AFFILIATED PHYSICIANS
THE LEADER IN CORPORATE HEALTH SOLUTIONS

COVID Vaccine Event - Leadership Roles & Responsibilities

Site Manager (SM) and Head Clinicians (HC) Responsibilities:

The following are key, but not exclusive, responsibilities for SM and HC. Responsibilities may vary and may be client-specific. All responsibilities are to coincide with Affiliated Physicians Policies and Procedures and must be adhered to at all times.

Site Manager/Program Manager (PM): *Operational Responsibilities*

- ✓ Liaison for Site Contact and AP Corporate Team, including emergencies
- ✓ Manage the design or flow of the program (take in to consideration logistics/space/ventilation)
- ✓ Monitor operation program flow
- ✓ Familiarize self with site operations layout and emergency response plans according to site and client specific 'Emergency Preparedness' procedures.
- ✓ Report missing staff and/or need for additional staff in conjunction with Head Clinician (HC) if and when needed.
- ✓ Rotate RNs by station as needed, in collaboration with the HC.
- ✓ Monitor PPE adherence
- ✓ Manage vaccine vial deliveries
- ✓ Monitor vaccine vial temperature and temperature equipment (coolers, refrigerators, thermometers, etc.)
- ✓ Monitor number of available vials/doses with number of participants in conjunction with HC (in best effort to not waste any doses)
- ✓ Troubleshoot equipment as needed
- ✓ Manages and oversee paperwork process
- ✓ Manage and oversee Walk-In Policy
- ✓ Coordinate meal breaks and confirm appropriate coverage
- ✓ Manage biohazard waste and garbage disposal
- ✓ Review Incident Reports for accuracy and thorough completion. Must sign all Incident Reports before submitting at the end of an event.
- ✓ Any additional tasks as directed by Operations Managers and/or client

Head Clinician (HC): *Clinical Responsibilities*

- ✓ Liaison between the Site Contact and AP Team on site (RN's, Admins, etc.)
- ✓ Liaison between AP and AP Team on site (RN's, Admins, etc.)
- ✓ Troubleshoot potential issues that arise during the event. Escalate to CQC Team/AP as appropriate.
- ✓ Review/train new on site AP Team (RN's, Admins, etc.) as needed.
- ✓ Complete competency checklist with staff members as needed.
- ✓ Teach new nurses each station with special attention to the vaccination and observations stations.
- ✓ Communicate program updates to on site AP Team.
- ✓ Reinforce AP policies with staff during pre-event huddles and throughout event.
- ✓ Quality control of program paperwork during event

- ✓ Review Incident Reports for accuracy and thorough completion. Must sign all Incident Reports before submitting at the end of an event.
- ✓ **At Dose 2 Events: Call hotline with any reported delayed adverse reactions**
  - If participant states they experienced a delayed reaction after leaving a Dose 1 event, it **must** be reported to the hotline & reviewed by Compliance team before participant can receive their 2nd dose
- ✓ Any additional tasks specific to the program
- ✓ Submit VAERS report for all severe adverse reactions
- ✓ COVID Vaccine Management ***(additional details found under Vaccination Management)***
  - Manage vial distribution once vaccination nurses' previous vial is empty
  - Manage thawing of vials (if required)
  - Manage and monitor vial warming to room temperature
  - Dispose of used, empty vials in sharps container
  - Ensure vaccination nurse labels vial with appropriate date and time of first puncture
    - *Viability information listed under Vaccination Management and on 3 Vax Chart*
  - Monitor number of available vials/doses with number of participants in conjunction with SM (in best effort to not waste any doses)
    - Decline vaccinating 1-2 participant(s) & ask to reschedule their appointment(s) to avoid puncturing a new vial for if the remaining doses will expire and get discarded.
    - **MUST be diligent NOT to waste any doses.**
  - Confirm lot numbers on vial match any pre-printed lot info stickers
    - Ensure lot information is being placed on Proof of Vaccination (POV) card and consent forms/inside EMR
  - **Monitor dilution process**
    - Bring vial to room temperature before diluting.
      - Vials at room temperature need to be refrigerated/placed back in cooler if not diluted/punctured within 2 hours.
    - Vaccination Nurses will sign out vials that are provided to them by the HC and/or ML.
      - Reconstitution process for Pfizer and dispensing of vials is completed by the HC and/or ML and/or designated assistant managed by the HC/ML.
  - **For sites without refrigeration:** Monitor and record vaccine temperature inside of cooler using the WarmMark sticker
    - WarmMark is to remain in the cooler throughout the day.
    - Confirm WarmMark is attached to a vaccine box and **not** stuck on an ice pack or one of the cooler walls
    - Foil packs are used for transport ONLY. Should not be stored in fridge inside foil packs. Remove all vaccine from foil packs and place directly in cooler, making sure there is a barrier between icepacks and the vaccine.
    - To activate, fold 'up' WarmMark Time – Temp Tag at perforation and 'pull'.
    - WarmMark temp tags are valid unless color changes have occurred (see below)

