Monitoring Vaccine Adverse Event Reporting System (VAERS) Reports Related to COVID-19 Vaccination Efforts in Rhode Island

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INTRODUCTION

Co-developed and maintained by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA), the Vaccine Adverse Event Reporting System (VAERS) serves as a national passive surveillance system for continuous monitoring of vaccine safety once it has been distributed in the marketplace.[1,2] Any individual may report an adverse event following immunization (AEFI) to VAERS, without temporal limits or specifications of what type of events constitute an adverse reaction. Reports can be submitted online or email/faxed to the CDC. VAERS accepts and monitors spontaneous reports of adverse reactions or side effects that individuals may experience post immunization, some of which have not been observed during clinical trials and may indicate a possible safety concern with the vaccine.[3]

Prior to the 2019 coronavirus (COVID-19) pandemic, the immunization program at the Rhode Island Department of Health (RIDOH) had limited interaction with the VAERS operations at CDC; RIDOH did not receive state-level VAERS data regularly and had no protocol or necessity for receiving, storing, and reviewing RI VAERS reports. Following the release of the COVID-19 vaccines in the United States, the CDC has actively shared Rhode Island resident VAERS reports with RIDOH. A vaccine surveillance team was established within the COVID-19 Epidemiological Operations (Epi-Ops) Unit to maintain and review VAERS reports following COVID-19 immunization. The purpose of the state program is to organize and summarize both the operations of RIDOH COVID-19 vaccine surveillance team and the information included in VAERS reported in Rhode Island.

METHODS

Anyone can submit a report of a suspected vaccine adverse event to VAERS, including a patient, family member, or health care provider. When a person calls RIDOH with information on an event or requests assistance regarding the VAERS reporting process, the COVID-19 vaccine surveillance team assists the caller in completing and submitting a VAERS report. After receipt and review by the federal VAERS program, VAERS report data is shared with the appropriate state Department of Health. The CDC sends Rhode Island VAERS reports in an excel format to the RIDOH. The vaccine surveillance team at RIDOH maintains an internal cumulative spreadsheet of all the VAERS reports pertaining to RI residents. The clinical staff on the team review the VAERS report details and classify the reported event.[4] Classification of VAERS reports into specific categories helps the team summarize adverse events following AEFIs to identify cases of significant interest and respond to media and data requests in a timely manner.

Reported adverse events are classified by VAERS as:[5]

1. Serious adverse events (as defined by federal law), regardless of causality, including:

- death
- a life-threatening event
- inpatient hospitalization or prolongation of existing hospitalization
- persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- congenital anomaly/birth defect
- an important medical event that, based on appropriate medical judgement, may jeopardize the individual and may require medical or surgical intervention

2. Non-serious adverse events:

- non-life-threatening events that resolves with or without the assistance of medications
- fever, arm soreness, and mild irritability.

3. Vaccine administration errors whether or not associated with an adverse event:[6]

- any preventable events that may cause or lead to patient harm or inappropriate vaccine use
- some vaccine administration errors that have been reported include immunization of unauthorized age groups, incorrect administration of a higher or lower dose, and inappropriate storage and handling of the vaccine

4. Cases of COVID-19 infection only

5. Reports that indicate no adverse event occurred

Reports that indicate diagnosis of COVID-19 infection only and reports that did not indicate any adverse event occurred are removed from the final VAERS count. Sub-categories by intervention received and events of interest allow for further classification of VAERS reports. Interventions include self-treatment (where the patient receives no clinical support and only undergoes self-care at home with or without use of over-the-counter medications), medical (minimum of a medical evaluation by a healthcare professional at the vaccine site or at another clinical location. These may also include other interventions such as lab work, IV fluids, medication, steroid treatment etc.), and surgical interventions, which may be minor (e.g., incision and drainage) or major. Events of interest include reports of anaphylaxis, Guillain-Barré syndrome, immediate allergic reactions, thromboembolic events, myocarditis/pericarditis, and select others.[7] Events of interest are included when the event or condition noted on the VAERS report can be confirmed by a medical provider.

Due to the nature of a passive surveillance system, not all VAERS reports received will have complete information and may be missing individual patient identifiers, vaccine and dose information, or have incomplete descriptions of the reaction. The epidemiologist and nurses on the team utilize additional data sources and outreach to the patient or adverse event reporter to obtain more detailed information when appropriate. For example, the team can leverage resources like the state's immunization registry to confirm vaccine date and dose information if the patient identifiers are shared in the VAERS report. Other reports may require additional follow-up with the reporting physician or hospital for medical records to gain a clearer understanding of the significance of the event. These types of outreach efforts are focused on reported cases of deaths and other events of interest. The cumulative list is analyzed to produce a weekly VAERS report describing the outcomes and trends seen in the VAERS data. The COVID-19 vaccine surveillance team meets weekly to review new reports and trends in the volume and types of reports received.

