



CO-KID: Covid vaccine for kids

CLINICAL QUESTION

What are the benefits and harms of the available COVID-19 vaccines for children and adolescents?

BOTTOM LINE

Pfizer/BioNTech vaccine is 91% effective in preventing symptomatic COVID-19 in children 5-11 years. Both Pfizer/BioNTech and Moderna are 100% effective in adolescents at ~2 months. Real world evidence might differ. Both vaccines appear safe with primarily injection site reactions.

EVIDENCE

- Study participants mostly white and healthy, 2 doses given 21-28 days apart. Median follow-up ~2 months. Cases were symptomatic, laboratory confirmed COVID-19. Severe COVID-19 is defined as cardiac, respiratory, other end organ failure, or ICU admission.
 - **Children:**
 - Pfizer/BioNTech: Multi-country, blinded, randomized controlled trial (RCT) of 2268 children 5-11 years old.¹
 - Efficacy: ≥7 days post second dose.
 - COVID-19 cases: 3 versus 16 (placebo), relative risk reduction (RRR): 91%.¹

- Severe COVID-19: None.¹
 - Most cases occurred when Delta variant was predominant strain.¹⁻³
 - Solicited adverse effects:¹ Similar between 1st and 2nd doses.
 - Localized pain ~73%; redness: ~17%.
 - Fatigue: ~37% versus 28% (placebo).
 - Myalgia: 10% versus 7% (placebo).
 - Serious adverse effects: 0 versus 1 (placebo).
 - Myocarditis or anaphylaxis: None.
 - Moderna: Enrolling 6-months to 11-year-olds.⁴
 - Only immunogenicity currently reported.⁵
- **Adolescents:**
 - Pfizer/BioNTech: Blinded RCT, 2600 American 12-15 year-olds.⁶
 - Efficacy: ≥7 days post second dose:
 - COVID-19 cases: 0 versus 18 (placebo), 100% RRR.
 - Severe COVID-19: None.
 - Subjects enrolled prior to Delta variant.²
 - Solicited adverse effects:
 - Localized pain: ~83% vaccine.
 - Fatigue: ~63% versus ~33% (placebo).
 - Headache: ~60% versus 31% (placebo).
 - Moderna: Blinded RCT, 3732 American 12-17 year-olds.⁷
 - Efficacy: ≥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: ~58% versus ~33% (placebo).
 - Headache: ~58% versus ~35% (placebo).

CONTEXT

- National Advisory Committee on Immunization recommends 2 doses 8 weeks apart for children, adolescents, and adults.⁸⁻¹⁰
 - Risks of COVID-19 in children <19 years:
 - Hospitalization: 0.5%, (12% required ICU).¹¹
 - ~80% of admissions are in healthy children.¹²
 - Children can get “long COVID”, but likely lower rates than adults.¹³
 - Myocarditis after mRNA vaccines:
 - Highest in boys 16-19 years: excess risk ~14 per 100,000 doses.¹⁴
 - 75% occur after second dose.¹⁵
 - Females: ~10% male risk.¹⁵
 - Most cases are mild.^{13, 15}
 - 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 ~65 cases of myocarditis.¹⁴

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