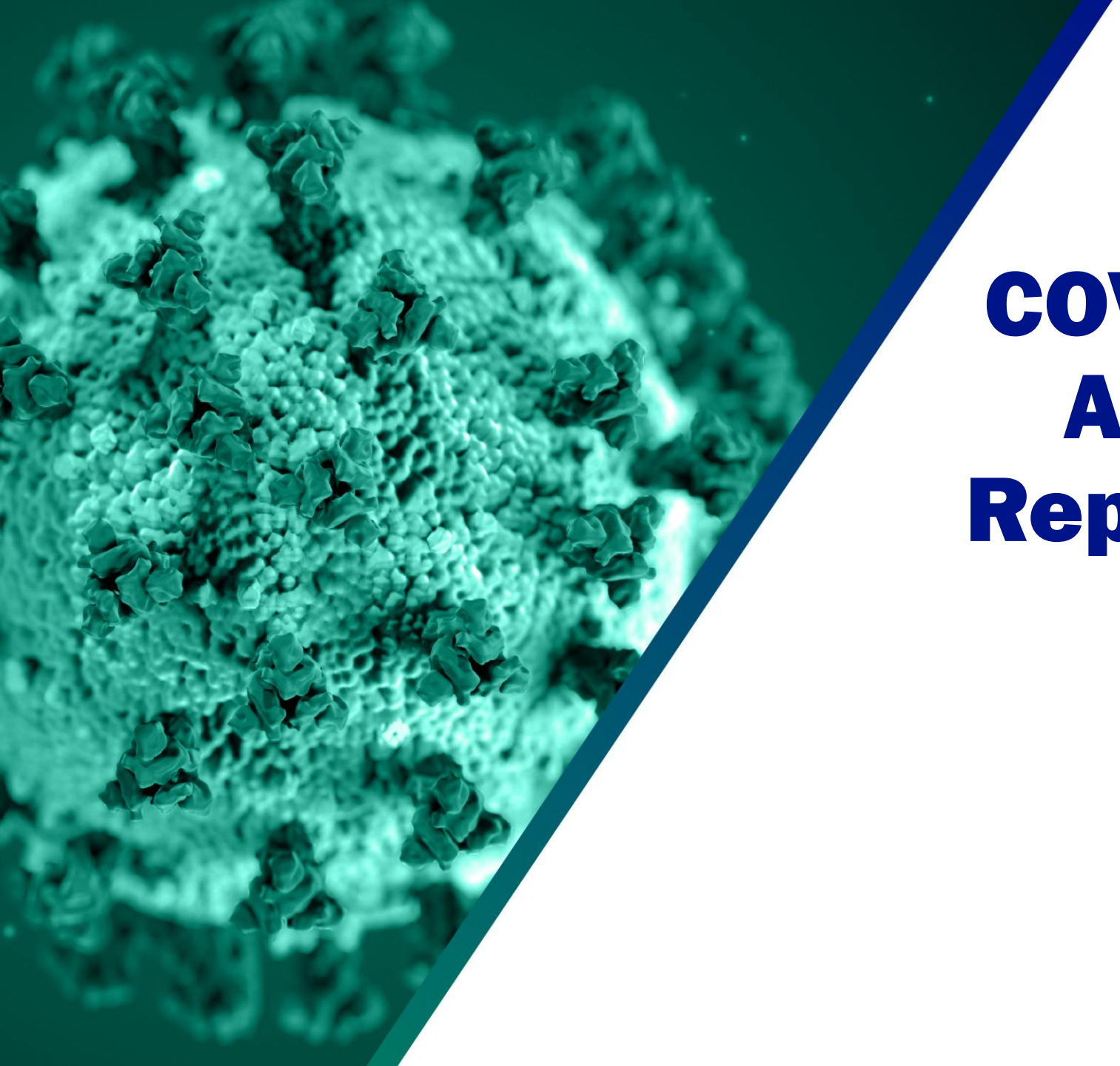


COVID-19 Vaccine Adverse Event Reporting in Idaho

Christine Hahn, MD
Idaho Division of Public Health
CVAC 1/8/2021

IDAHO DEPARTMENT OF HEALTH & WELFARE

Vaccines currently in use or in advanced stage of development in the U.S.

