Vaccine Adverse Event Reporting System (VAERS)
Standard Operating Procedures for COVID-19
(as of February 2, 2022)

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This document is a draft planning document for internal use by the Centers for Disease Control and Prevention, with collaborating contractors. Numerous aspects (including but not limited to specific adverse events to be monitored, timeframes for report processing, data elements to be reported, and data analysis) are dynamic and subject to change without notice.

Executive Summary

CDC and FDA will perform routine VAERS surveillance to identify potential new safety concerns for COVID-19 vaccines. This surveillance will include generating tables summarizing automated data from fields on the VAERS form for persons who received COVID-19 vaccines (e.g., age of vaccinee, COVID-19 vaccine type, adverse event).

Enhanced surveillance (i.e., automated data and clinical review) will be implemented after reports of the following adverse events of special interest (AESIs): death, Guillain-Barre Syndrome (GBS), seizure, stroke, narcolepsy/cataplexy, anaphylaxis, acute myocardial infarction, myopericarditis, coagulopathy (including thrombocytopenia, disseminated intravascular coagulopathy [DIC], and deep venous thrombosis [DVT]), Kawasaki's disease, multisystemic inflammatory syndrome in children (MIS-C), multisystemic inflammatory syndrome in adults (MIS-A), thrombosis with thrombocytopenia syndrome (TTS) and transverse myelitis. Abstraction of medical records associated with reports of these conditions will be performed using an internal CDC version of REDCap (i.e., behind CDC's firewall). Data entered into REDCap will be stored on CDC servers and used to populate data tables, from which reports will be generated and analyzed on a periodic basis. Enhanced surveillance (i.e., automated data and clinical review) will also be implemented after all pregnancy reports, with emphasis on pregnancy complications, maternal and neonatal deaths, spontaneous abortion, stillbirths, and congenital anomalies. However, abstraction of medical records after these conditions will be performed on an as needed basis. These efforts will assist in CDC's efforts to monitor the safety of COVID-19 vaccines.

1.0 Introduction

The Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) use the Vaccine Adverse Event Reporting System (VAERS) as a front-line system to monitor the safety of vaccines licensed or authorized for use in the United States. In addition to conducting general surveillance, each year VAERS activities focus on new formulations and types of vaccine, new populations who may be vaccinated because of changes in licensed indications or Advisory Committee on Immunization Practices (ACIP) recommendations, and any new safety concerns identified. This Standard Operating Procedures (SOP) document describes the following activities for COVID-19 vaccine safety monitoring:

1) Approach for CDC-FDA VAERS monitoring
2) Plans for coordinating with FDA VAERS staff, particularly around data mining and VAERS data interpretation
3) Overall COVID-19 vaccine safety monitoring coordination for The VAERS Team within CDC's Immunization Safety Office (ISO)

This SOP does not describe details of FDA surveillance procedures for COVID-19 vaccine safety or CDC surveillance or evaluation of COVID-19 vaccines in systems other than VAERS.

Vaccines to monitor:

Pfizer/BioNTech (trade name for licensed product: Comirnaty)
Moderna (trade name for licensed product: Spikevax)
Janssen
Other COVID-19 vaccines as they are authorized or licensed for use in the United States

For each adverse event of special interest (AESI), the rationale for enhanced monitoring, case definitions (if available), and references are provided in Table 1:

Table 1: Adverse Events of Special Interest (AESIs), with case definitions (if available)

Adverse Event of Special Interest	Rationale for enhanced monitoring	Case definition (if available)*	References
†Acute myocardial infarction (AMI)	• Has been reported as a presenting sign of COVID-19 disease and could indicate vaccine-enhanced disease (VAED)	• International consensus case definition available at https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000000617	• https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7179991/
†Anaphylaxis	• Can represent a severe allergy of life-threatening severity	• Brighton Collaboration case definition available at https://www.sciencedirect.com/science/article/pii/S0264410X07002642?via%3Dihub	• https://www.sciencedirect.com/science/article/pii/S00916749193002 0X?via%3Dihub
‡Appendicitis	• Can be a medical emergency • An imbalance between vaccinees and placebo was noted in clinical trials with the Pfizter/BioNTech COVID-19 vaccine	• No case definition exists; will track on the basis of physician diagnosis	• https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-manufacturer%2Fpfizer%2Freactogenicity.html
‡Bell's Palsy	• Can affect daily functions • An imbalance between vaccinees and placebo was noted in clinical trials with the Pfizter/BioNTech COVID-19 vaccine	• Brighton Collaboration case definition available at https://www.sciencedirect.com/science/article/pii/S0264410X16303139?via%3Dihub	• https://www.fda.gov/media/144245/download

†Coagulopathy	• Thrombocytopenia, DIC, and DVT have all been reported as part of COVID-19 disease and could indicate VAED	• Brighton Collaboration case definition for thrombocytopenia available at https://www.sciencedirect.com/science/article/pii/S0264410X0700268X?via%3Dihub • Scientific Standardization Committee of the International Society of Thrombosis and Haemostasis scoring for DIC available at https://www.tandfonline.com/doi/full/10.1080/17474086.2018.1500173 • Modified Wells' score (widely acknowledged standard for DVT/PE) available at https://academic.oup.com/clinchem/article/57/9/1256/5620938	• https://www.thelancet.com/journals/lanhae/article/PIIS2352-3026(20)30151-4/fulltext
†Death	• Public concern and interest in deaths after vaccination in persons and recipients of newly licensed vaccines	• Report of death certificate or autopsy report	• https://academic.oup.com/cid/article/61/6/980/451431

GBS	• Is a vaccine-associated adverse event of historical interest	• Brighton Collaboration case definition available at https://www.sciencedirect.com/science/article/pii/S0264410X1000798X?via%3Dihub	• https://www.cdc.gov/vaccinesafety/concerns/guillain-barre-syndrome.html
†Kawasaki's disease	• Could be confused with MIS-C, which could be an indication of VAED	• CDC case definition available at https://www.cdc.gov/kawasaki/case-definition.html	• https://www.cdc.gov/mmwr/volumes/69/wr/mm6932e2.htm
Multisystem Inflammatory Syndrome in Adults (MIS-A)	• Could be an indication of VAED	• Interim case definition available at https://www.cdc.gov/mmwr/volumes/69/wr/mm6940e1.htm	• https://www.cdc.gov/mmwr/volumes/69/wr/mm6940e1.htm
Multisystem Inflammatory Syndrome in Children (MIS-C)	• Could be an indication of VAED	• Interim case definition available at https://www.cdc.gov/mmwr/volumes/69/wr/mm6932e2.htm	• https://www.cdc.gov/mmwr/volumes/69/wr/mm6932e2.htm
Myopericarditis	• Has been reported as part of COVID-19 disease pathology and could indicate VAED	• Joint Smallpox Vaccine Safety Working Group of the Advisory Committee on Immunization Practices (ACIP) and the Armed Forces Epidemiology Board (AFEB) case definition available at	• https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7199677/