- Red noted on brief, moderate or prolonged circles indicates specific exposure.
  - Brief – if red, indicates WarmMark has been exposed to greater than 46°F for at least 2 hours
  - Moderate – if red, indicates WarmMark has been exposed to greater than 46°F for at least 12 hours
  - Prolonged – if red, indicates WarmMark has been exposed to greater than 46°F Incident Reports (IR's) need to be completed for ALL patient symptom complaints, regardless of severity. Failure to follow incident reporting procedure may result in future removal of all Programs with Affiliated Physicians. Example of IR attached for example only; subject to change.

Submitting an Incident Report

***Note: All severe incidents must be reported to the nurse hotline immediately!* If EMS called, hotline must also be called.**

*Non-severe reactions no longer need to be reported to the Hotline, but still require completion of an Incident Report

Incident reports must be completed in entirety for **all** adverse events/reactions, workplace injuries, and occupational exposure incidents.

a. All sections with an *asterisk* must be completed. Do not leave any sections blank.

No Exceptions!

- If section not applicable, write N/A.

b. Chief Patient Complaint must be filled in. (Ex: dizzy, nausea, syncope, etc.)

c. Allergies must be listed.
   - If no known allergies verbalized by patient, write NKDA or NKA.

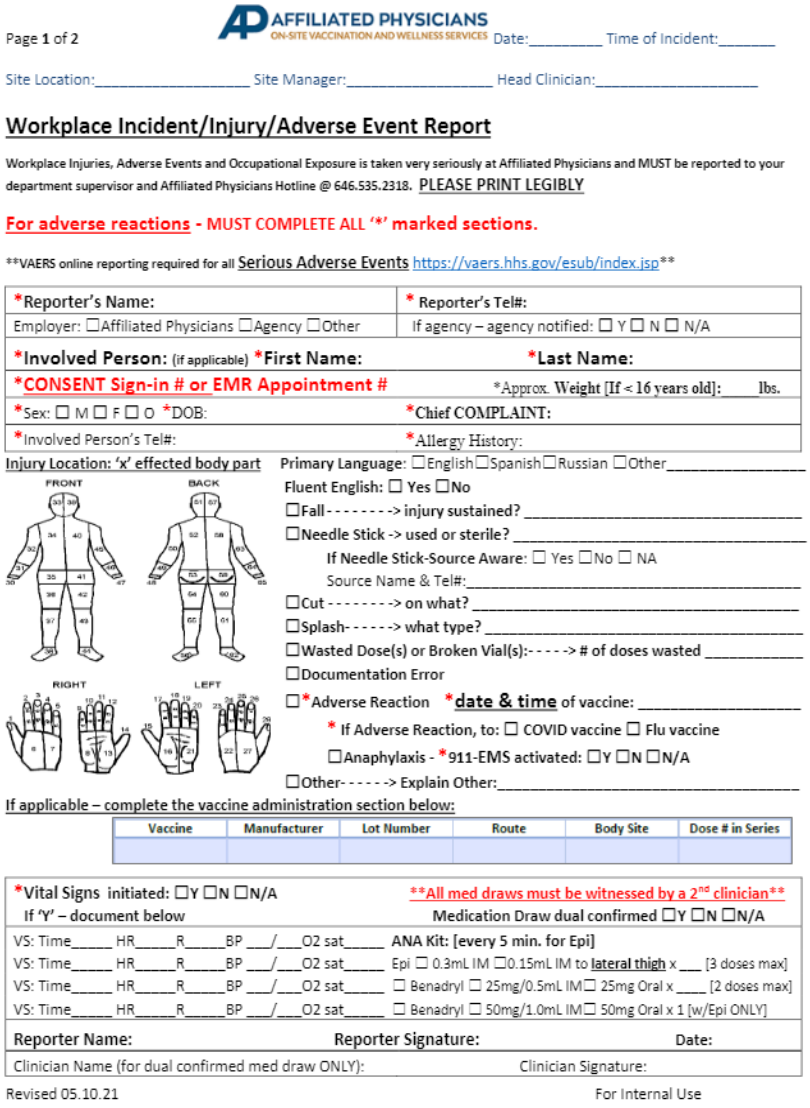
d. **Incident time is most likely DIFFERENT than vaccine time – both must be written in**

e. Page 1 and 2 must be signed by the person who initiates the form
   - The SM and/or HC must review, confirm all information is completed and accurate – then sign Page 2

f. If Vaccine administered, do not leave Vaccine information blank.

g. Vitals must be taken for adverse events/patient symptom complaints. At least 2 complete vital signs must be taken 15 minutes apart to show improvement and/or stable condition before patient can be discharged from observation. If patient is not improving enough for discharge, continue vital signs and alert HC/SM.

h. Indicate if EMS activated



Page 1 of 2 — AFFILIATED PHYSICIANS ON-SITE VACCINATION AND WELLNESS SERVICES — Date:_____ Time of Incident:_____

Site Location:_____ Site Manager:_____ Head Clinician:_____

Workplace Incident/Injury/Adverse Event Report

Workplace Injuries, Adverse Events and Occupational Exposure is taken very seriously at Affiliated Physicians and MUST be reported to your department supervisor and Affiliated Physicians Hotline @ 646.535.2318. PLEASE PRINT LEGIBLY

For adverse reactions - MUST COMPLETE ALL '*' marked sections.

VAERS online reporting required for all Serious Adverse Events https://vaers.hhs.gov/esub/index.jsp

*Reporter's Name:	* Reporter's Tel#:
Employer: ☐Affiliated Physicians ☐Agency ☐Other	If agency – agency notified: ☐ Y ☐ N ☐ N/A
*Involved Person: (if applicable) *First Name:	*Last Name:
*CONSENT Sign-in # or EMR Appointment #	*Approx. Weight [If < 16 years old]: ____lbs.
*Sex: ☐ M ☐ F ☐ O *DOB:	*Chief COMPLAINT:
*Involved Person's Tel#:	*Allergy History:

Injury Location: 'x' effected body part

FRONT BACK RIGHT LEFT

Primary Language: ☐English ☐Spanish ☐Russian ☐Other_____

Fluent English: ☐ Yes ☐No

☐Fall - - - - - - - -> injury sustained? _____

☐Needle Stick -> used or sterile? _____

If Needle Stick-Source Aware: ☐ Yes ☐No ☐ NA

Source Name & Tel#:_____

☐Cut - - - - - - - -> on what? _____

☐Splash- - - - - -> what type? _____

☐Wasted Dose(s) or Broken Vial(s):- - - - -> # of doses wasted _____

☐Documentation Error

☐*Adverse Reaction *date & time of vaccine: _____

* If Adverse Reaction, to: ☐ COVID vaccine ☐ Flu vaccine

☐Anaphylaxis - *911-EMS activated: ☐Y ☐N ☐N/A

☐Other- - - - - -> Explain Other:_____

If applicable – complete the vaccine administration section below:

Vaccine	Manufacturer	Lot Number	Route	Body Site	Dose # in Series

*Vital Signs initiated: ☐Y ☐N ☐N/A If 'Y' – document below	**All med draws must be witnessed by a 2nd clinician** Medication Draw dual confirmed ☐Y ☐N ☐N/A
VS: Time_____ HR_____R_____BP ___/___O2 sat_____	ANA Kit: [every 5 min. for Epi]
VS: Time_____ HR_____R_____BP ___/___O2 sat_____	Epi ☐ 0.3mL IM ☐0.15mL IM to lateral thigh x ___ [3 doses max]
VS: Time_____ HR_____R_____BP ___/___O2 sat_____	☐ Benadryl ☐ 25mg/0.5mL IM☐ 25mg Oral x ____ [2 doses max]
VS: Time_____ HR_____R_____BP ___/___O2 sat_____	☐ Benadryl ☐ 50mg/1.0mL IM☐ 50mg Oral x 1 [w/Epi ONLY]
Reporter Name:	Reporter Signature: Date:
Clinician Name (for dual confirmed med draw ONLY):	Clinician Signature:

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i. If emergency medications given, note name of med, time, dosage, and site of administration.