Authorized and Recommended Vaccines

As COVID-19 vaccines are authorized and then recommended for use in the United States, it will be important to understand what is known about each vaccine. CDC will provide information on who is and is not recommended to receive each vaccine and what to expect after vaccination, as well as ingredients, safety, and effectiveness.

Currently, two vaccines are authorized and recommended to prevent COVID-19:

- Pfizer-BioNTech COVID-19 vaccine
- Moderna's COVID-19 vaccine

Vaccines in Phase 3 Clinical Trials

As of December 28, 2020, large-scale (Phase 3) clinical trials are in progress or being planned for three COVID-19 vaccines in the United States:

- AstraZeneca's COVID-19 vaccine
- Janssen's COVID-19 vaccine
- Novavax's COVID-19 vaccine

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html

National vaccine safety monitoring

	Monitoring systems	Population	Healthcare workers	LTCF residents
early	**VAERS** (CDC & FDA) VA ADERS DoD VAECS CDC NHSN	General U.S. population, VA and DoD patient populations, NHSN acute care and long-term care facilities	Yes	Yes
early	**V-safe** (CDC)	All COVID-19 vaccine recipients eligible	Yes	Limited
later	**VSD** (CDC)	Insured patients in VSD sites	Yes	Limited
later	**FDA-CMS**	Medicare recipients (90+% of 65 y/o in the U.S., including 650K LTCF residents)	Limited	Yes
later	**BEST & PRISM** (FDA)	Insured patients in BEST & PRISM sites	Yes	Limited
later	**VA EHR & data warehouse**	Enrolled VA patients	Limited	Yes
later	**DoD DMSS**	Active duty military (limited info on beneficiaries [i.e., family members, retirees])	Yes	Limited
later	**Genesis HealthCare** (Brown U. & NIH-NIA)	Long-term care facility residents (~35,000 long stay residents)	No	Yes

Source: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/COVID-04-Shimabukuro.pdf

National vaccine safety monitoring

VAERS

- CDC/FDA
- Healthcare providers required to report adverse events, including administration errors
- Vaccine recipients can also report directly into VAERS

