Work Group considerations regarding maternal RSV vaccine

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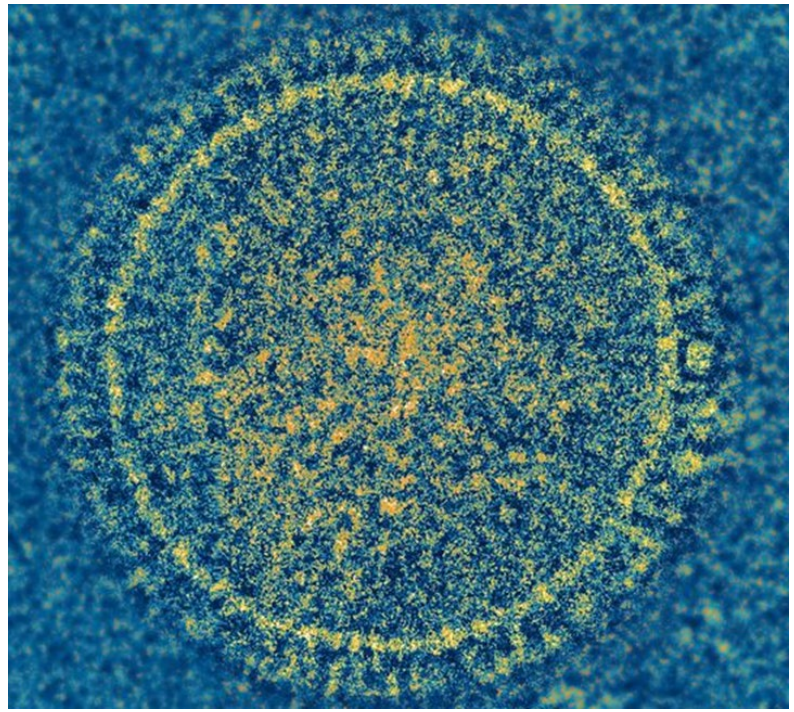

Policy question being considered by the work group

- Should the Pfizer RSV bivalent prefusion F vaccine be recommended for all pregnant people as a single dose given at 24–36 weeks gestation?

- This recommendation would be considered in the context of the current standard of care for prevention of RSV disease in infants at the time of ACIP vote.

Key considerations regarding RSV bivalent prefusion F vaccine: timing of dose within pregnancy

- Dosing window in the trial was 24 through 36 weeks gestation
- Currently there are no data available on efficacy stratified by gestational age at time of administration
- Majority of infants in phase 3 trial were born ≥37 weeks gestation (94% in RSV bivalent preF arm and 95% in placebo arm)
- Most doses in the phase 3 trial were given at ≥28 weeks gestation
  - 25% doses given at ≥24 to <28 weeks
  - 30% doses given at ≥28 to <32 weeks
  - 45% doses given at ≥32 to <37 weeks
  - 0.1% doses given at ≥37 weeks

Data provided by Pfizer

Key considerations for RSV bivalent prefusion F vaccine: number of total lifetime doses

- All pregnant people in the trial received their first and only dose of RSV vaccine
- Currently there are no data available on
  - Efficacy of the first lifetime dose during subsequent pregnancies
  - Safety of additional doses given in subsequent pregnancies

Proposed timeline of future ACIP presentations (tentative)

- June 2023
  - Summary of GRADE
  - Cost effectiveness analysis
  - EtR
- October 2023
  - ACIP vote (if product is licensed by this time)

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov