HealthCare
Pharmacy Services

COVID-19 Emergency Use Authorization Vaccine Adverse Event Reporting Processes

Applies only to COVID-19 vaccines issued emergency use authorization. For fully FDA approved COVID-19 vaccines [e.g., the 2 dose series of Pfizer COMIRNATY® (COVID-19 vaccine, mRNA) for patients ages 16 and older], it is up to the provider to determine clinical necessity of reporting internally and to VAERS; please follow the Adverse Drug Reaction reporting policy #A14.150.

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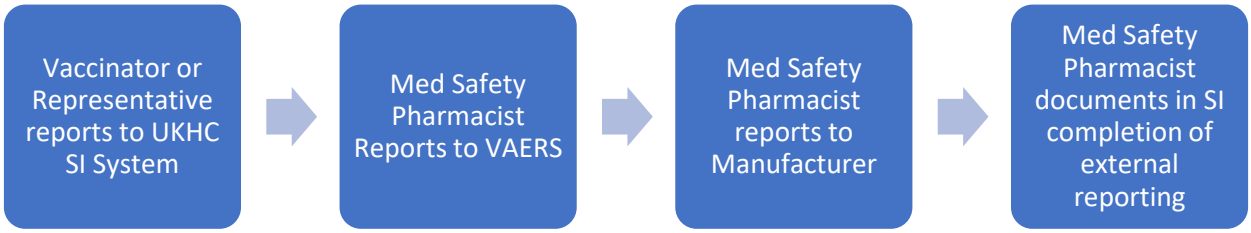
Voluntary reporting by the patient of ALL adverse events should be encouraged at time of vaccination. Vaccinator to counsel recipient on importance of enrolling in "V-safe", a CDC smart-phone based monitoring program for COVID-19 vaccine safety with electronic health check-ins. Patients can sign up at https://vsafe.cdc.gov/en/.

Mandatory reporting to Vaccine Adverse Event Report System (VAERS) is required in 4 scenarios per COVID-19 Vaccine FDA emergency use authorization (EUA) via the process outlined on page 2:

Scenario	Responsible Party
1. Vaccine administration errors whether or not associated with an adverse event	Vaccinator or Representative
2. Serious adverse events (irrespective of attribution to vaccination), defined as: • Death • A life-threatening adverse event • 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 judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above	Primary Provider or Representative
3. Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children	Primary Provider or Representative
4. Cases of COVID-19 that result in hospitalization or death	ID/MUS Pharmacy

Reporting on Day of Vaccination

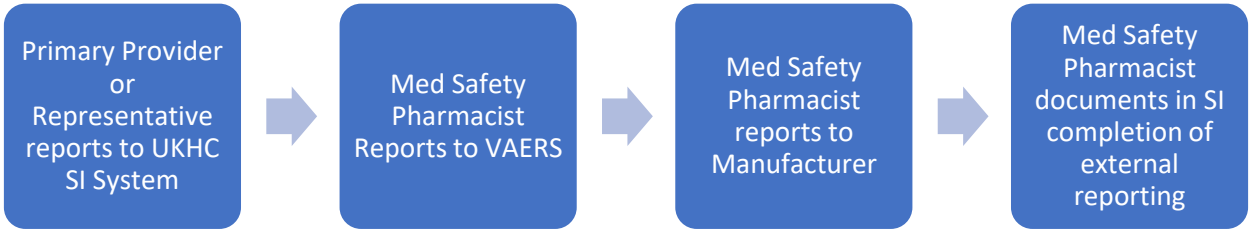
1. Vaccinator identifies vaccine error or serious adverse event.
2. Vaccinator or Representative reports to internal UKHC reporting system under the event type 'Adverse Drug Reaction' or 'Medication Event' as appropriate. - http://careweb.mc.uky.edu/psn/
3. Once reported internally, the Med Safety Pharmacist (Liz Hess) submits VAERS form to FDA - https://vaers.hhs.gov/reportevent.html. Reporting vaccinator will be contacted if there are additional questions.
4. Med Safety Pharmacist attaches VAERS Report to SI Report.
5. Med Safety Pharmacist reports adverse event to manufacturer online as needed and attaches to SI report.



Reporting Post-Vaccination

For any patients who experience inpatient hospitalization (mandatory reporting scenario #4 above) at UK HealthCare, a centralized process has been created with IPAC, ID Pharmacy and Medication Use Safety for reporting; primary team reporting is not required for cases of COVID-19 that result in hospitalization. In the case that a recipient of the vaccine experiences a side effect, adverse drug reaction, or adverse drug event and informs their provider, the following should occur. ***Vaccine information is located on recipient's COVID-19 Vaccination Record Card or the Kentucky Immunization Registry (available in Epic Immunization tab).*** *If the above information is not readily available, the provider is encouraged to contact the family and/or clinic site to obtain the specifics of the vaccine.*

1. The provider encourages patient to submit information through V-Safe application directly to the CDC (vsafe.cdc.gov)
2. The provider reports to internal UKHC reporting system under the event type 'Adverse Drug Reaction' as appropriate. - http://careweb.mc.uky.edu/psn/
3. Once an internal event (SI) is reported the Med Safety Pharmacist (Liz Hess) will follow steps 3-5 above, to report to VAERS and the vaccine manufacturer, if the event meets mandatory reporting criteria.



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Recommended COVID Vaccine Reporting Template

Use this template to report internally (copy/paste) or write down pertinent details, prior to internal reporting. Delete text that is not utilized (e.g. COVID hospitalization).

Patient Name: _____
DOB: ___/_____/_____
Patient phone: _____
Patient email:_____
Allergies (drug/food and reaction):_____

Date of Vaccination:____/_____/2021 (*include only if NOT in Epic Immunizations tab*)
Dose: 1 or 2
Vaccine Manufacturer: _____
Lot #: _____
Clinic Administering Vaccine: _____
Injection site:_____
Description of event/reaction:
_____
_____
_____

Date of Clinic Visit or Hospitalization: ____/_____/2021
Reason for clinic visit or hospitalization: _____
COVID-19 positive test result: Yes or No; if Yes, date ____/____/2021
Plans to monitor (include medications if prescribed):_____
_____