not qualify for the VICP and patients will need to submit with the CICP.[20] More information on VICP and CICP will be provided later in the course.

## Solution VAERS ESP

While shortcomings exist in the current VAERS system, one solution lies in VAERS application of ESP, or Electronic Support for Public Health. ESP is defined on www.esphealth.org as “an open-source software platform that organizes and maps electronic health record data, analyzes the data for conditions of public health interest, and can transmit either case reports or aggregate summaries to health departments.”[21] That means that this program can be obtained freely by anyone and implemented to recognize certain patterns in public health. In short, ESP was developed by Harvard Medical School through a collaboration with the Massachusetts Department of Public Health, is free for anyone to use, and is compatible with any EMR that can download data. The technology was supported by the CDC, NIH, and the Office of the National Coordinator for Health Information Technology.[22]

ESP utilizes data points including vital signs, lab values, hospitalizations, and ER visits for a set time frame after vaccination to monitor for indicators of an AE. Once a suspected AE is



identified, the software can either file an automatic report with VAERS or it will send a message to the provider for confirmation. If the provider agrees an AE occurred, a report will be sent to VAERS. Automation in VAERS reporting has been tested and shown to be successful.[23,34]

VAERS ESP was implemented in MetroHealth of Cleveland, OH from 2012-2013. VAERS ESP utilized algorithms to identify potential AEs, then sent automated messages to providers for follow-up. The system also automatically reported low acuity events to VAERS. Overall, the project boasted a 30-fold increase in VAERS reporting with most clinicians reporting automated messages as helpful.[23] More information about the applications of ESP can be found at esphealth.org, including VAERS ESP.

Benefits of VAERS ESP include automation, security, and most importantly it is free of charget.[21] The program has also been shown to be user-friendly, since it automatically reports low acuity AE, it decreases the data entry time for the provider. ESP resulted in 30x more VAERS reports,[23] providing much needed post market data on vaccination to determine if there is any causality of the vaccination on the AE. Most clinicians stated that the messages were helpful and did not impede workflow.[23] Widespread implementation of VAERS ESP may increase confidence in vaccine safety science and remedy the greatest pitfall of VAERS, which is the need for patients and healthcare personnel to spontaneously report AE.

Astute healthcare personnel are probably asking, “How do we get access to this program?” Individuals will need to approach their employer's administration and provide them with this education. Employers may be reluctant to expend time and energy into a program that, at face value, does not provide return on investment. The individual will need to educate the employer on how this program will not only satisfy the legal obligations of VAERS reporting, but it will also improve provider workflow, save time, and improve patient outcomes by early identification of suspected AE or injury. All medical professionals know and understand the earlier a patient can be diagnosed and begin treatment, the less severe the symptom burden and the better the long term patient outcomes. Some side effects may be unavoidable. However, early treatment can have a significant impact on the patient. Patient safety is the number one priority, but contributions to vaccine safety science and confidence are added benefits.

While VAERS ESP will undoubtedly alleviate some of the burden on health care personnel, it is important to remember the tool is not perfect. Healthcare providers will need to remain vigilant and continue to monitor for AE even in the presence of VAERS ESP. VAERS ESP only monitors for a specified time after vaccination, and due to the potential of delayed AE or a delay in the detection of an AE, it is imperative that providers are not dependent on this tool. Remember, VAERS is designed to identify safety signals as a means to augment clinical trial findings as well as monitor for discrepancies in batches post market. Healthcare providers must not become complacent.

# Additional information

### What is the Vaccine Injury Compensation Program?

The 1986 NCVIA removed liability from the manufacturers of vaccines added to the childhood schedule and those given to pregnant women.[3] As a result, the Vaccine Injury Compensation Program (VICP) was created as an alternative to civil litigation. A list of covered vaccinations can be found on the VICP website.[3] The program is funded by a $0.75 excise tax charge for each antigen included in vaccinations recommended for routine administration to children and pregnant women by the CDC. Vaccinations like pneumococcal are $0.75 and those with more than one antigen like the DTaP, which contains three, are $2.25.[25]

In order for an individual to receive compensation, they must file a petition with the Department of Health and Human Services within the following time frames:

- **Injury**: within **three years after the first symptom** or manifestation of onset or of the significant aggravation of the injury;
- **Death**: within **two years of the death and within four years of the first symptom** or manifestation of onset or of the significant aggravation of the injury from which the death resulted;
- **Certain Vaccine Injury Table (Table) changes**: **two years from the date** of the Table change for injuries or deaths that occurred **up to eight years before the Table change**. A Table change includes new vaccines or injuries added to the Table or other changes to the Table, if the revision makes a petitioner eligible to seek compensation or significantly increases the likelihood of a petitioner obtaining compensation.
- **The Court** may extend a deadline using equitable tolling in very limited circumstances.

