ONLINE FEATURE | COVID-19 Vaccine Adverse Event Reporting System

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Background

The U.S. Department of Health and Human Services (HHS) has established a website to guide professionals and consumers on how to report a suspected adverse event after receiving either the Moderna or Pfizer COVID-19 vaccines. This is also true for any new vaccines approved by the U.S. Food and Drug Administration (FDA) under its Emergency Use Authorization (EUA) program. Audiologists and other health-care workers have a legal obligation to report these adverse events to the HHS (2021a).

The Vaccine Adverse Event Reporting System (VAERS) is a passive reporting system that relies on health-care workers and individuals to send in reports of their COVID-19 vaccine experiences (HHS, 2021b). The program is similar to the MedWatch Program—the FDA's Safety Information and Adverse Event Reporting Program for pharmaceutical and dietary supplements side effects (FDA, 2021a).

In 2017, HHS developed a Table of Reportable Events Following Vaccination (also known as the Reportable Events Table or RET) that reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS). This includes conditions found in the manufacturer package insert.

In addition, health-care professionals must report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET (including the Moderna or Pfizer vaccine). Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine (HHS, 2021c).

Current Clinical Trials for COVID-19 Biologics

According to the National Library of Medicine's website for clinical trials, as of January 24, 2021, over 780 clinical trials are currently underway worldwide with 316 occurring in the United States (National Library of Science, 2021).

It will be during these trials that the researchers will identify and report any adverse events (immediate or late onset) to the Food and Drug Administration and the HHS.

Resources

The Centers for Disease Control and Prevention has several important webpages on COVID-19 vaccines:

COVID-19 Vaccination (general information)

For Clinicians/Health-Care Providers

COVID-19 Vaccine Product Information

Key information for each specific COVID-19 vaccine including administration, storage and handling, safety, and reporting.

For the General Public

COVID-19 Vaccine Information Overview

Overview of what everyone should know about the different COVID-19 vaccines.

COVID-19 Vaccine Fact Sheets

COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers

Fact sheets for each COVID-19 vaccine authorized under the Emergency Use Authorization (EUA).

The Emergence of Adverse Events

Under Section 564 of the Federal Food, Drug, and Cosmetic Act, the FDA Commissioner can allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives (FDA, 2021b).

Because of this, Pfizer's and Moderna's vaccine for COVID-19 intervention have each been given Emergency Use Authorization (EUA). The disadvantage of the EUA is that not all adverse events could emerge during the initial roll out.

Known Vaccine Adverse Events

Currently, for COVID-19 vaccines, the Centers for Disease Control and Prevention website lists pain, swelling, fever, chills, tiredness, and headache as the most common adverse events/side effects of the vaccines being used. The CDC also reports that the side effects should subside in a few days (CDC, 2021).

Late Onset of Adverse Events

It should be noted that because of the FDA's EUA long-term adverse events or late-onset of these adverse events may not immediately appear. These 'long-hauler' patients may not report hearing loss, tinnitus, and/or vestibular problems for weeks or months after intervention. DiSogra (2020) provides a review of the most current research on audiologic 'long-haulers.'

Reporting COVID-19 Vaccine Adverse Events to VAERS

According to HHS there are several ways to submit an adverse event report to VAERS:

1. **Online reporting:** Even if a health-care professional or individual is not sure whether the vaccine caused the adverse event, it should be reported. The report must be completed, submitted in one sitting, and cannot be saved and returned to later.
2. **Online Writable PDF Form**: Best used if the professional or individual does not have time to complete the form all at once.
3. **E-mail:** info@VAERS.org
4. **Call:** 800-822-7967

More information about the VAERS can be found on the HHS's Frequently Asked Questions webpage to learn the details about the Vaccine Adverse Event Reporting System

Conclusion

We are at the first anniversary of the COVID-19 pandemic. Research is emerging on COVID-19 survivors who have experienced long term medical problems directly related to the disease as well as experiencing side effects of FDA-approved biological intervention.

The U.S. Department of Human Services is collecting data from health-care professionals whose patients are reporting COVID-19 related adverse events. To that end, the Vaccine Adverse Event Reporting System (VAERS) program has been set-up to establish a database of adverse events related to COVID-19 vaccines.

As the body of knowledge on COVID-19 continues to emerge, audiologists will need to know how to report any auditory/vestibular suspected adverse events from any COVID-19 vaccine.

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