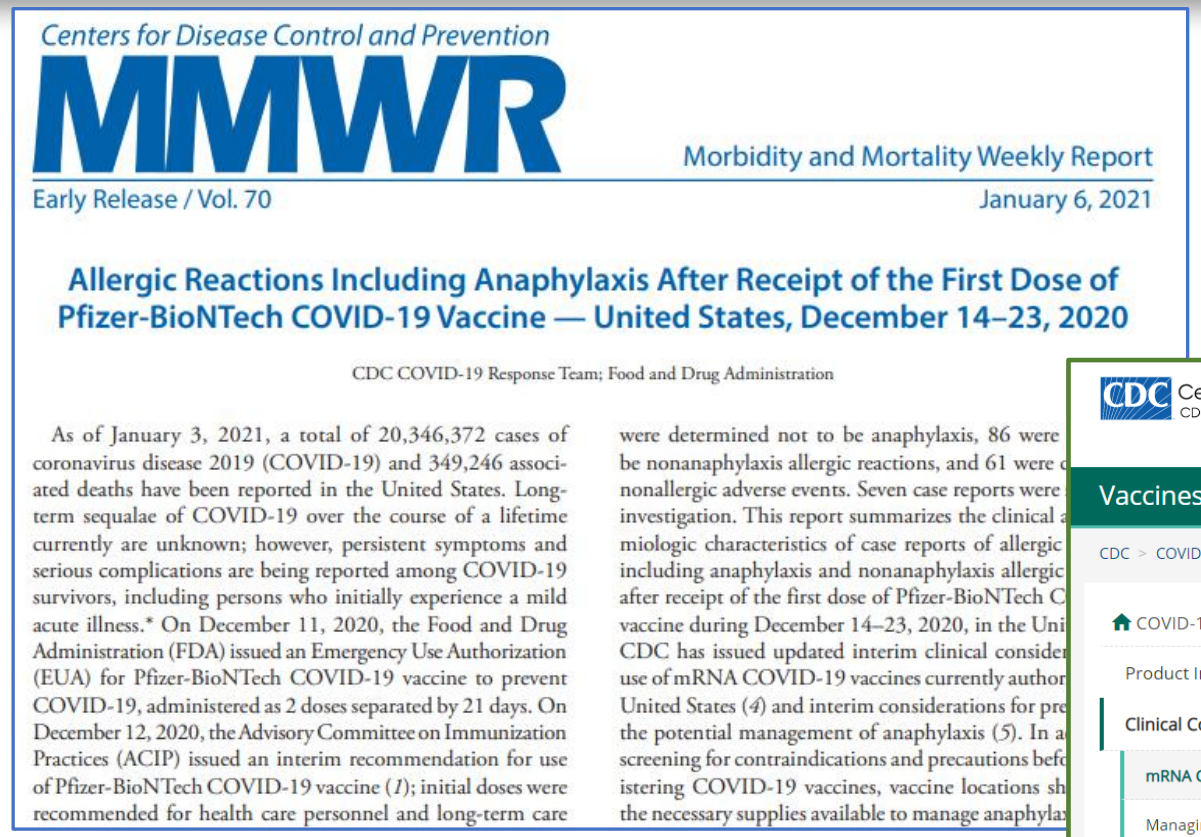
V-safe

- Smartphone-based tool that uses text messaging and web surveys
- Vaccine recipients voluntarily participate to report any side effects; over a million people have signed up so far
- CDC may call recipient if adverse events are reported via v-safe

v-safe℠ after vaccination health checker

Source: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/COVID-04-Shimabukuro.pdf