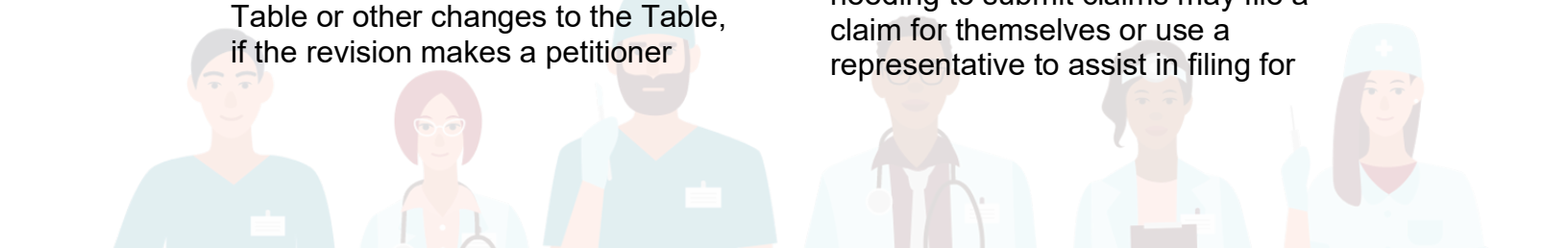
If a petition prevails, the VICP court typically awards reasonable attorneys' fees and other legal costs.[25] The VICP website contains more information on filing a claim.

### What is the Countermeasure Injury Compensation Program?

Much like vaccine manufactures covered in VICP, manufacturers of countermeasures are exempt from liability. CICP is in place to allow an avenue for compensation for those injured by countermeasures. A countermeasure is a vaccination, medication, device, or other item recommended to diagnose, prevent or treat a declared pandemic, epidemic, or security threat.

The following vaccines and medications may fall under this program in the event of an injury: COVID-19 (may include: remdesivir, baricitinib, monoclonal antibodies, ventilators, invasive testing, N-95, surgical masks, cloth masks, etc), Marburg, Ebola, Nerve Agents and Certain Insecticides (Organophophorus and/or Carbamate), Zika, Pandemic Influenza, Anthrax, Acute Radiation Syndrome, Botulinum Toxin, and Smallpox.[20]

CICP claims must be filed within one year from the date the countermeasure was administered.[20] Injury claims may be filed on the HRSA website. Individuals needing to submit claims may file a claim for themselves or use a representative to assist in filing for



medical and/or lost employment income benefits. A representative may be a parent or guardian of a minor child, a spouse, a family member (e.g. sibling or adult child), an attorney, or any other legal or personal representative capable of filing for benefits such as a power of attorney. This program does not reimburse for attorney fees.[20]

## Conclusion

In conclusion, the VAERS is an integral part of patient safety and vaccine science. Though it has its fair share of shortcomings and barriers, many of these issues can be addressed through education programs like this one and the use of VAERS ESP. As the VAERS Project continues to sweep the nation, healthcare personnel can take pride in knowing they were part of creating a culture of safety, improving vaccine safety science, and an enduring faith in the methods in which adverse events are monitored.

Please **complete the posttest** found on VAERSproject.com.

This condensed 1 page version of the pretest will help improve future versions of this material.

