

COVID Vaccine Adverse Event Reporting

Reporting for the COVID vaccine is the same as your current process for reporting adverse events for the pneumonia and influenza vaccines (review page 73 of the Consonus P and P). Adverse events from vaccines should always be reported to the Vaccine Adverse Event Reporting System VAERS (www.vaers.hhs.gov).

Remember, **you do not need to report ALL side effects for vaccines**. VAERS publishes a list of mandatory reportable events for each vaccine.

For the COVID vaccine, you only need to report the following*:

- Mistakes during vaccine administration (even if not associated with an adverse event)
- Death
- Anaphylaxis or other life-threatening response to the vaccine
- Any side effect that requires hospitalization
- Any side effect that persistently or significantly incapacitates the recipient beyond their normal baseline activity
- Multisystem Inflammatory Syndrome (MMS)
- COVID-19 positive diagnosis *only if it results in hospitalization or death*

If any of these occur while the Consonus Mobile Vaccine team is still on site, please let them know immediately! Consonus will report this to VAERS and give you a copy of the report information for your records.

If any of these occur after the team has left, you should report it to VAERS per your current policy.

If you report to VAERS, let Consonus know! Fax us a copy of the report for the pharmacy records.

If you have problems reporting to VAERS, let us know via phone (speak with a pharmacist) or fax and we will work on the report together.

*Per the Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Health Care Providers

CDC's v-safe Tool for Smart Phone Users

V-safe is a smart phone-based tool that uses text messaging and web surveys to monitor the side effects people experience after receiving the vaccine. The tool sends regular health check in surveys (less than 5 mins each) for up to 6 weeks after your second dose of vaccine. Depending on your answer, someone from the CDC may call you. You can stop participating at any time by texting the word "STOP".

We encourage anyone receiving the COVID vaccine who regularly uses a smart phone to sign up with v-safe and report their side effects and experiences directly to the CDC.

To register or learn more about v-safe, go to vsafe.cdc.gov, or aim your smartphone camera at the QR code.

For Serious Adverse Events among staff members:

All recipients of the vaccine, whether residents or staff, should report the same serious adverse events to the CDC.

These serious reportable events are*:

- Mistakes during vaccine administration (even if not associated with an adverse event)
- Death
- Anaphylaxis or other life-threatening response to the vaccine
- Any side effect that requires hospitalization or that persistently or significantly incapacitates the recipient
- Multisystem Inflammatory Syndrome (MMS)
- COVID-19 positive diagnosis *only if it results in hospitalization or death*
- Birth defects

Consonus wants to know if any of these serious events occurs in any resident or staff member!

Even if the staff member is using a v-safe report to the CDC, please call and speak with a pharmacist to tell us what happened.

Aim your smart phone camera at the QR code to learn more about

v-safe



*Per the Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Health Care Providers