		https://www.cdc.gov/mmwr/PDF/wk/mm5221.pdf (p. 494)	
†Narcolepsy/ Cataplexy	• Has been alleged as an adverse event associated with some adjuvanted vaccines; some COVID-19 vaccines might employ adjuvants	• Brighton Collaboration case definition available at https://www.sciencedirect.com/science/article/pii/S0264410X12017811?via%3Dihub	• https://www.cdc.gov/vaccinesafety/concerns/history/narcolepsy-flu.html •
†Seizure	• Is a vaccine-associated adverse event of historical interest • In young patients (i.e., 5 years and younger) might indicate febrile seizure	• Brighton Collaboration case definition available at https://www.sciencedirect.com/science/article/pii/S0264410X03006613?via%3Dihub	• https://www.cdc.gov/vaccinesafety/concerns/febrile-seizures.html
†Stroke	• Has been reported with COVID-19 disease and might therefore be an indication of VAED • Was also reported in a COVID-19 vaccine prelicensure clinical trial	• American Heart Association/American Stroke Association consensus definition available at https://www.ahajournals.org/doi/epub/10.1161/STR.0b013e318296aeca	• https://jamanetwork.com/journals/jamaneurology/fullarticle/2768098 •

Thrombosis with thrombocytopenia syndrome (TTS)	• Reports of a rare thromboembolic syndrome in early April 2021 following administration of the Janssen vaccine, similar to reports from Europe after receipt of the AstraZeneca Covid-19 vaccine.	• U.K. Expert Hematology Panel VITT case definition at https://b-s-h.org.uk/about-us/news/guidance-produced-by-the-expert-haematology-panel-ehp-focussed-on-vaccine-induced-thrombosis-and-thrombocytopenia-vitt/	• https://pubmed.ncbi.nlm.nih.gov/33929487/ • https://www.acpjournals.org/doi/pdf/10.7326/M21-4502
†Transverse myelitis	• One report of transverse myelitis observed in prelicensure clinical trial of ChAdOx1 nCoV-19 vaccine.	• No case definition exists; will track on the basis of physician diagnosis	• https://www.npr.org/sections/coronavirus-live-updates/2020/09/12/912281381/astrazeneca-resumes-its-covid-19-vaccine-trials-in-the-u-k
Vaccination during pregnancy	• Public interest and concern over adverse pregnancy events and fetal outcomes	• Report of vaccinated person being pregnant (during or after vaccination)	• http://www.sciencedirect.com/science/article/pii/S0002937810011051 •

† For ages 0-18 years

‡Not part of enhanced surveillance but included in prespecified weekly tables

* Draft case definitions for some conditions under development by the Brighton Collaboration

For details on the background, historical perspective and specific aims of VAERS surveillance, access https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html

In addition, selected AESIs will be monitored for awareness but not abstracted. These AESIs and available case definitions are listed in Table 2:

Table 2: AESIs to monitor (but not abstract), with definitions and available case definitions

AESIs to monitor but not abstract*	Reference definitions and available case definitions
Acute Respiratory Distress Syndrome (ARDS)	https://www.thoracic.org/professionals/career-development/residents-medical-students/ats-reading-list/adult/ards.php
Autoimmune disorders	Appendix 4.6 lists specific disorders to monitor
Other clinically serious neurologic AEs:	
Acute disseminated encephalomyelitis (ADEM)	Sejvar et al (2007)
Multiple sclerosis (MS)	NIH (last updated 5 Aug 2019)
Optic neuritis (ON)	Guier et al (last updated 10 Aug 2020)
Chronic inflammatory demyelinating polyneuropathy (CIDP)	Gogia et al (last updated 9 Oct 2020)
Encephalitis	Sejvar et al (2007)
Myelitis	Sejvar et al (2007)
Encephalomyelitis	Merriam Webster (last accessed 7 Nov 2020)
Meningoencephalitis	Merriam-Webster (last accessed 7 Nov 2020)
Meningitis	CDC (last updated 21 Jan 2020)
Encephalopathy	NIH (last updated 27 Mar 2019)
Ataxia	Johns Hopkins Medicine Dept of Neurology and Neurosurgery (last accessed 7 Nov 2020)
Non-anaphylactic allergic reactions	Varies with specific symptom; see Appendix 4.6
Vaccination errors	See Section 4.4

* Will be specified by a list of MedDRA PTs (see Appendix 4.6, p. 27)

2.0 Overview of VAERS Surveillance Activities

The specific tasks and frequency of these tasks for surveillance will be adjusted to meet public health needs, with consideration of staff time and resources. For example, in the event of a significant increase in the number of adverse events (AEs) reported to VAERS that warrant clinical review, additional ISO staff will be assigned to perform reviews. An algorithm of the process to monitor vaccine AEs is shown in Appendix 4.1.

CDC will perform clinical reviews for AESIs listed in Table 1. Results from automated data assessment will identify additional conditions potentially warranting further clinical review.

CDC will perform Proportional Reporting Ratio (PRR) analysis (see section 2.3.1, p. 14), excluding laboratory results, to identify AEs that are disproportionately reported relative to other AEs.

FDA routinely assesses all serious* and other medically important condition (OMIC) reports daily and performs data mining analyses.

* *Serious reports are defined by Code of Federal Regulations (FDA CFR 1997) if at least one of the following was reported: death, hospitalization, life-threatening illness, permanent disability and /or prolonged hospitalization, and congenital anomaly.*

Summaries (or other deliverables, as needed) will be based on data processing, coding and follow-up, automated data, and clinical review, as well as field investigations as appropriate. COVID-19 vaccine safety coordination meetings among ISO team members and FDA will be scheduled weekly (or more frequently, as needed) to discuss results of the automated data and (if indicated) clinical review.

2.1 Data processing and coding and follow-up

The CDC contractor for VAERS receives, processes, and manages VAERS reports. The contractor receives reports online and by mail, fax, or telephone. Using standard procedures, contractor staff will review each U.S. report following COVID-19 vaccines and assign standard codes to each reported sign, symptom, and diagnosis using Medical Dictionary for Regulatory Activities terminology [10]. The staff will enter all MedDRA terms and other information from each VAERS report form into a computerized database. Vaccine type codes in the VAERS database are shown in Appendix 4.2.

Trained contractor staff will request additional information including hospital records and autopsy reports when appropriate (Appendices 4.3 and 4.4). Medical records are routinely requested for all serious reports, including deaths.

Contractor clinical staff will summarize data and assign additional MedDRA codes for symptoms, signs, and diagnoses identified from the requested additional information. They will then add these additional codes to the data originally entered into the database for the specific VAERS report.

Table 3 lists the AESIs for which medical records will be requested and reviewed. Manual review of serious reports is routinely performed by FDA (a more in-depth clinical review will be performed by CDC as indicated).