j. Personal Statement should include detailed account of how, when, and why adverse event happened. Include treatments, interventions, and any additional details.

k. Outcome should include how patient tolerated treatments/interventions, how long observation lasted, if symptoms resolved, how and with whom patient was discharged
   - Don't forget to record discharge vital signs

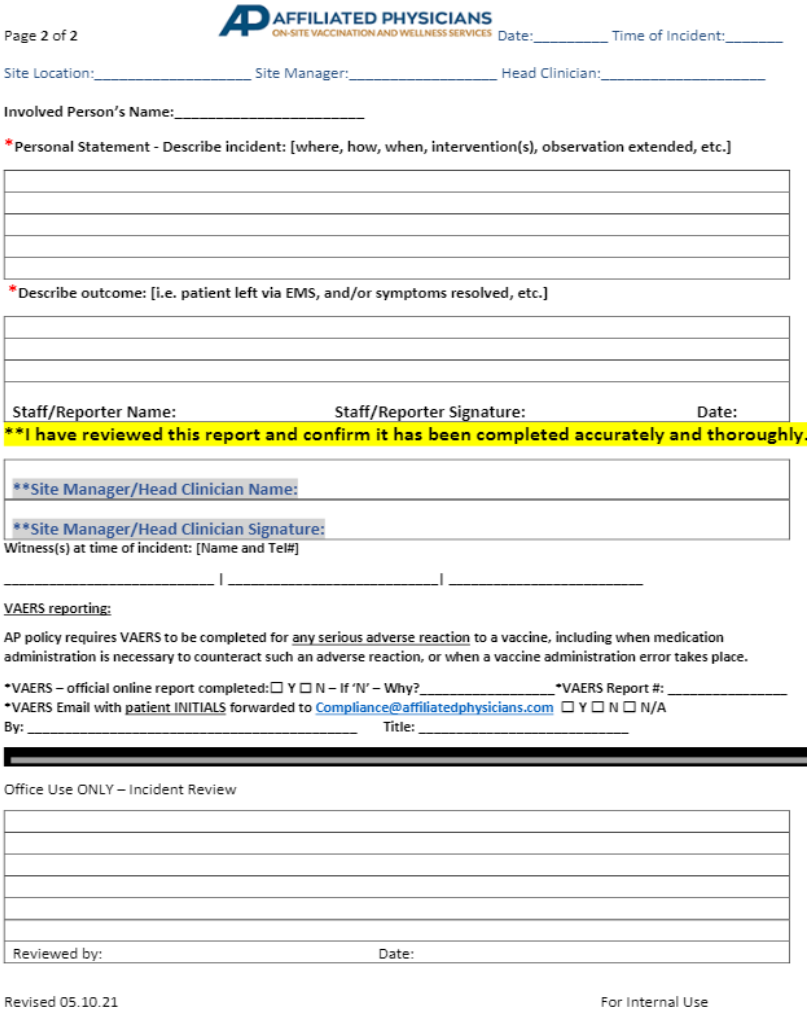
l. Include any staff name and telephone number if they witnessed or were involved with event.

2. Only serious reactions need to be reported to the hotline, including EMS activation, emergency medications administered, anaphylaxis, patient injury, etc. When HC/SM calls in adverse event(s), the following should be provided:
   a. HC & SM Names
   b. Location and Shift
   c. Patient Name
   d. Type of Adverse Reaction or Event
   e. Time of Adverse Reaction or Event
   f. Symptoms and/or incident

g. Intervention
h. Resolution/Outcome

3. HC/SM must report any serious adverse reaction to VAERS online.

4. All incident reports must be scanned into appropriate computer folder. Place original on top of program paperwork being returned to the office. Do not attach to patient's consent form.



Page 2 of 2

AFFILIATED PHYSICIANS
ON-SITE VACCINATION AND WELLNESS SERVICES

Date:_____ Time of Incident:_____

Site Location:_____ Site Manager:_____ Head Clinician:_____

Involved Person's Name:_____

*Personal Statement - Describe incident: [where, how, when, intervention(s), observation extended, etc.]

*Describe outcome: [i.e. patient left via EMS, and/or symptoms resolved, etc.]

