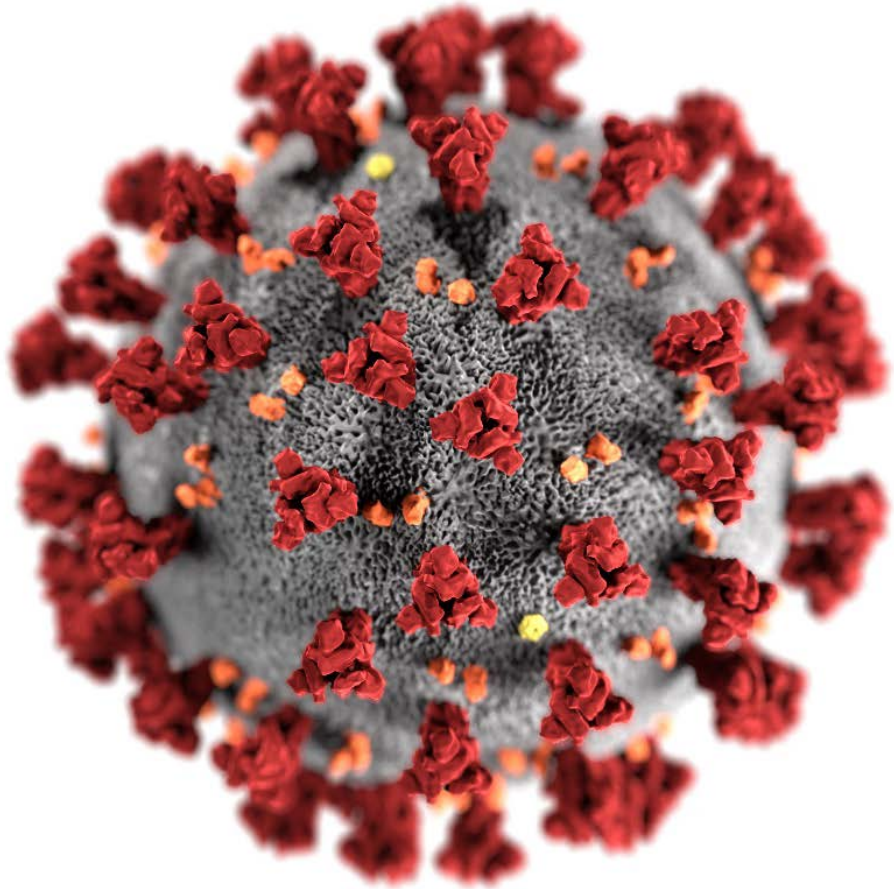
Anaphylaxis Following m-RNA COVID-19 Vaccine Receipt



Thomas Clark, MD, MPH

December 19, 2020

Anaphylaxis in UK Following COVID-19 Vaccination

- December 8, 2020 – UK initiated vaccination with Pfizer-BioNTech COVID-19 vaccine
- December 9 – UK authorities confirmed 2 cases of anaphylaxis after vaccination
- Prescribing information for both Pfizer-BioNTech and Moderna COVID-19 vaccines contains information on anaphylaxis
  - Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine is a contraindication to vaccination
  - Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine

CDC Guidance on Anaphylaxis Following COVID-19 Vaccination

- ACIP considered anaphylaxis risk during deliberations on Pfizer-BioNTech COVID-19 vaccine during December 11-12 meetings
- December 12 – CDC published clinical considerations for use of Pfizer-BioNTech COVID-19 vaccine
  - Included guidance on contraindications and precautions (https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html#contraindications-precautions)

Anaphylaxis in US Following COVID-19 Vaccination

- December 18*, 2020 – CDC has identified 6 case reports of anaphylaxis following Pfizer-BioNTech vaccine meeting Brighton Collaboration criteria for anaphylaxis
  - Cases were Brighton Collaboration levels 1 or 2
  - Additional case reports have been reviewed and determined not anaphylaxis
- Cases occurred within recommended observation window and were promptly treated
- One case had a history of anaphylaxis following rabies vaccination
- All suspect cases were notified through VAERS or CDC notification processes
- These case reports are undergoing/will undergo clinical case review by CISA
- December 19** – 272,001 doses of vaccine have been administered

