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Update on 50 µg Booster Dose of Moderna COVID-19 Vaccine in Individuals ≥18 Years of Age

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ACIP

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EUA for Use of Moderna COVID-19 Vaccine as a Booster

FDA authorized, Nov 19, 2021

- The booster dose of the Moderna COVID-19 Vaccine is **0.25 mL**.
- A single Moderna COVID-19 Vaccine booster dose (0.25 mL) may be administered intramuscularly at least 6 months after completing a primary series of the Moderna COVID-19 Vaccine to individuals 18 years of age or older.
- A single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

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Safety Summary - 50 µg Booster Dose

ACIP, Oct 21, 2021

- Rates of adverse reactions (ARs) with 50 µg booster dose comparable to those observed after Dose 2 of primary series
  - Pain at injection site most common solicited local AR in both groups
  - Headache, fatigue and myalgia most common systemic ARs in both groups
  - Majority of ARs were mild-to-moderate in severity
  - Axillary swelling or tenderness was the only AR more frequently reported after booster dose as compared to dose 2 in Study 301

- No vaccine-related SAEs or deaths in Study 201B

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Immunogenicity Summary - 50 µg Booster Dose

ACIP, Oct 21, 2021

- Pre-specified co-primary hypotheses (GMR & SRR difference) were met on pooled dataset
- 50 µg booster dose following 100 µg primary series results in
  - Higher antibody responses to original virus (D614G) than post- dose 2 in Study 301 (GMR = 1.8)
  - 13-fold rise from pre-booster titers for original virus
  - 17-fold rise from pre-booster titers for Delta variant
- Consistently high antibody titers in both age groups (18-64 and ≥ 65 year olds)

GMR = geometric mean ratio
SRR = seroresponse rate

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Ongoing Studies of 50 µg Booster Dose

- Administration of booster dose to participants in COVE Efficacy trial ongoing
  - To date, >15,000 participants have received a booster 6-14 months after completion of primary series
  - Safety & immunogenicity data being compiled
  - No unexpected reactions reported
  - Immunogenicity data expected on subset of subjects early 2022
- 6 month persistence of antibody (P201B study) data from ~300 subjects
  - Sera currently being tested
- Will update Work Group/ACIP when data available

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