Feedback to Providers and Public



Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

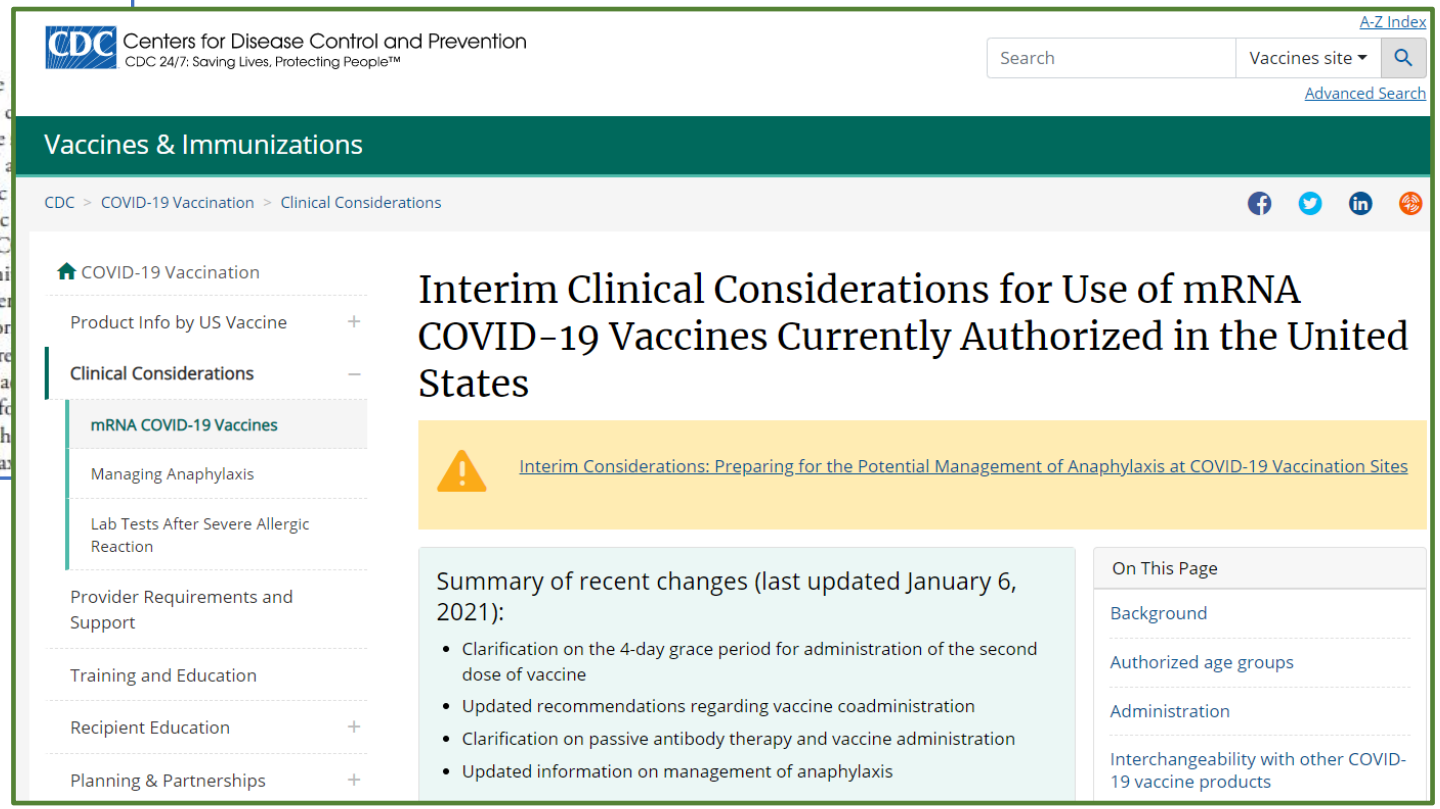
Early Release / Vol. 70 January 6, 2021

Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020

CDC COVID-19 Response Team; Food and Drug Administration

As of January 3, 2021, a total of 20,346,372 cases of coronavirus disease 2019 (COVID-19) and 349,246 associated deaths have been reported in the United States. Long-term sequalae of COVID-19 over the course of a lifetime currently are unknown; however, persistent symptoms and serious complications are being reported among COVID-19 survivors, including persons who initially experience a mild acute illness.* On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 vaccine to prevent COVID-19, administered as 2 doses separated by 21 days. On December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of Pfizer-BioNTech COVID-19 vaccine (*1*); initial doses were recommended for health care personnel and long-term care

were determined not to be anaphylaxis, 86 were
be nonanaphylaxis allergic reactions, and 61 were
nonallergic adverse events. Seven case reports were
investigation. This report summarizes the clinical
miologic characteristics of case reports of allergic
including anaphylaxis and nonanaphylaxis allergic
after receipt of the first dose of Pfizer-BioNTech C
vaccine during December 14–23, 2020, in the Uni
CDC has issued updated interim clinical consider
use of mRNA COVID-19 vaccines currently author
United States (*4*) and interim considerations for pre
the potential management of anaphylaxis (*5*). In a
screening for contraindications and precautions befo
istering COVID-19 vaccines, vaccine locations sh
the necessary supplies available to manage anaphyla



CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

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COVID-19 Vaccination

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mRNA COVID-19 Vaccines

Managing Anaphylaxis

Lab Tests After Severe Allergic Reaction

Provider Requirements and Support

Training and Education

Recipient Education +

Planning & Partnerships +

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States

Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

Summary of recent changes (last updated January 6, 2021):

- Clarification on the 4-day grace period for administration of the second dose of vaccine
- Updated recommendations regarding vaccine coadministration
- Clarification on passive antibody therapy and vaccine administration
- Updated information on management of anaphylaxis