*December 18, 2020 at 2300 hrs EST

**December 19, 2020 at 0945 hrs EST

CDC Actions Following Reports

- Close coordination with FDA
- Discussions with CISA investigators, NIH, Medicine and Healthcare products Regulatory Agency (UK), Allergy/Immunology experts, and other partners
- Published Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites (https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html)

V-safe Active Surveillance for COVID-19 Vaccines

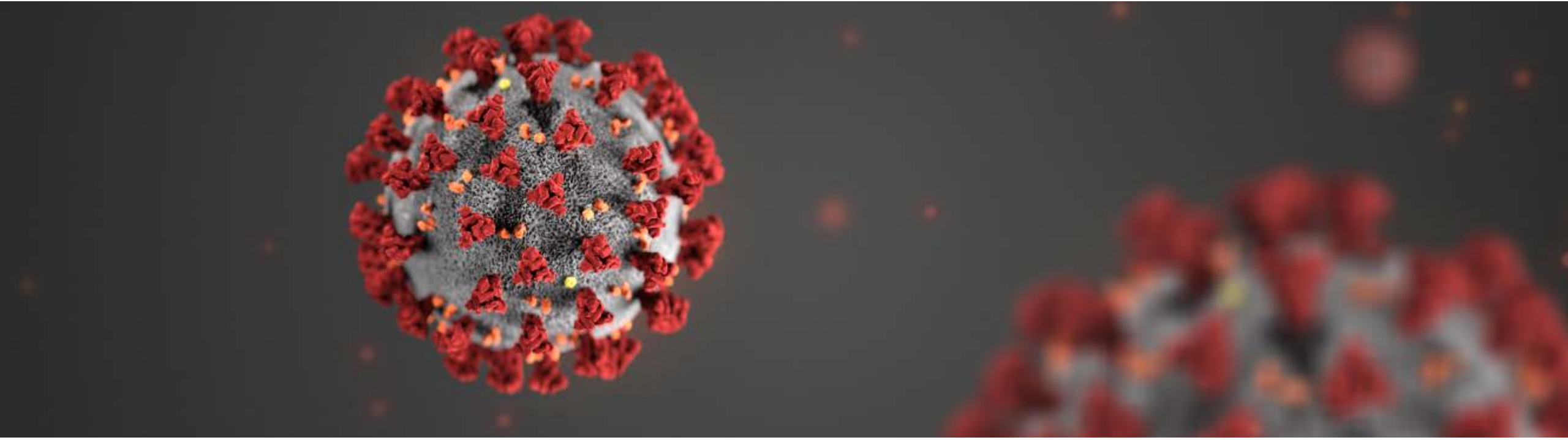
	Dec 14	Dec 15	Dec 16	Dec 17	Dec 18*
Registrants with recorded 1st dose	679	6,090	27,823	67,963	112,807
Health Impact Events**	3	50	373	1,476	3,150
Pregnancies at time of vaccination	5	29	103	286	514

*Dec 18, 5:30 pm EST

**unable to perform normal daily activities, unable to work, required care from doctor or health care professional

CDC Assessment and Further Actions

- Post-authorization pharmacovigilance systems have detected and confirmed 6 anaphylaxis cases following vaccination
  - Notifications received have been timely
  - Notifications ruled out suggests systems are sensitive
- Reinforce measures to recognize, respond, and report anaphylaxis
- Persons with anaphylaxis following COVID-19 vaccination should not receive additional doses of COVID-19 vaccine
- Consultation with allergy/immunology experts to provide guidance on evaluation of persons following anaphylaxis to COVID-19 vaccine



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.