Table 3: AESIs for which medical records will be requested and reviewed

AESI	Medical and vaccination records obtained by contractor†	Clinical review by CDC*
Acute Myocardial Infarction (AMI)	Yes	Yes (0-18)
Anaphylaxis	Yes	Yes (0-18)
Coagulopathy	Yes	Yes (0-18)
Death	Yes	Yes (0-18)
GBS	Yes	Yes
Kawasaki's disease	Yes	Yes (0-18)
Multisystem Inflammatory Syndrome in Adults (MIS-A)	Yes	Yes
Multisystem Inflammatory Syndrome in Children (MIS-C)	Yes	Yes (0-20)
Myopericarditis‡	No	Yes
Narcolepsy/ Cataplexy	Yes	Yes (0-18)
Pregnancy and Prespecified Conditions	Yes	Yes
Seizure/Convulsion	Yes	Yes (0-18)
Stroke	Yes	Yes (0-18)
Thrombosis with thrombocytopenia syndrome (TTS) ‡	No	Yes
Transverse myelitis	Yes	Yes (0-18)

†Medical records are requested only for serious reports, or upon request by CDC. Vaccination records are only obtained if the dose number is missing or if the vaccine manufacturer is unknown or the brand is not specified, and the lot number is unknown, not specified or unclear
‡ Medical records requested by CDC's medical record abstraction team, NOT contractor

*Includes review of VAERS form and available medical records by primary ISO staff. Initial review will be performed and documented within CDC internal COVID-19 medical abstraction website. More detailed review will be performed as needed

All COVID-19 vaccine reports will be entered into the VAERS database and assigned a unique identifying (ID) VAERS number during normal business hours. The contractor will send daily e-mail alerts (Daily Priority Reports) to CDC/FDA with a list of VAERS

ID numbers for all deaths, non-death serious and non-serious reports after COVID-19 vaccines.

2.1.1 Jurisdiction-specific data in VAERS reports after COVID-19 vaccines

ISO will make selected VAERS data available to Vaccine Safety Coordinators (VSCs) in requesting jurisdictions on a weekly basis via Epi-X. The selected data will include the following:

- Unredacted initial report data for reports of residents* within the VSC's jurisdiction (i.e., local, state, or territorial health department) who experience AEs after receiving COVID-19 vaccines; report data of state or territorial jurisdictions will include unredacted report data of local jurisdictions within that state or territory. These unredacted data will not be accessible by other jurisdictions. These unredacted data will be refreshed on Epi-X weekly.

- Cumulative counts of VAERS reports after vaccination with COVID-19 vaccines, cross-tabulated in the following manner:

    - Rows listing each jurisdiction by total cumulative counts, stratified by seriousness (non-serious, serious non-death, and death)
    - Rows listing selected AESIs by total cumulative counts among all jurisdictions combined (to avoid small cell counts and potential unintended identification of affected persons), stratified by age group, in years (0–4, 5–17, 18–49, 50–64, 65–74, 75–84, ≥85, not reported, and total)
    - These cumulative counts will include all reports to date and will be refreshed on Epi-X weekly.

* Residency will be assigned in the following hierarchy: 1) state or territory of reported patient residency; if not available, 2) state or territory where COVID-19 vaccine was administered; if not available, 3) state or territory of person making the VAERS report; absent these data, residency will be decided per standard contractor business rules. Residence within a local jurisdiction will be determined in similar fashion, based upon city and ZIP code information comprising the local jurisdiction.

Weekly redacted data will be made available publicly via CDC WONDER (https://wonder.cdc.gov/), HHS (https://vaers.hhs.gov), and Epi-X on the same date. Case counts on Epi-X and public websites should be equal; any differences in case counts may result from data processing (e.g., data cleaning) and will be reconciled as the data mature.

2.1.2. Vaccination Errors

Reports of vaccination errors will be identified by conducting an automated search using MedDRA preferred terms (PTs) and organized into vaccination error groups shown in Appendix 4.5.

- Some reports that use the MedDRA PT codes in Appendix 4.5 do not always document a vaccination error.
- Vaccination errors will be summarized by vaccination error group based on automated data and include any error involving COVID-19 vaccines and any other coadministered vaccine(s). Clinical review of VAERS reports may be performed for vaccination error reports that are classified as serious (see p.11) , and vaccination error PTs with elevated PRRs.

The data from this automated search will be provided as a weekly automated table that will be reviewed as described below in sections 2.4 and 3.0.

2.2 Automated tables:

A series of tables will be generated using the VAERS automated data.

2.2.1 VAERS daily tables

Data tables for internal use demonstrating frequency of general characteristics and preferred terms will be generated automatically using pre-defined variables populated by VAERS data.

The following weekly tables will be available every Monday (data as of the previous Friday):

Table 1. All reports following COVID-19 vaccines by severity and selected manufacturer/brand name

Table 2. Top 25 most frequently reported AEs following COVID-19 vaccines by dose number

Table 3. Daily counts of GBS cases following Janssen COVID-19 vaccine

2.2.2 VAERS weekly table

A version of the cumulative count table by jurisdiction and seriousness from section 2.1.1 will be refreshed weekly for internal use (i.e., inside ISO). This version will be generated independently of the jurisdictional Epi-X/CDC WONDER data and will be almost identical in appearance and content. Because this internal version will use supplemental data not for public release, counts may vary from counts on Epi-X/CDC WONDER.

In addition, a table summarizing select AESIs by age groupand will be presented in weekly and cumulative format.

Table 1. Reports after vaccination with COVID-19 vaccines by Jurisdicton and Seriousness (Death, Non-Death Serious, Non-Serious)

Table 2. Reports of the following AESIs after vaccination with COVID-19 vaccines, stratified by age group (ages <18 years, 18–49 years, 50–64 years, 65-74 years, 75–84 years, 85+ years, unreported):

- Anaphylaxis
- Acute Myocardial Infarction
- Appendicitis
- Bell's palsy
- Coagulopathy
- Death
- Guillain Barre Syndrome (GBS)
- Kawasaki Disease
- Multisystemic Inflammatory Syndrom in Adults (MIS-A)
- Multisystemic Inflammatory Syndrom in Children (MIS-C)
- Myopericarditis
- Narcolepsy/Cataplexy
- Pregnant
- Seizure
- Stroke
- Transverse Myelitis

2.3 Signal detection methods and data analyses

The analyses for COVID-19 vaccine safety signals will focus on identifying deviations from preliminary safety data, and possibly from other vaccines, using disproportionality analyses and comparisons of reporting rates.

Two main approaches to data mining are Proportional Reporting Ratios (PRRs) and Empirical Bayesian Geometric Means [11–13]. Both have published literature suggesting criteria for detecting "signals" [14]. PRR will be used at CDC for potential signal detection; Empirical Bayesian data mining will be performed by FDA.

After initial licensure or approval of COVID-19 vaccines in the United States, initial reports may be too few to allow for data mining immediately. As the data mature, PRR and Empirical Bayesian data mining can then be used.

2.3.1 Proportional Reporting Ratio (PRR)

When sufficient data have accrued, CDC will perform PRR data mining on a weekly basis or as needed. PRRs compare the proportion of a specific AE following a specific vaccine versus the proportion of the same AE following receipt of another vaccine (see equation below Table 4). A safety signal is defined as a PRR of at least 2, chi-squared statistic of at least 4, and 3 or more cases of the AE following receipt of the specific vaccine of interest.

CDC will apply appropriate comparator vaccines (e.g., non-covid vaccines received in the last 5 years,) and adjust for severity and age distributions where applicable.

