

Due to the recent Health Canada authorization of COVID-19 vaccine for children, we are publishing this TFP a few days early.

TOOLS FOR PRACTICE #303 | November 24, 2021



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 Caucasian 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 $\sim 73\%$; redness: $\sim 17\%$.
 - Fatigue: $\sim 37\%$ 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: $\sim 83\%$ vaccine.
 - Fatigue: $\sim 63\%$ versus $\sim 33\%$ (placebo).
 - Headache: $\sim 60\%$ versus 31% (placebo).
 - Moderna: Blinded RCT, 3732 American 12–17-year-olds.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: $\sim 58\%$ 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.⁸⁻¹⁰
 - Risks of COVID-19 in children <19 years:
 - Hospitalization: 0.5% , (12% required ICU).¹¹
 - $\sim 80\%$ 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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