Dear Mr. Chaves,

Thank you for contacting CDC with your question about the increase in VAERS reports received in 2021.

The frontline system used to collect data and monitor adverse events that occur after vaccination is the Vaccine Adverse Event Reporting System (VAERS). VAERS is a national vaccine safety monitoring system managed by CDC and FDA. VAERS accepts reports of possible side effects (also called "adverse events") following vaccination. The system is not designed to determine whether a reported adverse event was caused by the vaccine but serves as an early warning system and helps CDC and FDA identify areas for further study.

VAERS accepts all reports of adverse events after vaccination, without regard to whether or not the vaccine caused the event. Because of this and other limitations, data in VAERS generally can't be used to determine if a vaccine caused the adverse event (including deaths). Importantly, reported events and deaths are not necessarily "due to vaccines".

VAERS received 49,674 reports in 2020; 752,541 reports in 2021; and 246,500 in 2022.

The authorized and approved COVID-19 vaccines have been administered under the most comprehensive and intensive vaccine safety monitoring effort in U.S. history. It is important to note that VAERS is only <u>one system among many</u> that monitor the safety of US-licensed or authorized vaccines. Each system has different strengths and weaknesses.

For a list of CDC safety monitoring systems, please see <u>COVID-19 Vaccine Safety Reporting</u> <u>Systems | Vaccine Safety Systems | CDC</u>.

Below is some information that may be helpful to understand why there are many reports in VAERS in 2021:

- 1. Different (and much broader) reporting requirements for COVID-19 vaccines as compared to other vaccines:
  - a. The reporting requirements for healthcare providers for COVID-19 are listed at <u>Reporting requirements for COVID-19 vaccines given under an Emergency Use</u> <u>Authorization (EUA)</u>
  - b. The reporting requirements for other vaccines are listed at <u>https://vaers.hhs.gov/docs/VAERS Table of Reportable Events Following Va</u> <u>ccination.pdf</u>
- 2. Higher denominator -the number of persons vaccinated in a short period of time increased as a new vaccine was introduced. The COVID-19 vaccine program was the largest vaccination campaign in the history of the US and thus the number of VAERS reports was quite large. In addition, influenza vaccine uptake increased during the 2020-21 season Historical Reference of Seasonal Influenza Vaccine Doses Distributed | CDC.
- 3. Stimulated reporting: since COVID-19 vaccination and VAERS have been a frequent topic in media, this has led to increased reporting of events following vaccination.

Sincerely,

Staff of the CDC Immunization Safety Office Atlanta, GA