Table 4. Calculation of Proportional Reporting Ratio (PRR)

	Specific AE	**All other AE**
Specific vaccine	**A**	**B**
All other vaccines	**C**	**D**

$$PRR = \frac{[a/(a+b)]}{[c/(c+d)]}$$

2.3.2 Data mining

FDA will perform data mining at least biweekly (with stratified data mining monthly) using empirical Bayesian data mining to identify AEs reported more frequently than expected following vaccination with COVID-19 vaccines, using published criteria [12, 14]. Vaccine product-specific AE pairs following specific COVID-19 vaccines with reporting proportions at least twice that of other vaccines in the VAERS database (i.e., lower bound of the 90% confidence interval of the Empirical Bayesian Geometric Mean [EB05] >2) will be evaluated. Data mining runs can be adjusted and/or stratified by possible confounding variables such as age, sex, season of administration, and type of vaccines. FDA and CDC will share and discuss results of data mining analyses and signals.

2.3.3 Crude reporting rates

If needed for internal purposes, crude reporting rates will be calculated based on COVID-19 vaccine doses administered .

2.4 Review of VAERS forms, medical records, and automated tables for reports of interest

- Daily priority reports will provide VAERS ID numbers and seriousness (Death, Non-Death Serious, Non-Serious); these reports can be reviewed by VAERS personnel for initial information.

- Daily line list will provide VAERS ID numbers, associated AESIs, and assigned medical abstractor names. Medical abstractors will then access the VAERS VPN, review available medical records, and complete abstraction using an internal REDCap database (Figure).

- Automated tables referenced in section 2.2.2 will be reviewed weekly for potential safety signals.

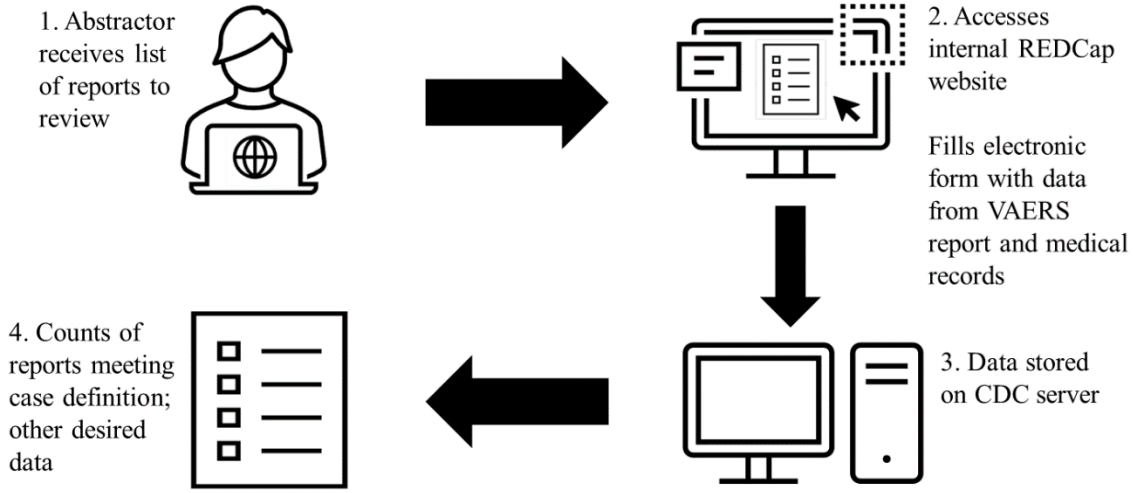


Figure: abstraction process

MedDRA terms identified as safety signals due to stastistically significant finding on data mining will be reviewed as appropriate. The pattern or trend of data mining results over a period of time (e.g., several weeks) will be monitored before initiating a clinical review. Other factors, such as clinical importance, whether AEs are unexpected, seriousness, and whether a specific syndrome or diagnosis is identified rather than non-specific symptoms will be considered in determining if clinical review will be performed.

Identification of a cluster of reports or unexpected AEs will be further investigated, and additional information on serious AEs will be shared with CDC leadership. A list of lot numbers of vaccines that may be of concern will be requested from FDA. In the event of review of difficult or rare cases, subject matter experts (e.g., neurologist, the Clinical Immunization Safety Assessment network) may be consulted.

Clinical review will include reviewing reports (and associated medical records) containing the identified MedDRA terms, confirming appropriate coding, confirming diagnosis (e.g., by applying a case definition), confirming time from vaccination to symptom onset, reviewing the patient history and course of illness to identify risk factors, and potentially comparing to comparable data for another vaccine.

A summary of the data review described in this section will be provided monthly, or as needed, to pertinent stakeholders (e.g., Immunization Safety Office leadership, FDA partners).

2.5 Signal assessment

Signal detection can occur in VAERS surveillance through FDA empirical Bayesian data mining, through CDC PRR data mining, and through descriptive analysis. When a

potential signal is detected, ISO VAERS staff shall take a series of steps to assess the potential signal. Steps may include, but are not limited to:

- Assess if the potential signal merits further investigation (e.g., expected AEs might not warrant further analysis)
- Consult with FDA colleagues to coordinate response
- Perform quality checks on data management and data analysis that led to signal detection
- Individual report review to:
    - Confirm the accuracy of MedDRA coding
    - Confirm the AE outcome and apply a standardized case definition if appropriate
    - Confirm onset interval to assess biological plausibility
    - Assess for other risk factors that might contribute to the AE
    - Assess the clinical seriousness
- Perform comparative analysis with other vaccines (e.g., compare frequencies and proportions with influenza vaccine)
- Analyze reporting rates and compare reporting rates with other vaccines or background rates

If, after an initial assessment, VAERS investigators determine a signal warrants further investigation, the VAERS team lead will notify ISO leadership and develop a coordinated response plan. Any appropriate investigation will be conducted in collaboration with FDA. FDA will share with CDC reports of possible concern based of the data mining results and assess product-specific or lot safety as appropriate. ISO leadership will be responsible for notifying NCIRD and the CDC COVID-19 Vaccine Task Force (VTF) in a timely manner.

