Idaho Hospital Association

COVID-19 Report to Members ~ January 7, 2021

Reports are sent on Mondays and Thursdays, unless there's breaking news.

Quality & Patient Safety

Early surveillance ~ low anaphylaxis from Pfizer vaccine

The Pfizer-BioNTech COVID-19 vaccine received an EUA on December 11, 2020, with the first U.S. doses administered on December 14. The public health and medical communities are keenly monitoring adverse effects associated with the roll-out of this new vaccine. Yesterday (Jan 6th) the CDC published a **summary of adverse events** reported after receipt of Pfizer-BioNTech vaccine during December 14 - 23. Of particular concern was anaphylaxis – a severe, potentially life-threatening allergic reaction, which was not observed during the Phase III clinical trial, but was identified for clinical consideration prior to vaccine administration.

As of December 23, 1,893,360 initial doses of this vaccine had been administered with 4,393 adverse events reported to the Vaccine Adverse Event Reporting System (**VAERS**) – a CDC- and FDA-operated national surveillance system for post-immunization adverse events. Of the reported adverse events, 21 were determined to be anaphylaxis (rate of 11.1 per million administered doses). Among these 21 instances, 17 occurred in persons with a documented history of allergies or allergic reactions, of which 7 also had a history of anaphylaxis.

The median time from vaccine receipt to symptom onset was 13 minutes, with 18 occurring within the 30-minute observation period recommended for people with a history of allergic reaction to vaccination, and 3 outside of the 30-minute observation period (maximum time to symptom onset was 150 minutes). All 20 persons with follow-up information had recovered and were discharged home.

Additionally, 86 post-vaccination non-anaphylaxis allergic reactions were identified, 87% of which were determined to be non-serious adverse events.

Health care providers are encouraged to report any post-vaccination adverse events to VAERS.

The Pfizer-BioNTech COVID-19 vaccine is a critical tool in controlling the pandemic and continues to demonstrate a strong safety profile. To ensure patient safety and integrity of the vaccination process, health care providers and vaccination locations should follow **CDC recommendations** to:

1. ensure supplies are available to manage anaphylaxis, and in particular, epinephrine in prefilled syringes or autoinjectors;
2. screen potential vaccine recipients for vaccine contraindications and precautions;
3. observe vaccine recipients for either 15- or 30-minutes post-vaccination, depending on the patient's previous history of allergic reactions;
4. instruct patients to immediately seek medical care if they develop signs or symptoms of an allergic reaction after their observation period ends;
5. ensure that health care providers can recognize the signs and symptoms of anaphylaxis; and
6. immediately treat suspected anaphylaxis with intramuscular epinephrine.

Although exceedingly rare, due to the seriousness of anaphylaxis, CDC recommends that patients with a history of the following allergic reactions are contraindicated to receive vaccination with either the Pfizer-BioNTech or the Moderna COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG]) *
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG) *

Additional **information** describing these contraindications can be found on the CDC website.

Similar data on the Moderna COVID-19 vaccine are currently limited (vaccinations started December 21); CDC and FDA plan to publish similar findings describing adverse events related to the Moderna COVID-19 in the near future.

** These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available).*

Resources & Equipment

More change is coming - potential implications of variants

The concept of survival of the fittest is not limited to organisms that are, well, alive. The SARS-CoV-2 virus, a small amount of RNA surrounded by a protein coat, gains entry to host cells by docking on human angiotensin-converting–enzyme 2 (ACE2) receptors and replicates inside the cell. Although this replication activity includes a sort of "proofreading" step, which means that viral RNA copies are highly faithful to the original, these replications do at times include copy "errors" or mutations. Not unlike Darwin's finches, the genetic diversity introduced by these mutations can change characteristics of the virus, for example increase transmissibility or decrease virulence.

There are currently two known emerging variants of the SARS-CoV-2 virus: the "UK strain", or 20B/501Y.V1, VOC 202012/01, or B.1.1.7 lineage, and a variant identified in South Africa, referred to as 20C/501Y.V2 or B.1.351 lineage. These variants share some of the same mutations, but emerged independently.

Evidence suggests that the UK strain is 50% to 70% more infectious than other SARS-CoV-2 variants. Although any additional burden in the number of infections is of concern in terms of an increased number of persons needing treatment, there is currently no evidence to that B.1.1.7 causes more severe disease or decreases vaccine efficacy. As of January 5, B.1.1.7 has been detected in multiple U.S. states, including Colorado, California, Florida, Georgia, and New York.

The B.1.351 strain first identified in South Africa is also associated with higher rates of transmission – in particular in children. To date, there is no evidence that this strain is more virulent than others or that B.1.351 will impact vaccine efficacy. Although no cases of B.1.351 have yet been identified in the U.S., the strain has been found in Finland, the United Kingdom, Australia, Switzerland, Japan and South Korea.

The emergence of new strains also raises concerns about the sensitivity of assays currently in use to detect SARS-CoV-2. To date, there is no evidence to indicate that PCR tests in common use are less able to detect the new variants, largely due to the multiple targets employed in the molecular tests. Some laboratories and manufacturers have started to note patterns in SARS-CoV-2 positive tests that could potentially help identify isolates that could be prioritized for whole genome sequencing (WGS). For example, a person infected with the B.1.1.7 variant will test positive on Thermo Fisher's TaqPath COVID-19 assay, but the positive result could register with an S gene "drop out" result, indicating that the patient is infected with the B.1.1.7 variant that has the 69-70del mutation.

The U.S. is increasing efforts to conduct strain surveillance – which typically requires WGS, as opposed to standard PCR techniques. The National SARS-CoV-2 Strain Surveillance, housed at the CDC, is being scaled to process 750 samples per week. The CDC is also partnering with state and local health departments, universities, and national reference laboratories to increase sequencing efforts.

The impact of viral variants on transmissibility, virulence, and assay performance will remain areas of active research and surveillance. Additional information provided by CDC can be found **here**.

Virtual Meetings & Education

Vaccine Advisory Committee

The Vaccine Advisory Committee will meet this week to discuss progress on the state's vaccination program as well as a discussion on Idaho's priority subgroups.

Friday, January 8 ~ 12p MTN / 11a PAC
Agenda
View meeting via WebEx

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