Indian Health Service
National Pharmacy and Therapeutics Committee
COVID-19 Emerging Treatments Update

January 17, 2023

CDC and FDA Identify Preliminary COVID-19 Vaccine Safety Signal for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for Persons Aged 65 Years and Older

On January 13, 2023, the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) issued a joint safety statement indicating a preliminary safety signal had been identified with the following:

- **Possible safety concern with ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent**

Background

Transparency and vaccine safety are top priorities for the CDC, FDA and the Indian Health Service (IHS). These U.S. government agencies use multiple, complementary safety monitoring systems to help detect possible safety signals for vaccines and other medical countermeasures as early as possible and to facilitate further investigation, as appropriate. Often these safety systems detect signals that could be due to factors other than the vaccine itself.

The IHS currently has the most robust vaccine safety monitoring system in our history, including both passive and active safety surveillance in tribal communities. **To date, there are no safety signals related to bivalent COVID vaccine boosters across the I/T/U system of care.**

All signals require further investigation and confirmation from formal epidemiologic studies. When one system detects a signal, the other safety monitoring systems are checked to validate whether the signal represents an actual concern with the vaccine or if it can be determined to be of no clinical relevance.

Current Safety Signal

Following the availability and use of the updated (bivalent) COVID-19 vaccines, the CDC's Vaccine Safety Datalink (VSD), a near real-time surveillance system, met the statistical criteria to prompt additional investigation into whether there was a safety concern for ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Rapid-response investigation of the signal in the VSD raised a question of whether people 65 and older who have received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent were more likely to have an ischemic stroke in the 21 days following vaccination compared with days 22-44 following vaccination. This preliminary signal has not been identified with the Moderna COVID-19 Vaccine, Bivalent.

Current Vaccination Practice Recommendation

Although the totality of the data currently suggests that it is very unlikely that the signal in VSD represents a true clinical risk, it is important to share this information with the public, as has been done in the past, when one of the safety monitoring systems detects a signal. The CDC and FDA will continue to evaluate additional data from these and other vaccine safety systems. These data and additional analyses will be discussed at the upcoming January 26 meeting of the FDA's Vaccines and Related Biological Products Advisory Committee.

****No change in vaccination practice is recommended**.

The CDC continues to recommend that everyone ages 6 months of age and older stay up-to-date with COVID-19 vaccination; this includes individuals who are currently eligible to receive an updated (bivalent) vaccine. Staying up-to-date with vaccines is the most effective tool we have for reducing death, hospitalization, and severe disease from COVID-19, as has now been demonstrated in multiple studies conducted in the United States and other countries:

- Data have shown an updated COVID-19 vaccine reduces the risk of hospitalization from COVID-19 by nearly 3-fold compared to those who were previously vaccinated but have not yet received the updated vaccine.
- Data have shown that the updated COVID-19 vaccine also reduces the risk of death from COVID-19 by nearly 19-fold compared to those who are unvaccinated.
- Other preliminary data from outside the U.S. have demonstrated more than 80% protection against severe disease and death from the bivalent vaccine compared to those who have not received the bivalent vaccine.

Overall safety data for the bivalent COVID-19 vaccines are available here. Once again, **no change is currently recommended in COVID-19 vaccination practices**, which can be found here.

Vaccine Adverse Event Reporting

The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS) under the provider agreements for the CDC COVID-19 Vaccination Program:

- vaccine administration errors whether or not associated with an adverse event,
- serious adverse events* (irrespective of attribution to vaccination),
- cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
- cases of COVID-19 that result in hospitalization or death.

Federal, Tribal, and Urban programs are all encouraged to put "IHS" into field #26 of the form.

Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure whether the vaccine caused the event. Healthcare providers must also report any additional selected 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's Emergency Use Authorization (EUA) or any approved COVID-19 vaccine as outlined in the Fact Sheet for Healthcare Providers.

References:
1. U.S. Food and Drug Administration. CDC and FDA Identify Preliminary COVID-19 Vaccine Safety Signal for Persons Aged 65 Years and Older. Published online on January 13, 2023.