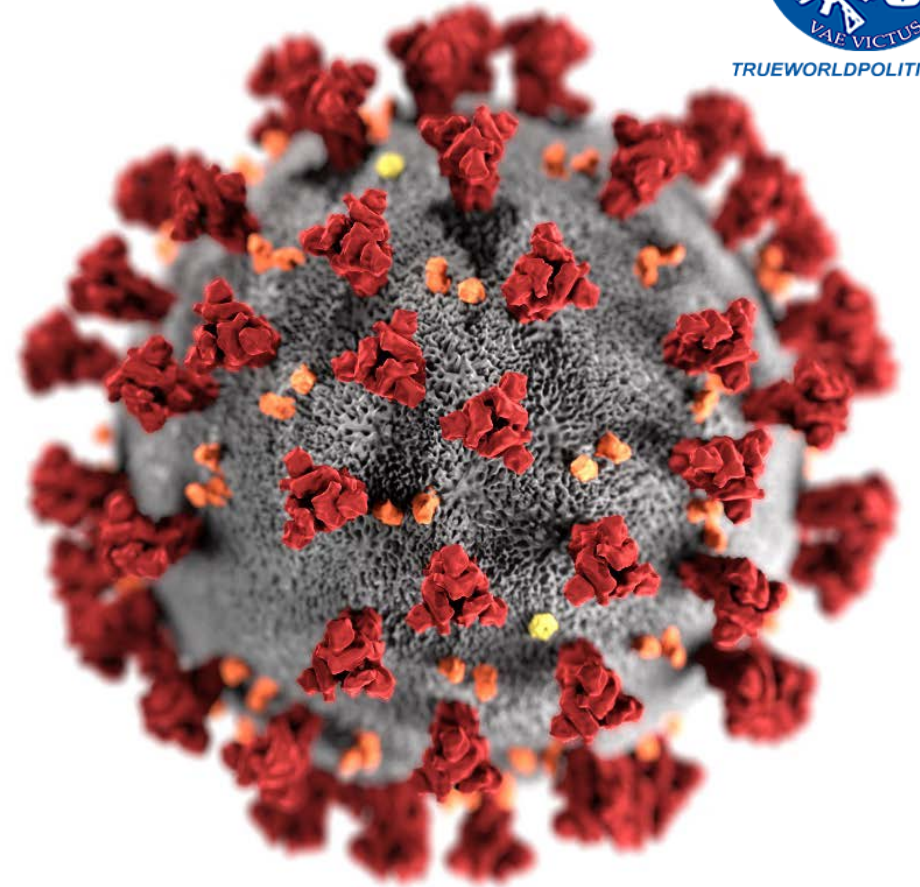


## Anaphylaxis Following m-RNA COVID-19 Vaccine Receipt

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<sup>\*</sup>, 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<sup>\*\*</sup> – 272,001 doses of vaccine have been administered

<sup>\*</sup>December 18, 2020 at 2300 hrs EST

<sup>\*\*</sup>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

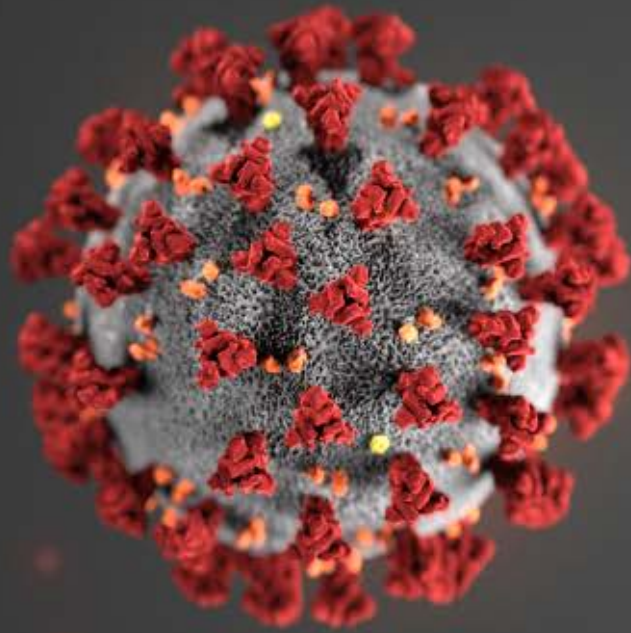
	Dec 14	Dec 15	Dec 16	Dec 17	Dec 18*
<b>Registrants with recorded 1<sup>st</sup> dose</b>	<b>679</b>	<b>6,090</b>	<b>27,823</b>	<b>67,963</b>	<b>112,807</b>
<b>Health Impact Events**</b>	<b>3</b>	<b>50</b>	<b>373</b>	<b>1,476</b>	<b>3,150</b>
<b>Pregnancies at time of vaccination</b>	<b>5</b>	<b>29</b>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

\*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](http://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.

