

COVID-19 Vaccine Safety Technical (VaST) Work Group

Assessment

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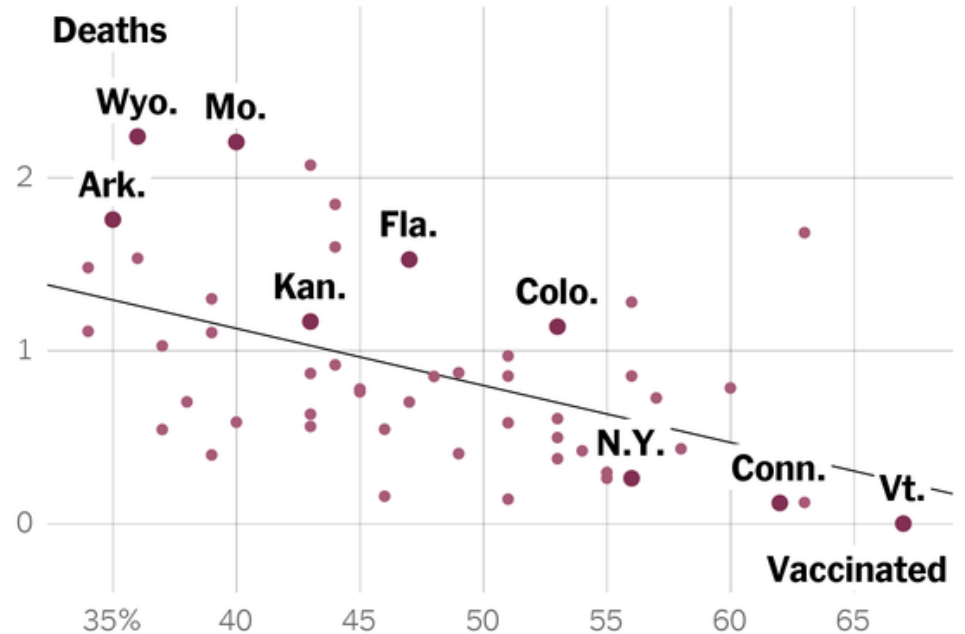
Advisory Committee on Immunization Practices

July 22, 2021

COVID-19 Vaccination in the United States

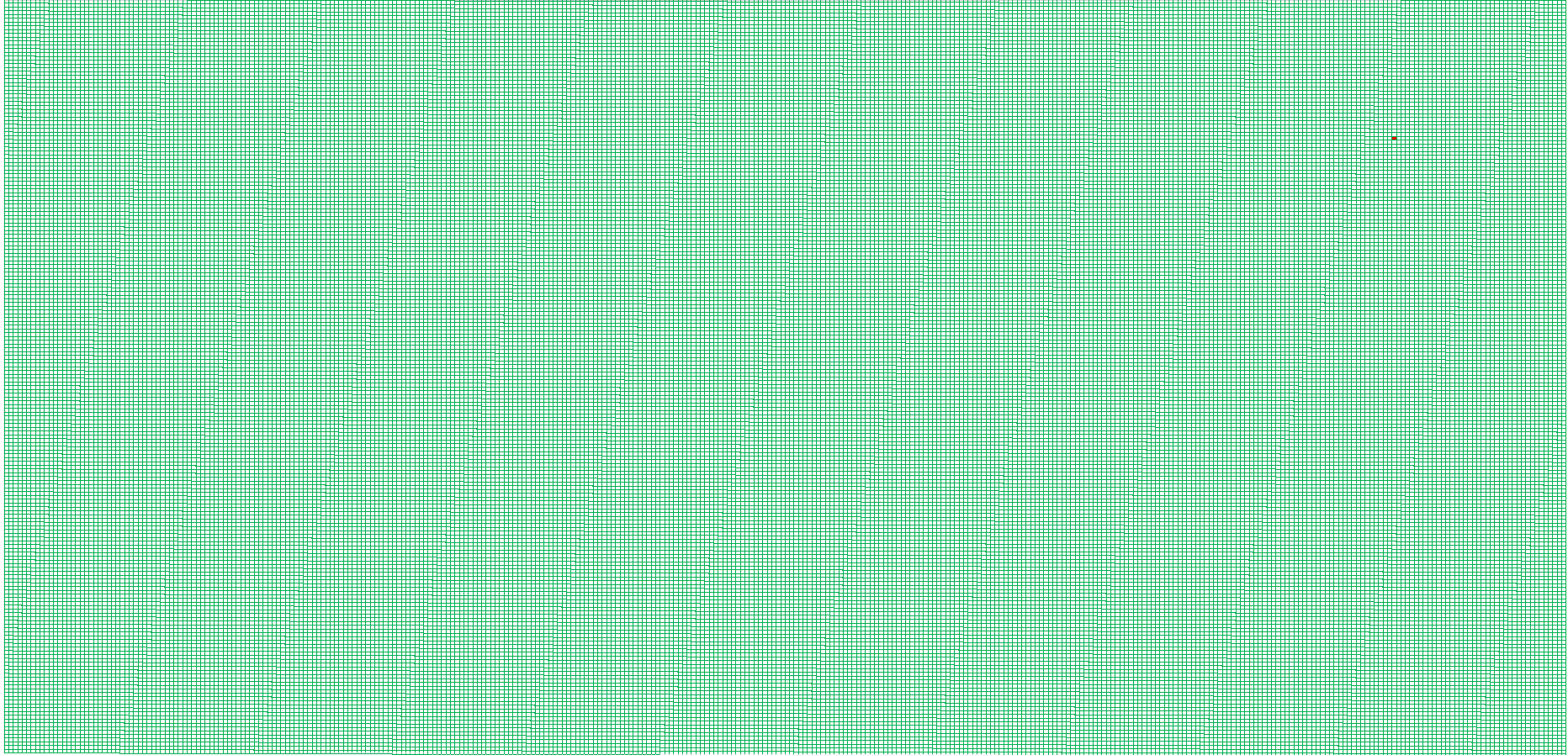
- 338 million doses administered
- 161 million individuals fully vaccinated