Staff/Reporter Name: Staff/Reporter Signature: Date:

**I have reviewed this report and confirm it has been completed accurately and thoroughly.

**Site Manager/Head Clinician Name:

**Site Manager/Head Clinician Signature:

Witness(s) at time of incident: [Name and Tel#]

_____ | _____ | _____

VAERS reporting:

AP policy requires VAERS to be completed for any serious adverse reaction to a vaccine, including when medication administration is necessary to counteract such an adverse reaction, or when a vaccine administration error takes place.

*VAERS – official online report completed: ☐ Y ☐ N – If 'N' – Why?_____ *VAERS Report #: _____
*VAERS Email with patient INITIALS forwarded to Compliance@affiliatedphysicians.com ☐ Y ☐ N ☐ N/A
By: _____ Title: _____

Office Use ONLY – Incident Review

Reviewed by: Date:

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Post
Program Tasks

Post Program Paperwork Check List and Organization

Return paperwork in one neat stack with no staples, paperclips, "dog ear", post it notes, etc. Complete the below checklist to ensure all program paperwork is accounted for **and in order.** Return signed checklist with paperwork. Head Clinician must sign. **Note: HC and SM required to check and initial.**

HC/SM may not leave event before all post program paperwork completed – also must confirm all electronic documentation and scans have been received by AP!

Data team has to pull data from consent forms in a timely fashion. Do not wait until end of event to start scanning; Start scanning and quality checking scans as soon as each sign in sheet is full and a batch of full sign in sheet with corresponding consents are ready to be sent.

If you leave an event before AP data team confirms all required documents have been received and scans are legible, it may result in removal from future programs.

Post Program Paper Work:
Please return paperwork clean with no staples, paperclips, "dog ear", post it notes, etc.

Paperwork must be organized in the following order when being returned:
Note: Second initial required if 2+ staff on site

☑	Check List	Initial #1 (HC)	Initial #2 (SM)	Logistics to complete ONLY
	1. Event Sheet			
	2. Incident Report (Also Scanned Separately)			
	3. Event Vaccine Tracker			
	4. Sign in sheets			
	5. Consent Forms			
	6. Registration list			
	7. Observation Sheet			
	8. Check list (initialed AND signed)			
	9. Medication Tracker			
	10. Denied/Refused Consents			
	11. Total Tally Document			

I certify above all paperwork in the mentioned order from top to bottom are provided in FedEx Envelope labeled for '15 Canal Rd Pelham, NY 10803'. I understand multiple attempts to fail to include all required paperwork may result in removal of all future programs.

(Signature of Head Clinician) Date

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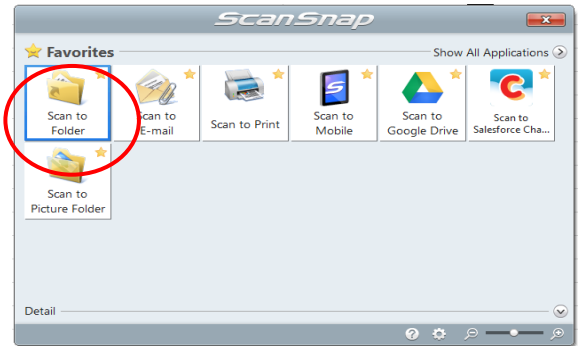
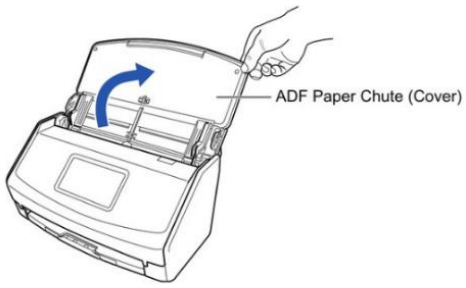
Scanning Post Program Paperwork Instructions

- Each vaccine station maintains their own sign-in sheet and 'batch' of corresponding consent forms. Hand sign-in sheet and corresponding consents to HC/SM when sign in sheet is full for scanning. Each batch needs to be scanned and labeled accordingly. When batch handed to HC, a new sign-in sheet will be provided



- Scan **in order** of Post Program Paper Work Checklist:
  1. **Event Summary**
  2. **Incident Reports (also scanned in separately)**
  3. **Event Vaccine Tracker**
  4. **Sign-In Sheets**
  5. **Consent Forms**
  6. **Registration/Appointment List**
  7. **Observation Sheet**
  8. **Post Program Checklist**
  9. **Medication Tracker**
  10. **Denied/Refused Consent Forms (if applicable)**
  11. **Total Tally Document**

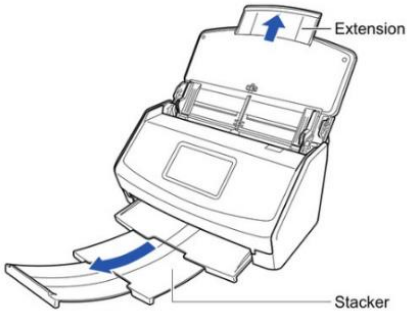
4. Open the ADF paper chute (cover) of the ScanSnap.