On This Page

Background

Authorized age groups

Administration

Interchangeability with other COVID-19 vaccine products

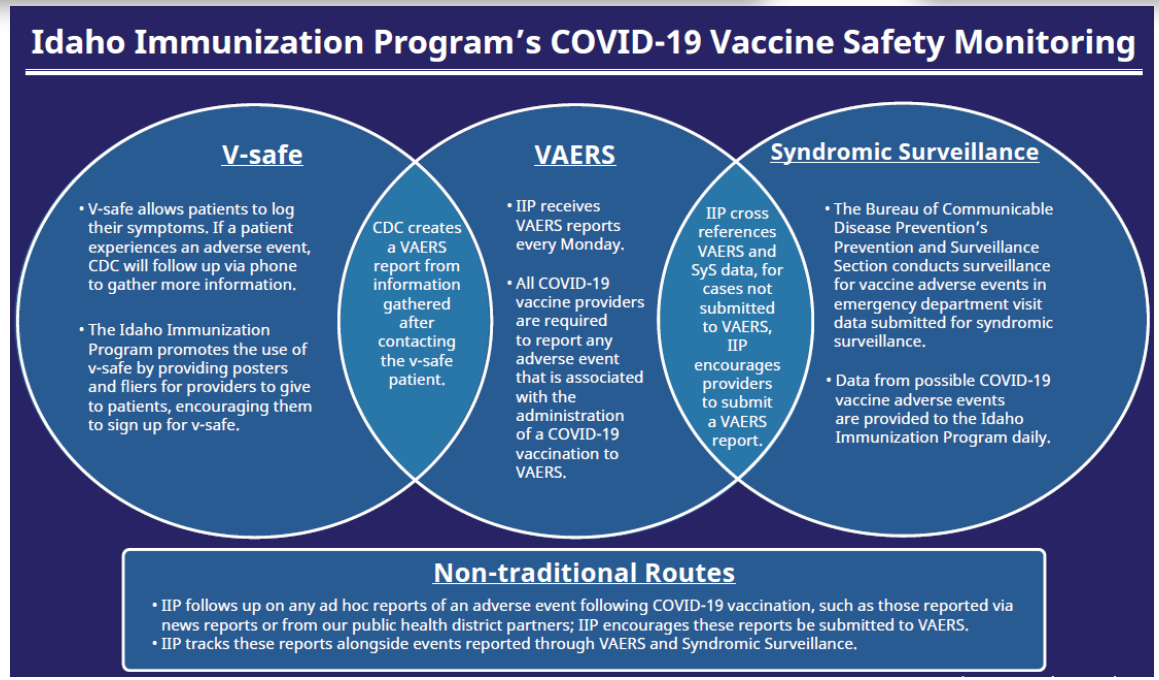
Idaho vaccine safety monitoring

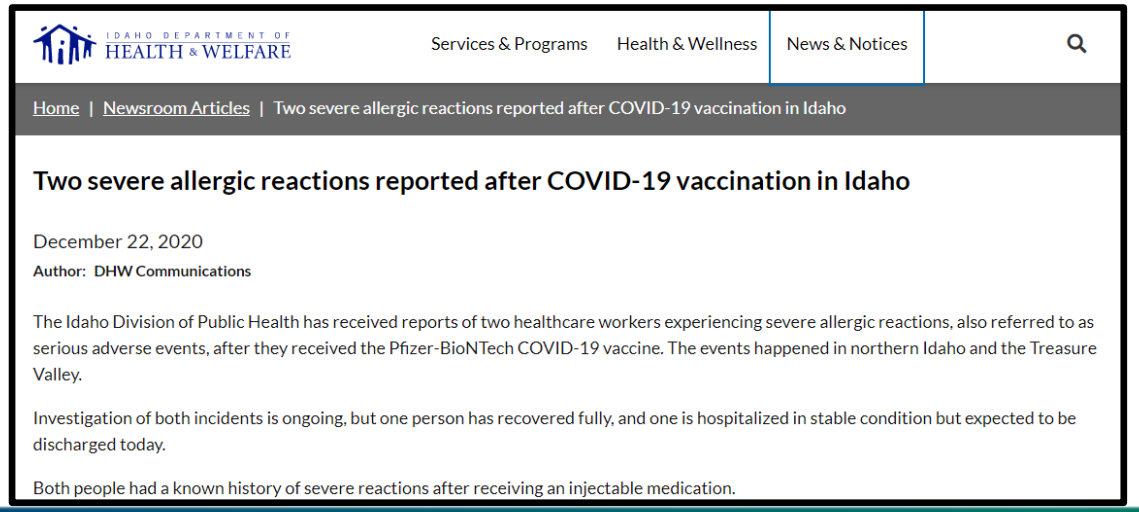
Staff members are coordinating to ensure follow-up of reports from:

- V-Safe → VAERS
- VAERS
- Idaho's syndromic surveillance system
- Direct reporting to Idaho public health by providers

10 VAERS reports have been received for Idaho to date

- CDC physicians screen all VAERS reports describing suspected severe allergic reactions and anaphylaxis
- Idaho staff tracking all incoming reports
- Press release issued 12/22 with recommendation to defer vaccination for now if previous severe reactions to injectable medication or vaccine, until more is known
- Ongoing effort and monitoring




IDAHO DEPARTMENT OF HEALTH & WELFARE

Services & Programs | Health & Wellness | News & Notices

Home | Newsroom Articles | Two severe allergic reactions reported after COVID-19 vaccination in Idaho

Two severe allergic reactions reported after COVID-19 vaccination in Idaho

December 22, 2020

Author: DHW Communications

The Idaho Division of Public Health has received reports of two healthcare workers experiencing severe allergic reactions, also referred to as serious adverse events, after they received the Pfizer-BioNTech COVID-19 vaccine. The events happened in northern Idaho and the Treasure Valley.

Investigation of both incidents is ongoing, but one person has recovered fully, and one is hospitalized in stable condition but expected to be discharged today.

Both people had a known history of severe reactions after receiving an injectable medication.