RESULTS

The vaccine surveillance team received the first reports of an adverse event related to the COVID-19 vaccine on January 8th, 2021. Overall, between January 8, 2021 and July 16, 2021, 1,510 vaccine adverse events were reported in Rhode Island. Excluding 18 reports that were classified as not true AEFIs and 13 reports that described COVID-19 infection only, there were 1,479 (97.95%) adverse events reported.

For outcomes of adverse events following immunization, most reports received have been for non-serious adverse events (79.4%). **[Table 1]** Serious events made up 11.13% of all Rhode Island VAERS reports. 39.15% of the VAERS reported having recovered from the adverse event at the time the report was completed. 89 VAERS reports (6.02%) indicated hospitalization after experiencing an adverse event following immunization. 16 reports (1.08%) resulted in death and while 6 AEFIs occurred during pregnancy, none resulted in a congenital anomaly or birth defect. 25 AEFIs (1.69%) reported persistent or significant incapacity. Some of these outcomes included incapacity or loss of feeling in limbs, persistent memory loss, facial paralysis, and loss of hearing. 15.75% AEFIs reported visits to either the emergency room or an urgent care clinic. 112 AEFIs (7.57%) indicated vaccine administration error. 89 VAERS reports (6.02%) resulted in hospitalizations following AEFIs, and among these, 4 resulted in death. There was a total of 16 deaths reported in VAERS. All deaths and hospitalizations following AEFI are reported to VAERS, regardless of cause. As a result, not all reported deaths and hospitalizations are attributable to COVID-19 vaccination.[8] **[Table 2]**

Table 1. Classification of reported VAERS in Rhode Island [1/8/2021–7/16/2021]

Classification of VAERS	Count (n=1510)	Percent
Non-serious	1199	79.40%
Serious	168	11.13%
Vaccine Administration Error	112	7.42%
Not a VAERS	18	1.19%
COVID-19 Infection Only	13	0.86%

Table 2. Outcomes from VAERS reports in Rhode Island [1/8/2021–7/16/2021]

Outcomes	Count	Percent
Non-serious		
Recovered at the time of adverse event	579	39.15%
Treated at Vaccine Site	174	11.76%
Office/clinical visit	321	21.70%
Serious		
Hospitalization	89	6.02%
Persistent or significant incapacity	25	1.69%
Congenital anomaly or birth defect	0	0%
Death	16	1.08%
Other		
Emergency room/urgent care visit	233	15.75%
Vaccine Administration Error	112	7.57%

Note: All vaccine adverse event outcomes listed in table are reported in VAERS. The total reported adverse events following vaccination may not equal the total number of VAERS reports received as one individual can have multiple outcomes.

DISCUSSION

As of 7/16/2021, over one million (1,301,183) doses of COVID-19 vaccine were administered to 701,708 RI residents.[9] The VAERS program received 1,479 reports of vaccine adverse events following COVID-19 vaccination among RI residents. The establishment of the COVID-19 vaccine surveillance team has equipped RIDOH with the ability to receive, review, classify and track RI VAERS data and monitor trends in reported events. Importantly, the team serves as a resource for individuals and health care providers who need information or assistance with submitting a VAERS report. Ensuring that all possible vaccine adverse events are reported improves the ability of the federal VAERS program to serve as an important component of maintaining vaccine safety.

States are limited in their ability to determine causality between vaccination and reported events due to the relatively low volume of reports per vaccinated persons. In addition, there is still a challenge to confirm validity of some self-reported reactions as VAERS does not require submission of clinical evidence of the reaction. It is difficult for the state to draw conclusions about vaccinations in Rhode Island or to make recommendations. However, because the VAERS program is national and pooling data from all states, it aims to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." At the national level, if a safety signal is found in VAERS, further analyses and studies are performed to better assess health risks and possible connections between adverse events and a vaccine.

Ensuring COVID-19 vaccine safety and building vaccine confidence are critical to ending the pandemic. RIDOH is committed to supporting Rhode Islanders in reporting to VAERS and to contribute to the national significance of this safety-monitoring program.

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Disclaimer

The views expressed herein are those of the authors and do not necessarily reflect the views of the Rhode Island Department of Health.

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