3.0 Coordination and Collaboration

Meetings and conference calls will be scheduled as follows, subject to change as needed:

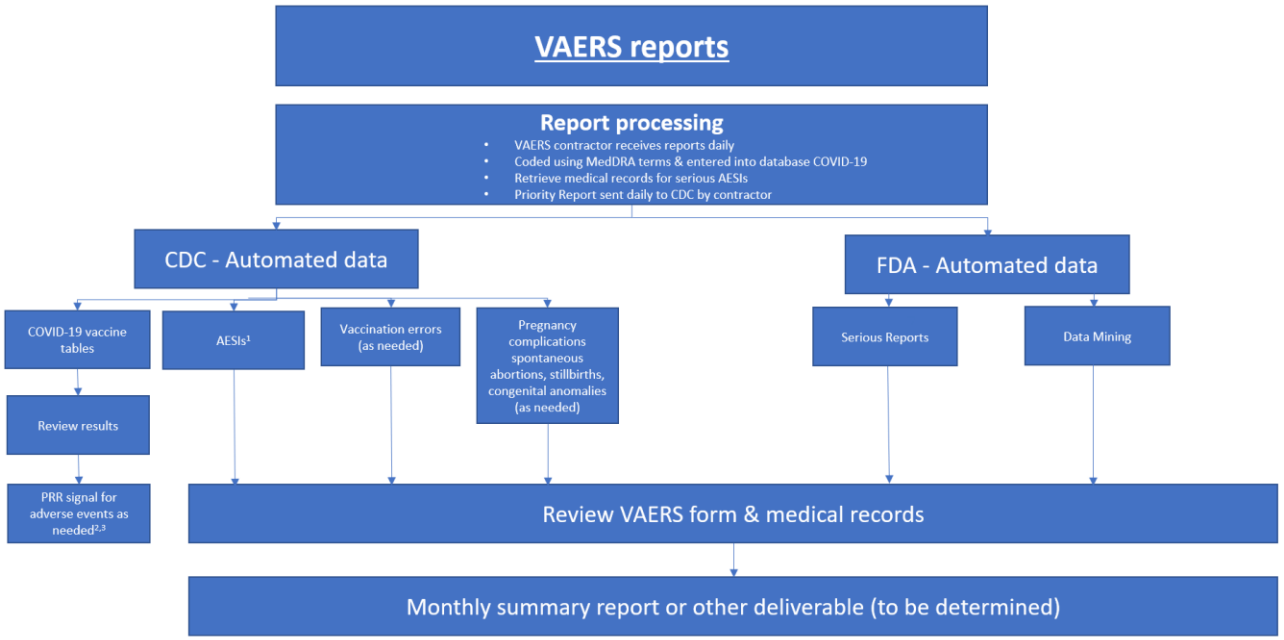
1) **Weekly review by team lead and ISO leadership,** to review counts of reports and selected subgroups (e.g., deaths)

2) **Weekly VAERS Team COVID-19 Meeting** among VAERS team members
    a. To review the automated tables and clinical summary
    b. To analyze and interpret the VAERS data
    c. To discuss signals or potential events of concern

3) **Weekly (or as needed) CDC/FDA COVID-19 Safety Coordination Meeting** with ISO leadership, NCIRD representatives, and FDA
    a. To present pertinent automated data and clinical summary (e.g., AEs resulting in signals) and FDA data mining results
    b. To provide updates on ISO VAERS team and FDA COVID-19 vaccine activities (e.g., scientific projects/publications, regulations, data from other vaccine safety systems)

4.0 Appendices

4.1 Process of monitoring of COVID-19 vaccine adverse events



[1] AESI = Adverse Event of Special Interest: acute myocardial infarction, anaphylaxis, appendicitis, Bell's palsy, coagulopathy, COVID-19 disease, death, Guillain-Barre Syndrome, Kawasaki's disease, multisystemic inflammatory syndrome in adults, multisystemic inflammatory syndrome in children, myopericarditis, narcolepsy/cataplexy, vaccination during pregnancy, seizure, stroke, transverse myelitis, thrombosis with thrombocytopenia (TTS)
[2] To determine if results need further clinical review, consider if clinically important, unexpected findings, seriousness, specific syndrome or diagnosis rather than non-specific symptoms
[3] Will NOT include laboratory results; PRR cut-off for N=5 vs. 0

4.2 VAERS codes for COVID-19 vaccines [pending]

Vaccine type	CDC code	Notes
(Fill as appropriate)		

4.3 NURFU (Nurses Follow-up) Guidance: requesting additional information for selected AESIs

Criteria			Actions[1]/ Documents Requested
Description	**Report Type**	**Vaccine Brand/Manufacturer/Dose**	
All	Serious (including manufacturer reports)	(Unknown/ Not Specified Brand/ Manufacturer AND Unknown/ Not Specified/ Unclear Lot Number) OR Dose Number Missing[2]	Vaccination records
All	Serious[3] (including manufacturer reports)	Any Brand/Manufacturer	Clinical follow-up
Special Interest Cases identified by VAERS ID	Serious/Non-serious- (including manufacturer reports)	Any Brand/Manufacturer	Clinical follow-up

[1]Continue to obtain medical records pertaining to reported adverse event up to 3 months. After 3 months of unsuccessful attempts, close out case unless patient remains hospitalized. For pregnancy reports, reengage follow-up at time of delivery of live birth for one year. (Reaccess Clinical Follow-up specifications for COVID-19 Pregnancy Cases in January 2022)

[2]Subject to change based on volume of initiations requested

[3]CDC will obtain medical records for Myopericarditis and TTS cases. They will send a weekly list of VAERS IDs to GDIT to NOT get medical records on, to reduce duplication of effort. GDIT should use medical judgment to identify Myopericarditis and TTS cases. CDC is using the following PTs to identify Myocarditis cases: Atypical mycobacterium pericarditis, Autoimmune myocarditis, Autoimmune pericarditis, Bacterial pericarditis, Coxsackie myocarditis, Coxsackie pericarditis, Cytomegalovirus myocarditis, Cytomegalovirus pericarditis, Enterovirus myocarditis, Eosinophilic myocarditis, Hypersensitivity myocarditis, Immune-mediated myocarditis, Myocarditis, Myocarditis bacterial, Myocarditis helminthic, Myocarditis infectious, Myocarditis meningococcal, Myocarditis mycotic, Myocarditis post infection, Myocarditis septic, Pericarditis, Pericarditis adhesive, Pericarditis constrictive, Pericarditis helminthic, Pericarditis infective, Pericarditis mycoplasmal, Pleuropericarditis, Purulent pericarditis, Viral myocarditis, Viral pericarditis

4.4 VAERS triaging of reports in business days[1,2]

Category	Serious reports		Serious/Prespecified Conditions follow-up initiation	Non-serious reports	
	Scan within	Complete process within[3]		Scan within	Complete process within[3]
1. US Deaths[4]	1	1	1	N/A	N/A
3. US 5-day	2	2	N/A	N/A	N/A
4. US 15-day	2	2	N/A	N/A	N/A
5. US[5]	2	3	3	2	5
6. US Malfunction Only[6]	2	20	N/A	2	20
7. Foreign Deaths	2	2	N/A	N/A	N/A
8. Foreign 5-day[7]	2	2	N/A	N/A	N/A
9. Foreign 15-day	2	90	N/A	N/A	N/A
10. Foreign Malfunction Only[6,7]	2	30	N/A	2	45
11. Foreign[7]	2	30	N/A	5	120

1. Subject to change after discussion between CDC and FDA in response to new public health policies and/or events and/or funding availability and/or technical issues and/or paper reporting.

2. Not applicable for GBS reports where a patient is confined to facility longer than the time allowed for follow-up (e.g., patient in rehabilitation after GBS)

3. Completion includes scanning, data entry, and coding

4.. If final autopsy report or death certificates are not received within 2 months, make request every 2 months

5. If no records received within 5 days from the original request, make additional monthly requests up to 3 months. After 3 months of unsuccessful attempts, close out case unless patient remains hospitalized.

