

# COVID-19 Vaccine Safety Technical (VaST) Work Group

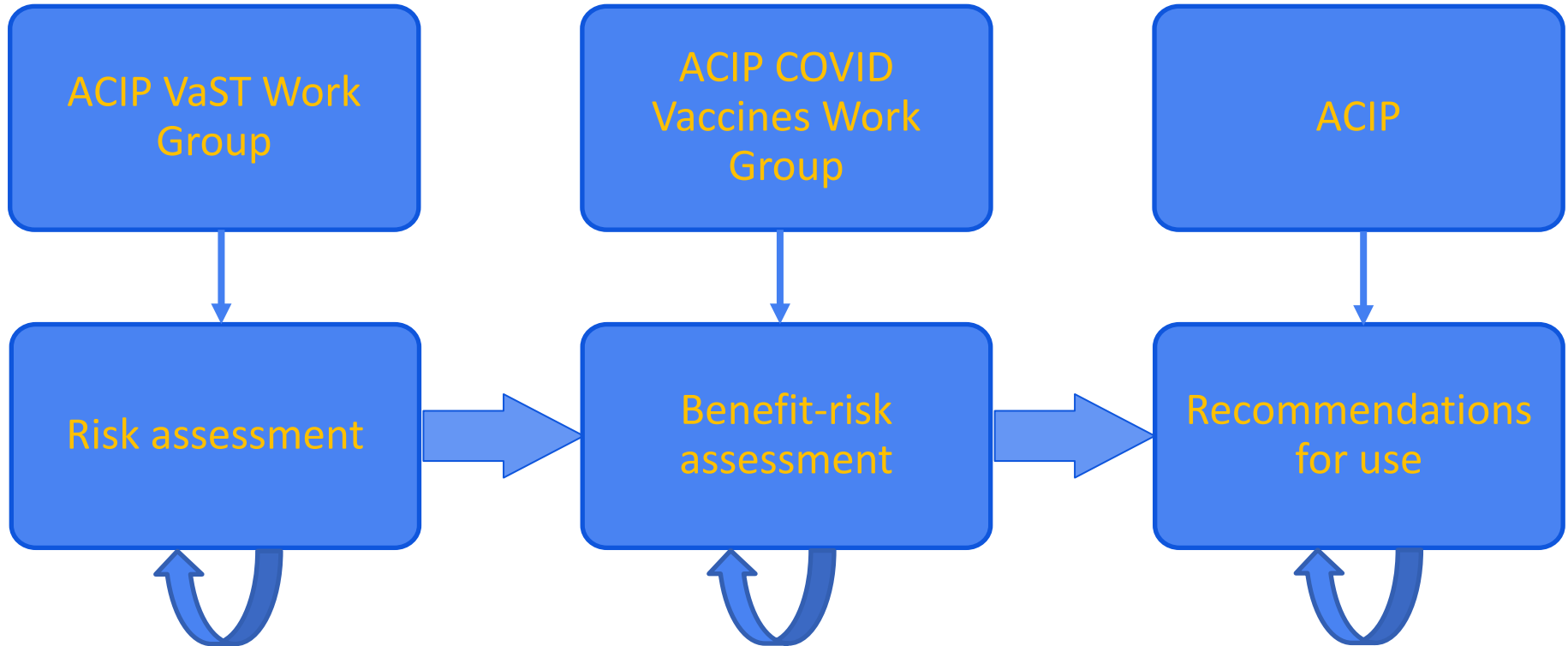
## Assessment

Grace M. Lee, MD MPH

Advisory Committee on Immunization Practices

April 23, 2021

# Dynamic decision-making process



# COVID-19 Vaccine Safety Technical (VaST) Work Group

## Objectives

- Review, evaluate, and interpret post-authorization/approval COVID-19 vaccine safety data
- Serve as the central hub for technical subject matter expertise from federal agencies conducting post-authorization/approval safety monitoring
- Advise on analyses, interpretation, and data presentation
- Provide updates to the ACIP COVID-19 Vaccines Work Group and the ACIP on COVID-19 vaccine safety

# VaST Activities

## Pre-authorization

Jun-Dec 2020

- 14 meetings to prepare for vaccine safety surveillance in the U.S.