⇨ The touch panel is activated.

In addition, the ScanSnap Manager icon in the Dock changes from to .

5. Pull out the extension and the stacker on the ADF paper chute (cover).



- Once paperwork is in order in the "batch", place in scanner with top sheet **facing down.**
- A window will pop up on laptop asking where scan should be saved
- After documents are scanned, a window will pop up – select "scan to folder"
- Save all documents in local PC. (Create a new folder or save it in a preexisting folder; just remember where scan is saved!)
- Scanned file must be saved in this format "Date_Location_Consent_Batch <<insert sign-in sheet number range>> Ex: **04_30_21_CONSENT_BATCH 26-50 (25)**

Note: When scanning last batch, format the file as: "Date_Consent_Batch <<insert range number on sign in sheet>> **END**"

EXAMPLE: **10_20_21_CONSENT_BATCH 27-32 (6) END**

Submitting VAERS Report for Severe Adverse Reactions/Events

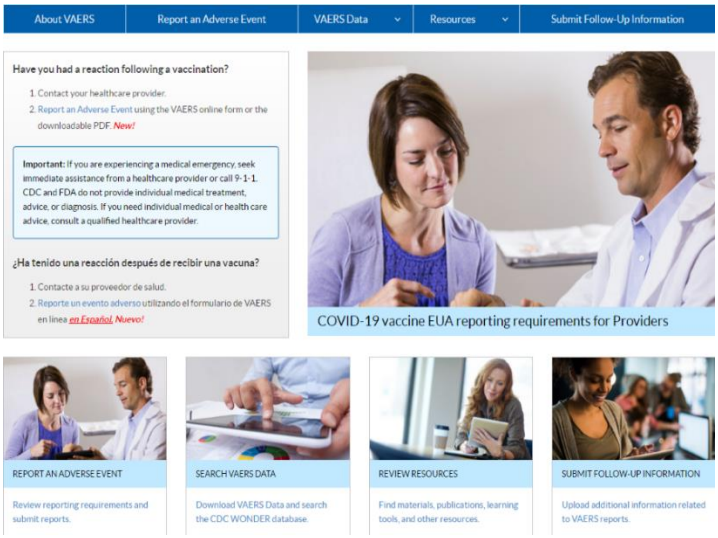
For sites with printer and computer capabilities, Head Clinician/Site Manager must complete the online VAERS reporting process for severe adverse reactions. [Vaccine Adverse Event Reporting System (VAERS) (hhs.gov)]

Step 1: Click on 'Report an Adverse Event'

Step 2: Complete Report

Step 3: Submit

Step 4: Forward VAERS report confirmation email to compliance@affiliatedphysicians.com



Report an Adverse Event to VAERS

VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences. Anyone can submit a report to VAERS, including parents and patients.

Healthcare providers are **required by law** to report to VAERS:

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

Click here for guidance to healthcare providers on reporting adverse events to VAERS after COVID-19 vaccination

Healthcare providers are strongly **encouraged** to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
- Vaccine administration errors

Vaccine manufacturers are required to report to VAERS all adverse events that come to their atte[illegible]

Online reporting is strongly encouraged. Please report clinically important adverse events that occur a[illegible]ccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.

What adverse events should healthcare providers report to VAERS after COVID-19 vaccination?

Healthcare providers are **required** to report to VAERS the following adverse events after COVID-19 vaccination [under Emergency Use Authorization (EUA)], and other adverse events if later revised by CDC:

- Vaccine administration errors, whether or not associated with an adverse event (AE)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
  1. Death;
  2. A life-threatening AE;
  3. Inpatient hospitalization or prolongation of existing hospitalization;
  4. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
  5. A congenital anomaly/birth defect;
  6. An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event.

Also report any additional select AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under an Emergency Use Authorization (EUA).

Which adverse events should healthcare providers report to VAERS after COVID-19 Vaccination?