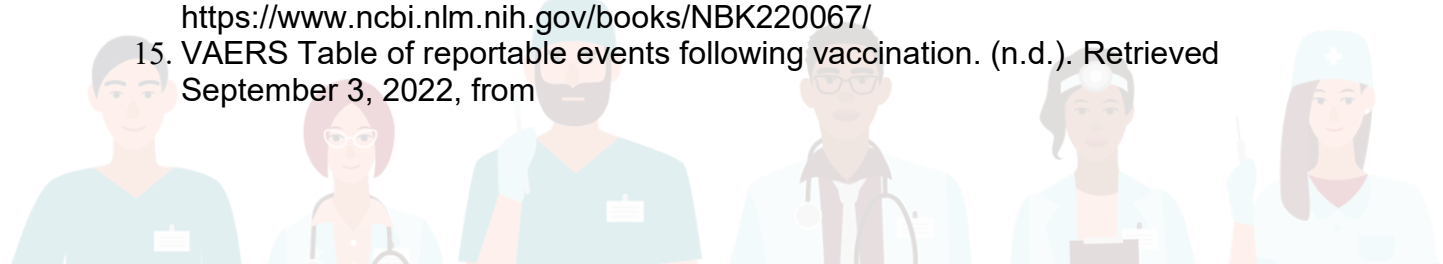
## Acknowledgements

This project and educational material would not have been possible without the extensive support of editors and volunteers. With greatest and most heartfelt thanks I would like to extend appreciation to:

Angela D.
Becca L. RN
Rebecca B. PA-C
Amber D. NP-C
Mary S. PT
Charles G.

## References


1. Vaccine Adverse Event Reporting System. (n.d.). About VAERS: Background and Public Health Importance. Retrieved September 3, 2022, from https://vaers.hhs.gov/about.html
2. VAERS. (n.d.). Frequently Asked Questions (FAQs). Retrieved September 3, 2022, from https://vaers.hhs.gov/faq.html
3. Health Resources & Services Administration. (September 2022). National Vaccine Injury Compensation Program: How Does the VICP work. Retrieved September 3, 2022, from https://www.hrsa.gov/vaccine-compensation
4. Vaccine Adverse Event Reporting System. (n.d.). VAERS Data. Retrieved September 3, 2022, from https://vaers.hhs.gov/data.html
5. Centers for Disease Control and Prevention. (Sept 2022). Vaccine Adverse Event Reporting System (VAERS): Strengths and Limitations of VAERS Data. Retrieved September 3, 2022, from https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html
6. Haber, P., Patel, M., Pan, Y., Baggs, J., Haber, M., Museru, O., Yue, X., Lewis, P., Destefano, F., & Parashar, U. D. (2013). Intussusception after rotavirus vaccines reported to US VAERS, 2006-2012. Pediatrics, 131(6), 1042–1049. https://doi.org/10.1542/peds.2012-2554
7. Centers for Disease Control and Prevention. (August 2022). Vaccine Safety Monitoring. Retrieved September 3, 2022, from https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/index.html
8. Centers for Disease Control and Prevention. (August 2022). Vaccine Safety Partners. Retrieved September 3, 2022, from https://www.cdc.gov/vaccinesafety/ensuringsafety/partners/index.html
9. Shimabukuro, T. T., Nguyen, M., Martin, D., & DeStefano, F. (2015). Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). Vaccine, 33(36), 4398–4405. https://doi.org/10.1016/j.vaccine.2015.07.035
10. Centers for Disease Control and Prevention. (March 2021). Understanding Adverse Events and Side Effects. Retrieved September 3, 2022, from https://www.cdc.gov/vaccinesafety/ensuringsafety/sideeffects/index.html
11. Centers for Disease Control and Prevention. (2022, September 8). Reporting Adverse Events Following Vaccination. Retrieved September 9, 2022, from https://www.cdc.gov/vaccinesafety/hcproviders/reportingadverseevents.html
12. VAERS. (n.d.). Report an Adverse Event to VAERS. Retrieved September 3, 2022, from https://vaers.hhs.gov/reportevent.html
13. Center for Biologics Evaluation and Research. (2021, August 12). VAERS Overview. U.S. Food and Drug Administration. Retrieved September 3, 2022, from https://www.fda.gov/vaccines-blood-biologics/vaccine-adverse-events/vaers-overview
14. Institute of Medicine (US) Committee on Review of Priorities in the National Vaccine Plan. Priorities for the National Vaccine Plan. Washington (DC): National Academies Press (US); 2010. Appendix C, 1986 National Childhood Vaccine Injury Act (Public Law 99-660) Available from: https://www.ncbi.nlm.nih.gov/books/NBK220067/
15. VAERS Table of reportable events following vaccination. (n.d.). Retrieved September 3, 2022, from