6. Malfunction reports defined as any ICSR with the "Local Criteria Report Type" data element (FDA.C.1.7.1) = "Malfunction only (No AE)".

7. Preferred timeframes are displayed; timeframes are subject to change due to volume of reports received and staffing resources

4.5 Vaccination error groups and MedDRA Preferred Terms (PTs) for COVID-19 vaccination errors

Administration Errors
- Accidental exposure to product
- Accidental exposure to product by child
- Drug administered in wrong device
- Exposure via direct contact
- Exposure via eye contact
- Exposure via skin contact
- Inadequate aseptic technique in use of product
- Incorrect product administration duration
- Incorrect product formulation administered
- Incorrect route of product administration
- Intercepted drug administration error
- Lack of administration site rotation
- Lack of injection site rotation
- Lack of vaccination site rotation
- Multiple use of single-use product
- Occupational exposure to product
- Paravenous drug administration
- Product administration error
- Product administered at inappropriate site
- Product commingling
- Product leakage
- Product use complaint
- Product use in unapproved indication
- Unintentional use for unapproved indication,
- Wrong technique in device usage process
- Wrong technique in product usage process

Contraindication to vaccination
- Contraindication to vaccination
- Contraindicated product administered
- Contraindicated product prescribed
- Documented hypersensitivity to administered product
- Labelled drug-disease interaction medication error
- Labelled drug-drug interaction medication error
- Labelled drug-food interaction medication error

Equipment
- Device breakage
- Device connection issue
- Device defective
- Device difficult to use
- Device dislocation
- Device failure
- Device leakage
- Device issue
- Device malfunction
- Device use issue
- Device use error
- Expired device used
- Exposure to contaminated device
- Exposure via contaminated device
- Incorrect dose administered by device
- Injury associated with device
- Medical device complication
- Needle issue
- Poor quality device used
- Syringe issue
- Wrong device used

General
- Medication error
- Intercepted medication error
- Product use issue
- Unintentional use for unapproved indication
- Vaccination error

Inappropriate schedule of drug administration
- Inappropriate schedule of product administration
- Product administered to patient of inappropriate age
- Wrong schedule

Incorrect dose
- Accidental overdose
- Accidental underdose
- Booster dose missed
- Dose calculation error
- Extra dose administered
- Incomplete course of vaccination
- Incorrect dose administered
- Incorrect dosage administered
- Incorrect product dosage form administered
- Overdose
- Product dose omission
- Single component of two component product administered
- Underdose
- Wrong dose
- Wrong strength

Prescribing and dispensing
- Drug dispensed to wrong patient
- Inappropriate prescribing
- Intercepted drug dispensing error
- Intercepted drug prescribing error
- Intercepted product selection error

- Prescribed overdose
- Prescribed underdose
- Product dispensing error
- Product preparation error
- Product preparation issue
- Product prescribing error
- Product prescribing issue
- Product selection error
- Transcription medication error

Product quality

- Discontinued product administered
- Expired product administered
- Incorrect product storage
- Poor quality product administered
- Product contamination
- Product contamination microbial
- Product contamination physical
- Product expiration date issue
- Product quality issue
- Product quality control issue
- Product reconstitution issue
- Product reconstitution quality issue
- Product sterility lacking
- Product storage error

Product labeling/packaging

- Product barcode issue
- Product container issue
- Product design confusion
- Product dosage form confusion
- Product identification number issue
- Product label confusion
- Product label issue
- Product label on wrong product
- Product lot number issue
- Product name confusion
- Product packaging confusion
- Product packaging issue
- Product outer packaging issue
- Product packaging confusion

Wrong Product

- Interchange of vaccine products
- Intercepted wrong patient selected
- Product substitution error
- Wrong drug
- Wrong patient received product
- Wrong product administered
- Wrong product procured

Vaccination Error groups shown on this list were updated to include several new PT codes that became available in MedDRA. Reports of exposure during pregnancy, fetal exposure during pregnancy, maternal exposure during pregnancy are not included. A review of pregnancy coded reports revealed that many reports were documenting that the patient was pregnant without an error occurring. A contraindication to vaccination code has captured true vaccine contraindication reports in pregnant women.

While most reports are documenting a medical error, some reports that use the MedDRA PT codes are not necessarily vaccination errors (e.g., product quality issue, needle issue, syringe issue).

4.6 AESIs to monitor, and identifying PTs

***** AESI to abstract

Pre-specified Condition (*Abstraction Website)	Search Strategy (Pts from VAERS 2.0 form: Item 18/19)
Acute Disseminated Encephalomyelitis (ADEM)	MedDRA Codes: Acute disseminated encephalomyelitis
Acute Myocardial Infarction*	MedDRA Codes: Acute myocardial infarction Myocardial infarction Silent myocardial infarction
Acute Respiratory Distress Syndrome (ARDS)	MedDRA Codes: Acute respiratory distress syndrome
Anaphylaxis*	MedDRA Codes: Anaphylactic reaction Anaphylactic shock Anaphylactoid reaction Anaphylactoid shock
Appendicitis*	MedDRA Codes: Appendicitis Appendicitis noninfective Appendicitis perforated Complicated appendicitis
Ataxia	MedDRA Codes: Ataxia Cerebellar ataxia Cerebral ataxia
Autoimmune Disorders	MedDRA Codes: Acute cutaneous lupus erythematosus Acute haemorrhagic leukoencephalitis Acute haemorrhagic ulcerative colitis Acute motor axonal neuropathy Acute motor-sensory axonal neuropathy Addison's disease Administration site vasculitis Alopecia areata Alveolar proteinosis Amyloidosis Amyloidosis senile Ankylosing spondylitis Anti-erythrocyte antibody

Anti-erythrocyte antibody positive
Anti-insulin antibody
Anti-insulin antibody decreased
Anti-insulin antibody increased
Anti-insulin antibody positive
Anti-insulin receptor antibody
Anti-insulin receptor antibody decreased
Anti-insulin receptor antibody increased
Anti-insulin receptor antibody positive
Anti-islet cell antibody
Anti-islet cell antibody positive
Anti-myelin-associated glycoprotein antibodies positive
Anti-myelin-associated glycoprotein associated polyneuropathy
Anti-neuronal antibody
Anti-neuronal antibody positive
Anti-neutrophil cytoplasmic antibody positive vasculitis
Antiphospholipid antibodies
Antiphospholipid antibodies positive
Antiphospholipid syndrome
Anti-platelet antibody
Anti-platelet antibody positive
Antisynthetase syndrome
Aplasia pure red cell
Arteritis
Arteritis coronary
Atrophic thyroiditis
Autoantibody positive
Autoimmune aplastic anaemia
Autoimmune arthritis
Autoimmune colitis
Autoimmune demyelinating disease
Autoimmune dermatitis
Autoimmune disorder
Autoimmune encephalopathy
Autoimmune endocrine disorder
Autoimmune haemolytic anaemia
Autoimmune hepatitis
Autoimmune hyperlipidaemia
Autoimmune hypothyroidism
Autoimmune inner ear disease
Autoimmune lymphoproliferative syndrome
Autoimmune neuropathy

