Question Follow Up from the Noontime Knowledge Regarding COVID-19 Vaccine Safety on February 11, 2021

1. Can I have clarification on priority: why are we vaccinating k-12 teachers and not college instructors that are teaching in person?

There has been a focus to get schools to in-person learning by March 1. We are aware that many college professors are teaching in person as well, but we are focusing on Preschool-12 with the limited amount of vaccine that is currently available.

2. If we are reporting in V-Safe, do we need to also report in VAERS?

This is not necessary, but to elaborate a bit further on this, if in the course of a V-safe "health-checker" follow-up, the vaccinee mentions a concern that resulted in a doctor/hospital/ER visit (i.e., medially attended), the V-safe program personnel will create a VAERS report for that event. If there are other events that occur but did not require or result in such a visit, a VAERS report can be submitted if the vaccinee or provider feels it is clinically significant. So, it would not hurt to report it to VAERS if you administered the vaccine.

3. Do we report a positive COVID-19 test in VAERS even if the person has only had the first of the 2-dose vaccine?

This answer was updated on 2-18-21 to further clarify what should be reported to VAERS after COVID-19 vaccination. According to current guidance (see https://vaers.hhs.gov/faq.html) it is required for health care providers 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

Health care providers are encouraged to report to VAERS any additional clinically significant AEs or health problems that occur after vaccination even if they are not sure if vaccination caused the event. Healthcare professionals are required by law to report certain adverse events

Although the guidance listed above does not specifically state if the report is required for vaccinees that report a positive COVID-19 test after receiving only one dose of COVID-19 vaccine (as opposed to two doses) it may be reported to VAERS.

As a reminder, it takes approximately two weeks for the body to build immunity after vaccination. That means it is possible a person could be infected with the virus that causes COVID-19 just before or just after vaccination and still get sick. This is because the vaccine has not had enough time to provide protection.

4. My health department has encountered persons reporting a history of anaphylaxis from oral medications that include PEG as an inactive ingredient. Would you consider such a history to be a pre-caution or contraindication for COVID-19 vaccination? CDC recently issued additional guidance to further clarify contraindications and precautions for mRNA vaccines. You can find the Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

Here is part of the update in the guidance but for further detail visit the link above: "Persons with a known (diagnosed) allergy to PEG, another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. Persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination."

5. If patients have not signed up for v-safe when receiving the first dose, is there a way for them to sign up after the second dose?

Yes. Please find the details here: V-safe After Vaccination Health Checker | CDC

6. If a person has had anaphylaxis before to oral meds is a 15-minute wait time enough? CDC has issued guidance in the Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

You can also find this information with the *Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination* at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

Here is what CDC recommends on this topic:

Routine observation periods following COVID-19 vaccination*

CDC currently recommends that persons without contraindications to vaccination who receive an mRNA COVID-19 vaccine be observed after vaccination for the following time periods:

- 30 minutes:
 - Persons with a history of an immediate allergic reaction of any severity to another (non-mRNA COVID-19) vaccine or injectable therapy
 - o Persons with a history of anaphylaxis due to any cause
- 15 minutes: All other persons
- * Note: Persons may be observed for longer, based on clinical concern. For example, if a person develops itching and swelling confined to the injection site during their post-vaccination observation period, this period may be extended to assess for development of any hypersensitivity signs or symptoms consistent with anaphylaxis (described below).
- 7. With multiple registered providers administering COVID-19 vaccines within, my health department would like to obtain a weekly line list of every person in our jurisdiction who has received a COVID-19 vaccine to aid our vaccination planning, scheduling, and outreach. Given that MCIR does not offer any such reporting, what options exist for obtaining such a list?

We completely understand the request for these data. We are working with the University of Michigan to generate these types of reports for our LHDs so that you can better understand the populations you have vaccinated in your communities and those that are still in need of vaccinations as well as areas that are pockets of need.

Two additional resources that you may find helpful are:

- MCIR region 2 tutorials: https://r2mcir.org/trainingvideos.html
 - COVID-19 Vaccines Administered Report (site-level patient list)
- MCIR Reminder/Recall generates a roster of person's needing a 2nd dose