https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf
16. VAERS. (n.d.). Privacy Policies & Disclaimers: The HIPAA Privacy Rule. Retrieved September 3, 2022, from https://vaers.hhs.gov/privacy.html
17. VAERS. (September 2022). VAERS Writable PDF. Retrieved September 3, 2022, form https://vaers.hhs.gov/uploadFile/index.jsp
18. VAERS. (September 2022). Submit Follow-Up Information. Retrieved September 3, 2022, form https://vaers.hhs.gov/autoupload.html
19. Centers for Disease Control and Prevention. (December 2021.). Vaccine Information Statements (VISs). Retrieved September 3, 2022, from https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html
20. Health Resources & Services Administration. (November 2020). Countermeasures Injury Compensation Program (CICP), Retrieved September 3, 2022, from https://www.hrsa.gov/cicp
21. Electronic Support for Public Health. (n.d.). What is it. Retrieved September 3, 2022, from, https://www.esphealth.org/
22. Electronic Support for Public Health. (n.d.). About us. Retrieved September 3, 2022, from, https://www.esphealth.org/contact
23. Baker, M.A., D.C. Kaelber, D.S. Bar-Shain, P.L. Moro, et al., Advanced Clinical Decision Support for Vaccine Adverse Event Detection and Reporting. Clin Infect Dis, 2015. 61(6): p. 864-70.
24. Lazarus R. Electronic Support for Public Health - Vaccine Adverse Event Reporting System (ESP:VAERS) - Final Report. (Prepared by Harvard Pilgrim Health Care, Inc. under Grant No. R18 HS017045). Rockville, MD: Agency for Healthcare Research and Quality, 2010.
25. Health Resources & Services Administration. (September 2022). About the National Vaccine Injury Compensation Program: What is the Vaccine Injury Trust Fund?. Retrieved September 3, 2022, from https://www.hrsa.gov/vaccine-compensation/about

# The VAERS Project

## Resources:

Esphealth.org

Vaccine package inserts found at
https://www.cdc.gov/vaccinesafety/vaccines/index.html

Found on VAERSproject.com

- Quick Reference guide for reporting
- Quick Reference guide for patient education
- Patient education hand out
- Preliminary Survey Results

## Definitions

Ordered as they appear in text

**VAERS Project** a grassroots initiative driven by nurses in collaboration with a multidisciplinary team. The objective of VAERSproject.com is to provide widespread reliable education to healthcare personnel. The objective will produce an increase in correct reporting as well as a reduction in the taboos of discussing adverse events, adverse reactions, and injury with patients and peers. Information and resources may be found by visiting VAERSproject.com. The VAERS Project has no association or affiliation with VAERS, the CDC, FDA, or NIH.

**VAERS** VAERS is co-administrated by the Centers for Disease Control (CDC), the US Food and Drug Administration (FDA), and the Department of Health and Human Services (HHS) as “an early warning system monitoring for safety signals” related to vaccines after their release to the public.[1,2] It is a passive system and is dependent on patients, caregivers, and healthcare personnel to identify an adverse event (AE) and complete a report.[1,2]

**Safety Signal** a hypothesis of risk

**Vaccine Adverse Events (AE)** any health problem happening at the time of or after a vaccination. AE may or may not be caused by the vaccination. They can be coincidental in timing.[9]

1. Vaccine Adverse Reactions (VAR) are defined as being directly related to the vaccine, may be mild, moderate, or severe, and often called a side effect.
2. *Unrelated Health Problem* following vaccination, which would have occurred even if the individual did not receive the vaccination.
3. Health Problems with Unknown Cause, where there is not enough information to confirm or refute the vaccine as a cause.

**Healthcare Providers** defined by the 1986 NCVIA "means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.[14]

**Table injuries** Injuries or reactions found on the Table of Reportable Events Following Vaccination[1]

## Abbreviations

| | |
|---|---|
| 1986 NCVIA | 1986 National Childhood Vaccine Injury Act |
| AE | Adverse Event (AE) *Used interchangeably with VAE |
| BEST | Biologics Effectiveness and Safety |
| CDC | Centers for Disease Control |
| CICP | Countermeasure Injury Compensation Program |
| CISA | Clinical Immunization Safety Assessment |
| EMR | electronic medical records |
| ESP | Electronic Support for Public Health |
| EUA | Vaccinations under Emergency Use Authorization |
| FDA | US Food and Drug Administration |
| HHS | Department of Health and Human Services |
| VAE | Vaccine Adverse Events *Used interchangeably with AE |
| VAERS | Vaccine Adverse Event Reporting System |
| VAR | Vaccine Adverse Reactions |
| VICP | Vaccine Injury Compensation Program |
| VICP | Vaccine Injury Compensation Program |
| VIS | Vaccine Information Statement |
| VSD | Vaccine Safety Datalink |

