COVID-19 Vaccine and Children and Adolescents

Campus Update Forum
November 16, 2021
Cumulative Number: Child COVID-19 Cases

- 6,625,847 total child SARS-CoV-2 cases reported
  - Overall rate: 8,803 cases per 100,000 children in the population
  - Current 27.0% of positive cases (children, under age 18, make up 22.2% of the US population)

*Fig 6. United States: Number of Child COVID-19 Cases Added in Past Week*

*Note: 5 states changed their definition of child cases: AL as of 8/13/20, HI as of 8/27/20, RI as of 9/10/20, MO as of 10/1/20, WV as of 8/12/21
TX reported age for only a small proportion of total cases each week (eg, 3-20%); TX cumulative cases through 8/26/21
As of 6/30/21, NE COVID-19 dashboard is no longer available; NE cumulative cases through 6/24/21
Due to available data and changes made to dashboard, AL cumulative cases through 7/29/21
Due to available data and calculations required to obtain MA child cases, weekly estimates fluctuate (eg, on 11/11/21, 5,437 cases were added)
See detail in Appendix: Data from 49 states, NYC, DC, PR and GU
All data reported by state/local health departments are preliminary and subject to change; Analysis by American Academy of Pediatrics and Children’s Hospital Association
Hospitalization and Mortality COVID-19 in Children

- 8,300 children 5-11 have been hospitalized COVID-19 in kids
  - Annual Flu hospitalizations 5-17 years: 5-19K

Per CDC

- 0-4 years: 210 death; 2019-20 flu season: 347
- 5-17 years: 490 deaths; 2019-20 flu season: 139
Leading Causes of Death in Children 5-11 Years of Age, NCHS, 2019

<table>
<thead>
<tr>
<th>Causes of Death</th>
<th>Death (n)</th>
<th>Crude rate per 100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accidents (unintentional injuries)</td>
<td>969</td>
<td>3.4</td>
</tr>
<tr>
<td>Malignant neoplasms</td>
<td>525</td>
<td>1.8</td>
</tr>
<tr>
<td>Congenital malformations, deformations and chromosomal abnormalities</td>
<td>274</td>
<td>1.0</td>
</tr>
<tr>
<td>Assault (homicide)</td>
<td>207</td>
<td>0.7</td>
</tr>
<tr>
<td>Diseases of the heart</td>
<td>115</td>
<td>0.4</td>
</tr>
<tr>
<td>Chronic lower respiratory diseases</td>
<td>107</td>
<td>0.4</td>
</tr>
<tr>
<td>Influenza and pneumonia</td>
<td>84</td>
<td>0.3</td>
</tr>
<tr>
<td>Intentional self-harm (suicide)</td>
<td>66</td>
<td>0.2</td>
</tr>
<tr>
<td>Cerebrovascular diseases</td>
<td>56</td>
<td>0.2</td>
</tr>
<tr>
<td>Septicemia</td>
<td>48</td>
<td>0.2</td>
</tr>
</tbody>
</table>

66 COVID-19 associated deaths in children 5–11 10/3/20-10/2/2021

Total population 5-17 years, 2019: 52,715,248

PASC: Post-Acute Sequelae of SARS-CoV-2 infection

- Early reports suggest that 4-58% of infected children have persistent symptoms

61% occurred in children who are Hispanic/Latino or Black, Non-Hispanic

MIS-C patients by age group

<table>
<thead>
<tr>
<th>Age (in years)</th>
<th>0-4</th>
<th>5-11</th>
<th>12-15</th>
<th>16-20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of total MIS-C cases</td>
<td>20%</td>
<td>45%</td>
<td>15%</td>
<td>10%</td>
</tr>
</tbody>
</table>

CDC
Safety Data for 5 to <12 Year Olds to Support EUA Application

Initial enrollment group
2268 participants

Median follow-up time 2.3 months

Additional follow-up time to 3.3 months

Safety expansion group
2379 participants

Median follow-up time 2.4 weeks

~3100 received the vaccine
Side effects generally similar to 12+

- Pain at the injection site slightly lower vs 12+
- Systemic effects *less* frequent and were *milder* in severity in the 5-11 year-old group
  - fever, fatigue, headache, chills, and muscle pain were generally reported
- Redness and swelling slightly higher
Adverse events

No FDA adverse events of special interest (AESI):
• No anaphylaxis
• No myocarditis/pericarditis
• No Bell’s palsy (or facial paralysis/paresis)
• No appendicitis
Efficacy

- **Immunobridging**: robust antibody levels similar to that seen in adolescents and young adults 16 to 25 years old
- **COVID-19 occurrence**

