Anaphylaxis Following m-RNA COVID-19 Vaccine Receipt

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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.
  - Included guidance on contraindications and precautions.
  - See: [https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html#contraindications-precautions](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html#contraindications-precautions)
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
V-safe Active Surveillance for COVID-19 Vaccines

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<th>Dec 14</th>
<th>Dec 15</th>
<th>Dec 16</th>
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<th>Dec 18*</th>
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<tr>
<td>Registrants with recorded 1st dose</td>
<td>679</td>
<td>6,090</td>
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<td>Health Impact Events**</td>
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<td>Pregnancies at time of vaccination</td>
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<td>29</td>
<td>103</td>
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*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
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.