# The VAERS Project

## Making a VAERS Report

**Who:** Patients, caregivers, and healthcare professionals.

**When:** When adverse events (AE) are suspected. Consider reporting non-routine appointments after vaccination.

**Why:** To satisfy the request of CDC/FDA, legal requirements, and to ensure highest level of vaccine safety.

**What:** Any clinically significant adverse event occurring after vaccination.

**How:** Gather needed information, visit **VAERS.HHS.GOV,** and use the online tool or downloading the writable PDF.

## Gather Information

### Required Fields:

**Patient Date of Birth:** _____ **Patient Sex:** ❑ Male ❑ Female ❑ Unknown

**Date & Time of Vaccination:** _____

**Date & Time AE Started:** _____

**Age at Vaccination:** _____
(list age in months if under two years)

} If unknown provide best guess. Time may simply be AM or PM.

**List All Vaccinations Given** (Route is HOW vaccine was given, Body site is WHERE vaccine was given)

| Vaccine (Type/Brand Name) | Manufacturer | Lot Number | Route | Body site | Dose # in series |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**Describe the adverse event(s), treatment, and outcome(s), if any:** (symptoms, signs, time, course, etc.
If using the online form, you may be able to copy and paste details from the electronic record)

**Result or outcome of adverse event(s):** (Check all that apply)

❑Doctor or other healthcare professional office/clinic visit

❑ Emergency room/department or urgent care visit

❑ Hospitalization: Number of days (if known) _____
Hospital name: _____
City: _____ State: _____

❑ Prolongation of existing hospitalization (vaccine received during existing hospitalization)

❑ Life threatening illness (immediate risk of death from the event)

❑ Disability or permanent damage

❑ Patient died – Date of death: _____

❑ Congenital anomaly or birth defect

❑None of the above

### Additional Fields:

Many of these fields can be copied directly into the VAERS report from the electronic record.

**About the Patient:**

❑ Street Address

❑ Phone

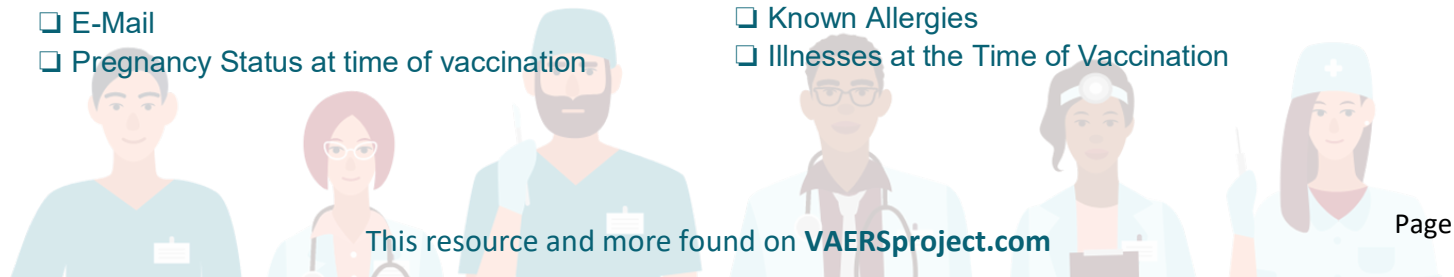
❑ E-Mail

❑ Pregnancy Status at time of vaccination

❑ Prescriptions, OTC, Supplements, Herbs at the time of vaccination

❑ Known Allergies

❑ Illnesses at the Time of Vaccination



# The VAERS Project

**About the Person Completing the Form:**

- ❑ Name
- ❑ Relation to the Patient
- ❑ Street Address
- ❑ Phone
- ❑ E-Mail
- ❑ Name & Phone of the Best Doctor/Healthcare Professional to Contact About the AE.

