

- **Adolescents:**
  - Pfizer/BioNTech: Blinded RCT, 2600 American 12–15-year-olds.<sup>6</sup>
    - Efficacy:  $\geq 7$  days post second dose:
      - COVID-19 cases: 0 versus 18 (placebo), 100% RRR.
      - Severe COVID-19: None.
    - Subjects enrolled prior to Delta variant.<sup>2</sup>
    - Solicited adverse effects:
      - Localized pain:  $\sim 83\%$  vaccine.
      - Fatigue:  $\sim 63\%$  versus  $\sim 33\%$  (placebo).
      - Headache:  $\sim 60\%$  versus  $31\%$  (placebo).
  - Moderna: Blinded RCT, 3732 American 12–17-year-olds.<sup>7</sup>
    - Efficacy:  $\geq 14$  days post second dose:
      - COVID-19 cases: 0 versus 4 (placebo), 100% RRR.
      - Severe COVID-19: Not reported.
    - Solicited adverse effects:
      - Localized pain, redness, swelling:  $>90\%$ .
      - Fatigue:  $\sim 58\%$  versus  $\sim 33\%$  (placebo).
      - Headache:  $\sim 58\%$  versus  $\sim 35\%$  (placebo).

## CONTEXT

- National Advisory Committee on Immunization recommends 2 doses 8 weeks apart for children, adolescents, and adults.<sup>8-10</sup>
  - Risks of COVID-19 in children  $<19$  years:
    - Hospitalization: 0.5%, (12% required ICU).<sup>11</sup>
      - $\sim 80\%$  of admissions are in healthy children.<sup>12</sup>
    - Children can get “long COVID”, but likely lower rates than adults.<sup>13</sup>
  - Myocarditis after mRNA vaccines:
    - Highest in boys 16-19 years: excess risk  $\sim 14$  per 100,000 doses.<sup>14</sup>
      - 75% occur after second dose.<sup>15</sup>
      - Females:  $\sim 10\%$  male risk.<sup>15</sup>
    - Most cases are mild.<sup>13,15</sup>
- Net Benefit: For 12–17-year-old males, for every million doses, vaccination may:
  - Prevent 215 COVID-19 hospitalizations, 71 ICU admissions, 2 deaths.
  - Cause  $\sim 65$  cases of myocarditis.<sup>14</sup>