Autoimmune neutropenia
Autoimmune pancreatitis
Autoimmune pancytopenia
Autoimmune retinopathy
Autoimmune thyroid disorder
Autoimmune thyroiditis
Autoimmune uveitis
Autonomic nervous system imbalance
Axial spondyloarthritis
Axonal neuropathy
Basedow's disease
Behcet's syndrome
Bickerstaff's encephalitis
Biliary cirrhosis primary
Birdshot chorioretinopathy
Butterfly rash
Caplan's syndrome
Cardiac amyloidosis
Cardiac sarcoidosis
Castleman's disease
Cell-mediated immune deficiency
Central nervous system lupus
Cerebral amyloid angiopathy
Cholangitis sclerosing
Cholecystocholangitis
Chronic cutaneous lupus erythematosus
Chronic inflammatory demyelinating polyradiculoneuropathy
Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids
Chronic recurrent multifocal osteomyelitis
Coeliac disease
Cogan's syndrome
Cold agglutinins
Cold agglutinins positive
Cold type haemolytic anaemia
Colitis ulcerative
Collagen disorder
Collagen-vascular disease
Concentric sclerosis
Coombs positive haemolytic anaemia
Crest syndrome
Crohn's disease
Cryofibrinogenaemia
Cryoglobulinaemia

Cutaneous amyloidosis
Cutaneous lupus erythematosus
Cutaneous sarcoidosis
Cutaneous vasculitis
Cystitis interstitial
Dermatitis herpetiformis
Dermatomyositis
Diabetic mastopathy
Dialysis amyloidosis
Diffuse vasculitis
Digital pitting scar
Dressler's syndrome
Encephalitis autoimmune
Endocrine ophthalmopathy
Eosinophilic fasciitis
Eosinophilic granulomatosis with polyangiitis
Erythema nodosum
Evans syndrome
Felty's syndrome
Gastrointestinal amyloidosis
Goodpasture's syndrome
Granulomatosis with polyangiitis
Granulomatous dermatitis
Haemolytic anaemia
Hashimoto's encephalopathy
Hashitoxicosis
Henoch-schonlein purpura
Henoch-schonlein purpura nephritis
Hepatic amyloidosis
Herpes gestationis
Human antichimeric antibody positive
Human anti-mouse antibody increased
Human anti-mouse antibody positive
Hypersensitivity vasculitis
Idiopathic pulmonary fibrosis
Immune agglutinins
Immune thrombocytopenic purpura
Immune-mediated adverse reaction
Immune-mediated necrotising myopathy
Immunoglobulin g4 related disease
Immunoglobulin therapy
Immunomodulatory therapy
Immunosuppressant drug level
Immunosuppressant drug level decreased
Immunosuppressant drug level increased

Immunosuppressant drug therapy
Inclusion body myositis
Injection site vasculitis
Insulin autoimmune syndrome
Interstitial granulomatous dermatitis
Intrinsic factor antibody
Intrinsic factor antibody abnormal
Intrinsic factor antibody positive
Juvenile idiopathic arthritis
Juvenile polymyositis
Juvenile psoriatic arthritis
Juvenile spondyloarthritis
Keratoderma blenorrhagica
Laryngeal rheumatoid arthritis
Latent autoimmune diabetes in adults
Lichen planus
Lichen sclerosus
Ligneous conjunctivitis
Limbic encephalitis
Linear iga disease
Liver sarcoidosis
Lupoid hepatic cirrhosis
Lupus cystitis
Lupus encephalitis
Lupus endocarditis
Lupus enteritis
Lupus hepatitis
Lupus myocarditis
Lupus nephritis
Lupus pancreatitis
Lupus pleurisy
Lupus pneumonitis
Lupus vasculitis
Lupus-like syndrome
Lymphocytic hypophysitis
Marine lenhart syndrome
Meniere's disease
Microscopic polyangiitis
Mixed connective tissue disease
Morphoea
Morvan syndrome
Multiple sclerosis plaque
Muscular sarcoidosis
Myasthenia gravis
Myasthenia gravis crisis

Myasthenia gravis neonatal
Myasthenic syndrome
Neonatal lupus erythematosus
Nephrogenic systemic fibrosis
Neuralgic amyotrophy
Neuromyelitis optica spectrum disorder
Neuromyotonia
Neuropsychiatric lupus
Neurosarcoidosis
Nodular vasculitis
Ocular myasthenia
Ocular pemphigoid
Ocular sarcoidosis
Ocular vasculitis
Overlap syndrome
Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
Palindromic rheumatism
Palisaded neutrophilic granulomatous dermatitis
Parietal cell antibody
Parietal cell antibody positive
Paroxysmal nocturnal haemoglobinuria
Pemphigoid
Pemphigus
Pericarditis lupus
Peritonitis lupus
Pernicious anaemia
Pityriasis lichenoides et varioliformis acuta
Poems syndrome
Polyarteritis nodosa
Polychondritis
Polyglandular autoimmune syndrome type i
Polyglandular autoimmune syndrome type ii
Polyglandular autoimmune syndrome type iii
Polyglandular disorder
Polymyalgia rheumatica
Polymyositis
Postpericardiotomy syndrome
Primary amyloidosis
Progressive facial hemiatrophy
Psoriasis
Psoriatic arthropathy
Pulmonary amyloidosis
Pulmonary renal syndrome
Pulmonary sarcoidosis

Pulmonary vasculitis
Pyoderma gangrenosum
Pyogenic sterile arthritis pyoderma gangrenosum and acne syndrome
Radiculitis brachial
Radiologically isolated syndrome
Rasmussen encephalitis
Raynaud's phenomenon
Reiter's syndrome
Renal amyloidosis
Renal vasculitis
Retinal vasculitis
Retroperitoneal fibrosis
Reynold's syndrome
Rheumatoid factor decreased
Rheumatoid factor increased
Rheumatoid factor positive
Rheumatoid factor quantitative decreased
Rheumatoid factor quantitative increased
Rheumatoid lung
Rheumatoid neutrophilic dermatosis
Rheumatoid nodule
Rheumatoid scleritis
Rheumatoid vasculitis
Sarcoidosis
Satoyoshi syndrome
Schnitzler's syndrome
Sclerodactylia
Scleroderma
Scleroderma associated digital ulcer
Scleroderma renal crisis
Scleroderma-like reaction
Secondary amyloidosis
Septal panniculitis
Shrinking lung syndrome
Silent thyroiditis
Sjogren's syndrome
Sle arthritis
Stevens-johnson syndrome
Stiff leg syndrome
Stiff person syndrome
Subacute cutaneous lupus erythematosus
Susac's syndrome
Sympathetic ophthalmia
Systemic lupus erythematosus