**Information About the Facility Where The Vaccine was Given:**

- ❑ Facility/Clinic Name
- ❑ Fax
- ❑ Street Address
- ❑ Phone
- ❑ Type of Facility

**Additional Information**

Any Other Vaccinations Given Within One Month:

| Vaccine (Type/Brand Name) | Manufacturer | Lot Number | Route | Body site | Dose # in series |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

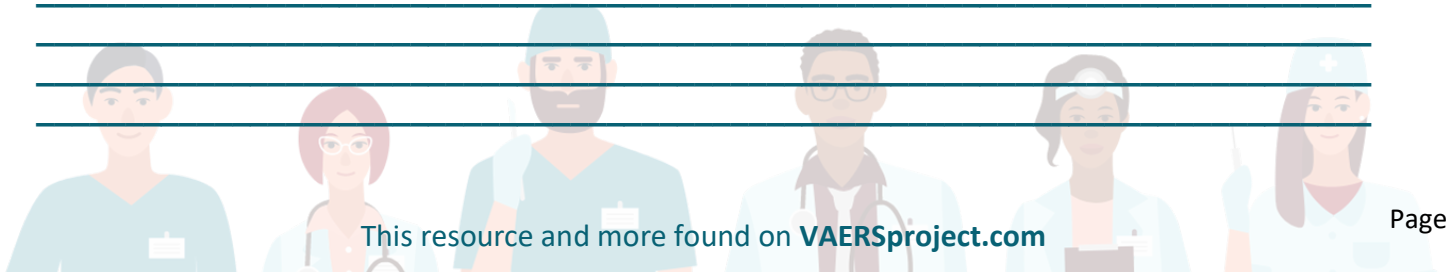
❑ Has the Patient Ever had an AE Following Any Previous Vaccines?
(If yes, describe AE, Pt Age at vaccination, Vaccination Date, Type & Brand Name.)

❑ Patient's Race

**After the Report is Completed**

- ❑ Report Confirmation Number: _____
- ❑ A Copy of the Report & Confirmation Number Placed on the Patient's Permanent Record
- ❑ The Patient has been Educated:
  - ❑ On VAERS & the Report
  - ❑ On VICP/CICP as Appropriate
  - ❑ Only One Report Should be Made
  - ❑ To Notify Other Providers & to Add a Copy of the Report to Their Permanent Record

**Notes**



# The VAERS Project

## Provider Tool: Education Reference Guide

**Who:** All patients who are recipients of vaccinations.

**When:** Prior to vaccination, non-routine appointments after vaccination, or with suspicion of Adverse Event (AE).

**Why:** So that patients can seek follow-up care, only one report is made, and to ensure highest level of vaccine safety.

**What:** Any AE occurring after vaccination.

**How:** Using VAERSproject.com resources and those available through a healthcare facility.

**Necessary information:**

- ☞ Ask the patient: "May I share information with you about the Vaccine Adverse Event Reporting System or VAERS?" The following mirror the information on the Patient VAERS Report Information Sheet which should be provided to the patient.

- ☞ VAERS is the national adverse event reporting system and is an important part of vaccine safety science.[1]

- ☞ VAERS is passive, meaning it needs help from patients and providers to ensure reports are made. Patients, caregivers, and healthcare providers are all encouraged to report to VAERS.[1]

- ☞ Reports should be made any time a patient has an unexpected health issue or, *adverse event*, after vaccination. The report does not mean that the issue is related to the vaccine. The CDC & FDA ask that all adverse events are reported. [1]

- ☞ By reporting all adverse events, VAERS scientists can look for rare side effects that can only be found when the vaccine is used in the large population after clinical trials. VAERS also helps make sure that manufacturing and handling doesn't impact certain vaccines or batches. It also can help identify administration errors.[1] VAERS serves a very important purpose.

- ☞ If you, or your child have an adverse event you can make a report or talk with your healthcare provider so they can make a report. No matter who makes the report, you should keep a copy of the confirmation number and report for your records. [2]

- ☞ Only one report needs to be made,[3] so it is also important that the VAERS report becomes part of your health history with all your healthcare practitioners. Be sure to share a copy of the report and confirmation number with each of your providers.

