ACIP COVID-19 Vaccines Work Group

Dr. Beth Bell, Work Group Chair

April 14, 2021
Overview

- Review of adenovirus vector COVID-19 vaccines
- Descriptions of rare clotting events seen after adenoviral vector vaccines:
  - Events after AstraZeneca vaccine in Europe
  - Events after Janssen vaccine in US
- ACIP Response
- Today’s Agenda
### Adenovirus vector vaccines

<table>
<thead>
<tr>
<th>Adenovirus Vector</th>
<th>Janssen/J&amp;J</th>
<th>AstraZeneca</th>
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<tr>
<td></td>
<td>One dose</td>
<td>Two doses</td>
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<td>Human Adenovirus 26 vector</td>
<td>Chimp adenovirus vector</td>
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<td>EUA in the US issued Feb 2021</td>
<td>Awaiting EUA application in the US</td>
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<td>EMA authorized for Europe</td>
<td>Approved in UK, Europe</td>
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<td>Doses not yet delivered/administered</td>
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- Concerns for rare clotting events seen after COVID-19 adenovirus vector vaccines
- Clinical syndromes after both vaccines appear similar
- However, extent to which the cases seen after both adenovirus vector vaccines represent the same syndrome is unknown

EUA: Emergency Use Authorization; EMA: European Medicines Agency
AstraZeneca (AZ) vaccine

- Last week, EMA’s safety committee (PRAC) released report concluding:
  - **Strong association** and **probable causal link** between the AZ vaccine and rare clotting events

**From the European Union:**
- 62 cases of CVST & 24 cases of splanchnic vein thrombosis with thrombocytopenia; 18 were fatal
- Most in females <60 years of age
- Within 2 weeks of AZ vaccine receipt
- Due to different ways vaccine used in each country, cannot exclude age/gender as risk factors

**From the United Kingdom:**
- 79 cases of thrombosis + thrombocytopenia; 19 were fatal
- 44 cases of CVST (14 fatalities) & 35 cases of other clots (5 fatalities)
- 51 cases were female; 28 were male
- 20.2 million doses given. Estimated risk ~4 per million pop. (‘slightly higher incidence’ in younger age groups)

CVST: Cerebral Venous Sinus Thrombosis

Vaccine-induced immune thrombotic thrombocytopenia

Reports of low platelets (thrombocytopenia) and blood clots (thrombosis) after AZ vaccine in Europe

Two publications describing cases of thrombotic thrombocytopenia from Germany & Austria, and Norway

Many cases had platelet activating antibodies directed against platelet factor 4 (PF4)

Authors propose syndrome entitled “Vaccine-induced immune thrombotic thrombocytopenia” (VITT)

Cerebral Venous Sinus Thrombosis (CVST) – a brief background

- Thrombosis within large vessels draining blood from the brain
- Mostly among people 20–50 years of age; female
- Risks: pregnancy, usual coagulation risks (e.g., oral contraceptives)
- Symptoms typically include headache, nausea, vomiting, other neurologic symptoms
  - Presentation acute → weeks, months

http://www.med.umich.edu%2F1libr%2FStroke%2FSinusVeinThrombosis.pdf&usg=AOvVaw3qjvm4UOFcHN-eR4O3Kyf8
AstraZeneca (AZ) vaccine:
Recommendations for use

- EMA's Pharmacovigilance Risk Assessment Committee (PRAC) does not make vaccine policy for the EU; each country weighs the risks and benefits of AZ vaccine individually

- Many countries have adopted age-based recommendations
  - UK: Adults ≥30 years of age; April 7, 2021
  - Australia: Adults ≥50 years of age; April 8, 2021
  - European countries: Adults ≥55 to ≥70 years of age
**Janssen/J&J COVID-19 vaccine:**
Joint CDC and FDA statement on Johnson & Johnson COVID-19 vaccine, April 13, 2021

- As of April 12, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S.
- CDC and FDA are reviewing data involving 6 cases of CVST in combination with low platelets
- “CDC will convene a meeting of the Advisory Committee on Immunization Practices on Wednesday to further review these cases and assess their potential significance”.
- “Until that process is complete, we are recommending a pause in the use of this vaccine out of an abundance of caution.”

https://www.cdc.gov/media/releases/2021/s0413JJ-vaccine.html
Janssen/J&J COVID-19 vaccine:
HAN released April 13, 2021

Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine

- Recommendations for Clinicians: diagnosis and treatment
- Recommendations for Public Health: case reporting through VAERS
- Recommendations for the Public: clinical signs and symptoms to monitor
Recommendations for Clinicians: diagnosis and treatment
- Evaluate patients with a screening PF4 enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune HIT. Consultation with a hematologist is strongly recommended.
- Do not treat with heparin, unless HIT testing is negative

Recommendations for Public Health: case reporting through VAERS
- Encourage healthcare providers and the public to report all serious and life-threatening adverse events and deaths following receipt of COVID-19 vaccines to VAERS

Recommendations for the Public: clinical signs and symptoms to monitor
- Contact healthcare provider, or seek medical care if you develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination with the J&J COVID-19 vaccine

- **Monday 4/12**: Vaccine Safety Technical Group (VaST) meeting
- **Tuesday 4/13**: ACIP COVID-19 vaccines Work Group meeting
- **Wednesday 4/14**: Emergency ACIP meeting

Purpose of Emergency ACIP meeting

- Consider implications of reported cases of thrombosis and thrombocytopenia after Janssen/J&J vaccine on vaccination policy
Today's Agenda
Wednesday, April 14

  Dr. Aran Maree (Janssen Pharmaceuticals Companies of Johnson & Johnson)

- Cerebral Venous Sinus Thrombosis with Thrombocytopenia after COVID-19 vaccines, VAERS, March 2-April 12, 2021
  Dr. Tom Shimabukuro (CDC)

- VaST assessment
  Dr. Grace Lee (ACIP, VaST Co-chair)

- Work Group interpretation
  Dr. Sara Oliver (CDC)

- Public Comment

- Discussion

- VOTE:
  Janssen COVID-19 vaccine: Updated interim recommendations for use
Work group members

**ACIP members**
- Beth Bell (chair)
- Matthew Daley
- Grace Lee
- Jose Romero
- Keipp Talbot

**Ex-officio/government members**
- FDA: Doran Fink, Rachel Zhang
- NIH: Chris Roberts
- IHS: Thomas Weiser, Uzo Chukwuma
- DOD: Bryan Schumacher
- CMS: Jeff Kelman
- BARDA: Christine Oshansky
- HHS: David Kim

**CDC Lead**
- Sara Oliver

**Liaisons**
- AAFP: Jonathan Temte
- AAP: Sean O’Leary
- ACOG: Denise Jamieson (primary), Laura Riley (alternate)
- ACP: Jason Goldman
- AGS: Ken Schmader
- AIM: Rob Shechter (primary), Jane Zucker (alternate)
- AMA: Sandra Fryhofer
- ANA: Kendra McMillan (primary), Ruth Francis (alternate)
- APhA: Michael Hogue
- ASTHO: Marcus Plescia
- CSTE: Susan Lett (primary), Christine Hahn (alternate)
- IDSA: Jeff Duchin (primary), Carol Baker (alternate)

**Liaisons, cont’d**
- NACCHO: Matt Zahn (primary), Jeff Duchin (alternate)
- NACI: Matthew Tunis
- NFID: Bill Schaffner (primary), Marla Dalton (alternate)
- NMA: Oliver Brooks
- SHEA: Marci Drees

**Consultants**
- Ed Belongia
- Kathy Kinlaw
- Dayna Matthew
- Kathleen Neuzil
- Stanley Perlman
- Peter Szilagyi
CDC participants

- Amy Blain
- Doug Campos-Outcalt
- Mary Chamberland
- Thomas Clark
- Amanda Cohn
- Jean Cox-Ganser
- Jonathan Duffy
- Kathleen Dooling
- Anthony Fiore
- Mark Freedman
- Julia Gargano
- Sue Gerber
- Jack Gersten
- Susan Goldstein
- Sam Graitcer
- Lisa Grohskopf
- Julie Garon
- Stephen Hadler
- Rita Helfand
- Susan Hiers
- Terri Hyde
- Cynthia Jorgensen
- Erin Kennedy
- Sarah Kidd
- Ram Koppaka
- Megan Lindley
- Nicole Lindsey
- Ruth Link-Gelles
- Jessica MacNeil
- Lauri Markowitz
- Mona Marin
- Sarah Mbaeyi
- Nancy Messonnier
- Danielle Moula
- Rebecca Morgan
- Titilope Oduyebo
- Anita Patel
- Janell Routh
- Stephanie Schrag
- Heather Scobie
- Edwin Shanley
- Tom Shimabukuro
- Heidi Soeters
- Mark Sotir
- Stephanie Thomas
- Natalie Thornburg
- Jennifer Verani
- Megan Wallace
- Annemarie Wasley
- Cindy Weinbaum
- Melinda Wharton
- Yon Yu
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.