Vaccination status and recent deaths per million residents, by state



Based on current vaccination status and deaths in the week ending July 15.

Vaccine Safety in Numbers



VaST Activities

Dec 21, 2020 – present:

- 28 independent meetings to review vaccine safety data
- 6 joint meetings with COVID-19 Vaccines Work Group focused on safety

ACIP votes following EUA

Dec 12 Pfizer (16+)
Dec 19 Moderna (18+)

Feb 28 Janssen (18+)

May 12 Pfizer (12-15)

Dec

Jan

Feb

Mar

Apr

May

Jun

Jul

VaST assessments at ACIP meetings or website

Jan 27 Anaphylaxis following mRNA vaccines

Mar 1 Anaphylaxis updates; Pregnancy vaccine safety data

Apr 14 CVST following Janssen

Apr 23 TTS updates; Janssen resumed with warning

May 12 TTS updates

May 17 & 24 Myocarditis

Jun 23 Myocarditis updates

Jun 28 GBS following Janssen

VaST Work Group Report – June 28

- In VAERS
 - Observed number of preliminary cases of GBS after Janssen vaccine was greater than the expected number
 - All age groups; no geographic clustering
 - Observed versus expected reporting rates not elevated for the mRNA vaccines
- In VSD and VA RCAs
 - No statistical signals for GBS for any COVID-19 vaccine
 - However, the rate of GBS following Janssen was higher than for mRNA vaccines in VSD

VaST Work Group Report – June 28 (continued)

- GBS cases reported after receiving AstraZeneca COVID-19 vaccine, which is used in other countries
- VaST members discussed need for:
 - Review and adjudication of VAERS case reports of GBS using Brighton collaboration criteria
 - Ongoing monitoring of GBS among persons who received the Janssen COVID-19 vaccine in the United States

<https://www.cdc.gov/vaccines/acip/work-groups-vast/index.html>

<https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-5-8-july-2021>

<https://brightoncollaboration.us/guillain-barre-and-miller-fisher-syndromes-case-definition-companion-guide/>

Regulatory Agency Updates

- July 9 – EMA announced the addition of a warning for GBS following Astra Zeneca COVID-19 vaccine
- July 12 – FDA announced revisions to the Janssen COVID-19 vaccine EUA fact sheets for providers and patients to include information about an observed increased risk of GBS following vaccination

VaST Meetings – July 12 and July 19

- Background rates of GBS generally increase with age and greater in males than females

GBS per million doses administered in VAERS and VSD, 18+ years

COVID-19 vaccine	Crude reporting rates in VAERS	Unadjusted, chart-confirmed rates in VSD
Janssen	8.1	20.2
mRNA	1.1	0.7
~1.6 cases of GBS per million doses <i>expected</i>		

VaST Discussion and Interpretation - GBS

- Risk for GBS following Janssen is substantially different than either the risk following mRNA COVID-19 vaccines or expected background rates
 - Median onset of 13 days in VAERS; males > females
- Fewer individuals receive Janssen in the U.S. (<4% of all doses administered)
- GBS cases following SARS-CoV-2 infection also reported*
 - Median onset ~12-14 days post-infection

VaST Discussion and Interpretation - GBS

- Medical record review of VAERS cases in process using Brighton collaboration criteria
 - Need to confirm the diagnosis of GBS and further characterize the clinical presentation, severity and outcomes of GBS cases following Janssen vaccine
- Continue to assess the benefit-risk analyses, given the dynamic epidemiology of COVID-19 infection

Monitoring and Responding to Safety Data

Safety monitoring

- mRNA COVID-19 vaccines
 - Anaphylaxis
 - Myocarditis
- Janssen COVID-19 vaccine
 - TTS
 - GBS
- Pre-specified AESI
- Communication between agencies

Incorporating safety data into decision-making

- Dynamic benefit-risk balance
- Risk mitigation strategies
 - Support informed discussions about benefits and risks of available vaccines
 - Clinical guidance to support early detection and appropriate management

VaST Members

VaST Members

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