### Subjects WITHOUT Evidence of Infection Prior to 7 Days After Dose 2

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>BNT162b2 (10 µg) N=1305</th>
<th>Placebo N=663</th>
<th>VE (%) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First COVID-19 occurrence ≥7 days after Dose 2</td>
<td>n=3 0.322 (1273)</td>
<td>n=16 0.159 (637)</td>
<td>90.7 (67.7, 98.3)</td>
</tr>
</tbody>
</table>
What about myocarditis/pericarditis

- **Myocarditis**: inflammation of the heart muscle
- **Pericarditis**: inflammation of the outer lining of the heart
Myocarditis and COVID-19 infection

CDC data/ MMWR

- 86 children less than 16 years old diagnosed with myocarditis per 65,000 hospitalized with COVID-19 (0.113% risk)
- In comparison, 132 of 3.6 million children hospitalized without COVID-19 developed myocarditis

Adjusting for patient and hospital characteristics, patients <16 years old were 37 times more likely to have myocarditis after COVID-19 infection
Vaccine Adverse Event Reporting System (VAERS): Reporting rates (per 1 million doses administered) of myocarditis after mRNA COVID-19 vaccines, 7-day risk period

- Reporting rates exceed background incidence*

<table>
<thead>
<tr>
<th>Ages</th>
<th>Pfizer (Males)</th>
<th>Dose 1</th>
<th>Dose 2</th>
<th>Pfizer (Females)</th>
<th>Dose 1</th>
<th>Dose 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-15</td>
<td>4.2</td>
<td>39.9</td>
<td></td>
<td>0.4</td>
<td>3.9</td>
<td></td>
</tr>
<tr>
<td>16-17</td>
<td>5.7</td>
<td>69.1</td>
<td></td>
<td>0.0</td>
<td>7.9</td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>2.3</td>
<td>36.8</td>
<td></td>
<td>0.2</td>
<td>2.5</td>
<td></td>
</tr>
<tr>
<td>25-29</td>
<td>1.3</td>
<td>10.8</td>
<td></td>
<td>0.2</td>
<td>1.2</td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>0.5</td>
<td>5.2</td>
<td></td>
<td>0.6</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td>40-49</td>
<td>0.3</td>
<td>2.0</td>
<td></td>
<td>0.1</td>
<td>1.1</td>
<td></td>
</tr>
<tr>
<td>50-64</td>
<td>0.2</td>
<td>0.3</td>
<td></td>
<td>0.3</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>65+</td>
<td>0.2</td>
<td>0.1</td>
<td></td>
<td>0.1</td>
<td>0.3</td>
<td></td>
</tr>
</tbody>
</table>

* An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for the 7-day risk period, this estimated background is 0.2 to 1.9 per 1 million person 7-day risk period
Care and outcomes of preliminary myocarditis cases reported to VAERS after mRNA COVID-19 vaccination in persons aged <30 years (N=1,640) (data thru Oct 6, 2021)

1,640 total preliminary reports

- 877 met CDC case definition* of myocarditis
- 637 under review

Of 877 meeting case definition:

- 829 were hospitalized
  - 789 discharged
  - 607/789 (77%) known to have recovered from symptoms at time of report
- 34 were not hospitalized (seen in emergency room, urgent care, outpatient clinic, not specified)
- Cardiac MRI abnormal in 72% of cases (223/312)

Vaccine Safety Datalink Confirmed Myocarditis/pericarditis 0-21 Days after Any Dose of mRNA Vaccine by Age Group/Product: 3 month follow-up review of Cases with at least 1 follow-up visit since initial episode

<table>
<thead>
<tr>
<th>3-month chart review status (not mutually exclusive)</th>
<th>12-17 Year-Olds (Pfizer-BioNTech) N=16</th>
<th>18-39 Year-Olds (Pfizer-BioNTech) N=14</th>
<th>18-39 Year-Olds (Moderna) N=18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recovered, no medication, without exercise restrictions or symptoms</td>
<td>5 (31%)</td>
<td>6 (43%)</td>
<td>9 (50%)</td>
</tr>
<tr>
<td>Still symptomatic</td>
<td>4 (25%)</td>
<td>5 (36%)</td>
<td>3 (17%)</td>
</tr>
<tr>
<td>Still on medication (primarily NSAIDS, colchicine)</td>
<td>2 (13%)</td>
<td>4 (29%)</td>
<td>7 (39%)</td>
</tr>
<tr>
<td>Still on exercise/physical activity restrictions</td>
<td>7 (44%)</td>
<td>2 (14%)</td>
<td>1 (6%)</td>
</tr>
</tbody>
</table>
91% of cardiologists or healthcare providers indicated the patient was fully or probably recovered
Summary

• Incidence of myocarditis post-mRNA vaccine 0.007% in highest risk group (16-17 year olds)
• Incidence of myocarditis post-COVID19 infection 0.133% in children/adolescents <16 years old (MMWR report) (19X in comparison to post-vaccine myocarditis)