	Systemic lupus erythematosus rash Systemic scleroderma Systemic sclerosis pulmonary Takayasu's arteritis Temporal arteritis Testicular autoimmunity Thromboangiitis obliterans Thromboplastin antibody positive Tolosa-hunt syndrome Type 1 diabetes mellitus Type iii immune complex mediated reaction Undifferentiated connective tissue disease Urticarial vasculitis Vaccination site vasculitis Vasculitis Vasculitis cerebral Vasculitis gastrointestinal Vasculitis necrotising Vitiligo Warm type haemolytic anaemia
Bell's Palsy*	MedDRA Codes: Bell’s Palsy Facial asymmetry Facial nerve disorder Facial palsy Facial paralysis Facial paresis Oculofacial paralysis
Chronic inflammatory demyelinating polyneuropathy (CIDP)	MedDRA Codes: Chronic inflammatory demyelinating polyradiculoneuropathy
Coagulopathy*	MedDRA Codes: Acquired amegakaryocytic thrombocytopenia Amegakaryocytic thrombocytopenia Axillary vein thrombosis Cavernous sinus thrombosis Cerebral venous thrombosis Deep vein thrombosis Disseminated intravascular coagulation Embolism venous Hepatic vein thrombosis Immune thrombocytopenia Intracranial venous sinus thrombosis

	Mesenteric vein thrombosis Portal vein thrombosis Pulmonary embolism Pulmonary thrombosis Pulmonary venous thrombosis Severe fever with thrombocytopenia syndrome Subclavian vein thrombosis Thrombocytopenia Thrombocytopenic purpura Thrombotic thrombocytopenic purpura Thrombosis Transverse sinus thrombosis Vena cava embolism Vena cava thrombosis Venous thrombosis
Death*	Died=Y
Encephalitis	MedDRA Codes: Encephalitis
Encephalopathy	MedDRA Codes: Encephalopathy Leukoencephalopathy
Encephalomyelitis	MedDRA Codes: Encephalomyelitis Leukoencephalomyelitis Noninfective encephalomyelitis
GBS*	MedDRA Codes: Acute motor axonal neuropathy Acute motor-sensory axonal neuropathy Autoimmune neuropathy Demyelinating polyneuropathy Demyelination Guillain-Barre syndrome Immune-mediated neuropathy Miller Fisher syndrome Subacute inflammatory demyelinating polyneuropathy
Kawasaki Disease*	MedDRA Codes: Kawasaki's disease
Meningitis	MedDRA Codes: Meningitis

	Meningitis aseptic Meningitis viral
Meningoencephalitis	MedDRA Codes: Meningoencephalitis viral
Multiple sclerosis (MS)	MedDRA Codes: Multiple sclerosis Multiple sclerosis relapse Primary progressive multiple sclerosis Progressive multiple sclerosis Progressive relapsing multiple sclerosis Relapsing multiple sclerosis Relapsing-remitting multiple sclerosis Secondary progressive multiple sclerosis Tumefactive multiple sclerosis
Multisystem Inflammatory Syndrome in Adults (MIS-a)*	Ages 21 and older AND MedDRA Codes: Multisystem inflammatory syndrome Multisystem inflammatory syndrome in adults Systemic inflammatory response syndrome
Multisystem Inflammatory Syndrome in Children (MIS-c)*	Ages 0-20 AND MedDRA Codes: Multisystem inflammatory syndrome in children OR Text String from VAERS 2.0 form (Item 18/19): "MIS ", "MISC ", "MIS-C ", or "Multisystem inflammatory syndrome"
Myelitis	MedDRA Codes: Myelitis Noninfectious myelitis
Myocarditis/Pericarditis*	MedDRA Codes: Atypical mycobacterium pericarditis Autoimmune myocarditis Autoimmune pericarditis Bacterial pericarditis Coxsackie myocarditis Coxsackie pericarditis Cytomegalovirus myocarditis Cytomegalovirus pericarditis Enterovirus myocarditis

	Eosinophilic myocarditis
	Hypersensitivity myocarditis
	Immune-mediated myocarditis
	Myocarditis
	Myocarditis bacterial
	Myocarditis helminthic
	Myocarditis infectious
	Myocarditis meningococcal
	Myocarditis mycotic
	Myocarditis post infection
	Myocarditis septic
	Pericarditis
	Pericarditis adhesive
	Pericarditis constrictive
	Pericarditis helminthic
	Pericarditis infective
	Pericarditis mycoplasmal
	Pleuropericarditis
	Purulent pericarditis
	Viral myocarditis
	Viral pericarditis
Narcolepsy/Cateplexy*	MedDRA Codes:
	Narcolepsy
	Cataplexy
Non-anaphylactic allergic reactions	MedDRA Codes:
	Allergy to vaccine
	Allergic bronchitis
	Allergic colitis
	Allergic cough
	Allergic cystitis
	Allergic gastroenteritis
	Allergic hepatitis
	Allergic keratitis
	Allergic pharyngitis
	Allergic reaction to excipient
	Allergic respiratory disease
	Allergic respiratory symptom
	Allergic sinusitis
	Conjunctivitis allergic
	Dermatitis allergic
	Encephalitis allergic
	Encephalopathy allergic
	Laryngitis allergic
	Nephritis allergic
	Pruritus allergic

	Rhinitis allergic
	Scleritis allergic
Optic neuritis (ON)	MedDRA Codes:
	Optic neuritis
Pregnancy and Prespecified Conditions*	MedDRA Codes:
	Abortion
	Aborted pregnancy
	Abortion complete
	Abortion early
	Abortion incomplete
	Abortion late
	Abortion missed
	Abortion spontaneous
	Abortion spontaneous complete
	Abortion spontaneous incomplete
	Abortion threatened
	Congenital anomaly
	Drug exposure during pregnancy
	Exposure during pregnancy
	Foetal death
	Maternal exposure during pregnancy
	Stillbirth
	OR
	Text String from VAERS 2.0 form (Item 11/12/18): 'preg' (*exclude ‘not pregnant’, ‘non-pregnant’,’ non pregnant’, ‘nonpregnant’, and 'no preg’)
	OR
	Pregnant Status (2.0 form-Q8)
Seizure/Convulsion*	MedDRA Codes:
	Atonic seizures
	Atypical benign partial epilepsy
	Autonomic seizure
	Clonic convulsion
	Complex partial seizures
	Convulsion in childhood
	Convulsion
	Convulsions local
	Epilepsy
	Epileptic encephalopathy
	Febrile convulsion
	Febrile infection-related epilepsy syndrome
	Generalised non-convulsive epilepsy
	Generalised onset non-motor seizure
	Generalised tonic-clonic seizure
	Grand mal convulsion

	Idiopathic generalised epilepsy Myoclonic epilepsy Neonatal seizure Partial seizures with secondary generalisation Partial seizures Petit mal epilepsy Seizure anoxic Seizure cluster Seizure like phenomena Seizure Simple partial seizures Status epilepticus Temporal lobe epilepsy Tonic clonic movements Tonic convulsion Tonic posturing
Stroke*	MedDRA Codes: Basal ganglia stroke Brain stem stroke Cerebellar stroke Cerebral infarction Cerebrovascular accident Embolic stroke Haemorrhagic stroke Haemorrhagic transformation stroke Ischaemic stroke Lacunar stroke Perinatal stroke Spinal stroke Thrombotic stroke Vertebrobasilar stroke
Transverse Myelitis*	Myelitis transverse
Vaccination Error	Please see Section 4.5

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