- ☞ If needed, you or your provider, can submit more information to VAERS after the initial report. If you didn't get a copy of your report, you may be able to get one from VAERS by calling (800) 822-7967 or info@vaers.org or the FDA.[2]

- ☞ Individuals who have been injured or deceased as the result of a vaccine injury may be eligible for compensation through the Vaccine Injury Compensation Program or the Countermeasure Injury Compensation Program. Petitions for compensation are time sensitive. Get more information from your provider or by visiting injurycompensation.hrsa.gov


1. Vaccine Adverse Event Reporting System. (n.d.). About VAERS: Background and Public Health Importance. Retrieved September 3, 2022, from https://vaers.hhs.gov/about.html
2. VAERS. (n.d.). Frequently Asked Questions (FAQs). Retrieved September 3, 2022, from https://vaers.hhs.gov/faq.html
3. Vaccine Adverse Event Reporting System. (n.d.). VAERS Data. Retrieved September 3, 2022, from https://vaers.hhs.gov/data.html

# The VAERS Project

## Patient VAERS Report Information Sheet

**Patient Name:** _____ **Date Adverse Event Started:** _____

**Symptoms of Adverse Event:** _____

_____

**VAERS Report Confirmation Number:** _____

**VAERS Report Made By:** _____

**Reporter/Facility Phone Number:** _____

**Follow-Up Care & Instructions:** _____

_____

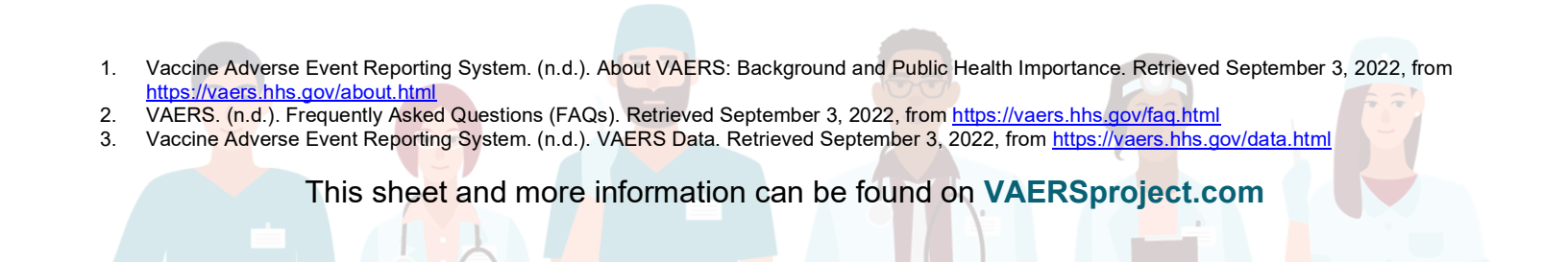
_____

**Share this sheet and a copy of the VAERS report with all your healthcare practitioners and have them add it to your health history.**

### Frequently Asked Questions

- VAERS is the national adverse event reporting system and is an important part of vaccine safety science.[1]
- VAERS is passive, meaning it needs help from patients and providers to ensure reports are made. Patients, caregivers, and healthcare providers are all encouraged to report to VAERS.[1]
- Reports should be made any time a patient has an unexpected health issue or, *adverse event*, after vaccination. The report does not mean that the issue is related to the vaccine. The CDC & FDA ask that all adverse events are reported.[1]
- By reporting all adverse events, VAERS scientists can look for rare side effects that can only be found when the vaccine is used in the large population after clinical trials. VAERS also helps make sure that manufacturing and handling doesn't impact certain vaccines or batches. It also can help identify administration errors.[1] VAERS serves a very important purpose.
- Keep a copy of this sheet and the report for your records.[2]
- Only one report needs to be made,[3]
- If needed, you or your provider, can submit more information to VAERS after the initial report. If you didn't get a copy of your report, you may be able to get one from VAERS by calling (800) 822-7967 or info@vaers.org or the FDA.[2]
- Individuals who have been injured or deceased as the result of a vaccine injury may be eligible for compensation through the Vaccine Injury Compensation Program or the Countermeasure Injury Compensation Program. Petitions for compensation are time sensitive. Get more information from your provider or by visiting injurycompensation.hrsa.gov


1. Vaccine Adverse Event Reporting System. (n.d.). About VAERS: Background and Public Health Importance. Retrieved September 3, 2022, from https://vaers.hhs.gov/about.html
2. VAERS. (n.d.). Frequently Asked Questions (FAQs). Retrieved September 3, 2022, from https://vaers.hhs.gov/faq.html
3. Vaccine Adverse Event Reporting System. (n.d.). VAERS Data. Retrieved September 3, 2022, from https://vaers.hhs.gov/data.html

This sheet and more information can be found on **VAERSproject.com**