## ACIP Recommendations

- Dec 12 – Pfizer/BioNTech
- Dec 14 – 1<sup>st</sup> dose administered in U.S.
- Dec 19 – Moderna
- Feb 28 – Janssen

## Post-authorization

Dec 21-present

- 17 independent meetings to review vaccine safety data across multiple surveillance systems

# VaST Meeting - April 12

## CVST with thrombocytopenia

- 6 cases of CVST with thrombocytopenia identified as a rare, but serious adverse event following Janssen vaccine
- Risk factors for CVST with thrombocytopenia not well understood
- Timely and transparent communication with healthcare providers and the public is crucial to maintain confidence in the vaccination program

# HAN Communication – April 13

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



- 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

# ACIP Meeting – April 14

## CVST with thrombocytopenia

- Review of reported cases of CVST with thrombocytopenia after COVID-19 vaccines
- Discussion about the need for additional information to support evidence-based decision making, including
  - Age and gender-specific risk estimates
  - Evaluation of the benefit-risk balance of using Janssen vaccine in specific subgroups

# VaST Meeting - April 19

## Thrombosis with Thrombocytopenia Syndrome

- Review of new Brighton Collaboration definition of Thrombosis with Thrombocytopenia Syndrome (TTS)
  - Will facilitate investigation across surveillance systems
- Health Network Alert (HAN) supported enhanced case finding
  - Age and gender-specific rates of TTS following Janssen vaccine requested for risk assessment
- Review of data from VSD RCA and VA RCA
  - No safety signal identified for CVST, other thromboembolic disease, or thrombocytopenia identified following Janssen vaccine (>200,000 doses)
- Update from Global Advisory Committee on Vaccine Safety (GACVS) on TTS cases following AstraZeneca vaccine



# VaST and CVWG Meeting - April 22

- Risk for TTS following Janssen vaccine
  - 7 per million doses in females <50 years\* (highest in 30-39 years)
  - <1 per million doses in female 50+ and males\*
- Other potential risk factors
  - Obesity (BMI>30), OCP use, hypothyroidism, hypertension
- Outcomes
  - 3 deaths, 7 remain hospitalized (4 in ICU), 5 discharged home
- Benefit-risk assessment and Evidence-to-Recommendation framework discussed

*\*Includes all doses (not adjusted for follow-up time)*

# VaST Summary

- Risk of TTS appears to be highest in female <50 years
  - Other risk factors for TTS not well established yet
- Risk mitigation strategies
  - Minimize exposure in high-risk populations
  - Increase awareness & ensure timely diagnosis and management of TTS
  - Educate patients about benefits and risks of available vaccines
- VaST will continue to monitor TTS, thromboembolic disease, and thrombocytopenia in all available vaccine safety surveillance systems
- VaST will update the ACIP COVID-19 vaccines workgroup, ACIP secretariat and ACIP on a regular basis

# VaST Members

## VaST Members

Grace Lee (ACIP)  
Robert Hopkins (NVAC)  
Matt Daley  
Veronica McNally  
Keipp Talbot  
Kathy Edwards  
Lisa Jackson  
Laura Riley  
Robert Schechter  
Patricia Whitley-Williams

## CDC Co-Leads

Lauri Markowitz  
Melinda Wharton

## Ex Officio and Liaison Representatives

Tatiana Beresnev (NIH)  
Karen Farizo; Hui Lee Wong (FDA)  
Judith Steinberg (OIDP)  
Jeffrey Kelman (CMS)  
Matthew Clark (IHS)  
Mary Rubin (HRSA)  
Fran Cunningham (VA)  
Limone Collins (DoD)

## Administrative Support

Susan Hiers  
Jared Woo