Severe COVID Less Likely in Children with the Bivalent Vaccine

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Key Findings:

- For all pediatric age groups (6 months to 4 years, 5 to 11 years, and 12 to 17 years), having the bivalent COVID-19 vaccine reduces the risk of a COVID-19-related emergency department (ED) visit.
- The 6 months to 4 years age group had the greatest reduction in COVID-19-related ED visits with a 79.6% reduction compared to patients without any COVID-19 vaccine.
- Hospital admissions were rare for all pediatric patients regardless of vaccination status.

The bivalent COVID-19 vaccine is recommended for use in patients aged 6 months and older by the U.S. Food and Drug Administration (FDA).[1-4] To understand the potential influence of the bivalent vaccine in pediatric patients, we compared the rate of COVID-19-related emergency department (ED) visits and admissions within 90 days after these patients received the bivalent COVID-19 vaccine. The comparison was made with a control group of children who received the flu vaccine but never received any COVID-19 vaccine. We studied 445,713 children aged 6 months to 17 years with data collected since each age group's bivalent vaccine authorization.

Our results showed that patients aged 6 months to 4 years who received the bivalent COVID-19 vaccine had a 79.6% lower rate of COVID-19-related ED visits compared to the control group (105.1 per 100,000 vs. 515.6 per 100,000). Similarly, patients aged 5 to 11 who received the bivalent COVID-19 vaccine had a 71.9% lower rate of COVID-19-related ED visits (43.6 per 100,000 vs. 155.0 per 100,000) and those aged 12 to 17 had a 66.1% lower rate (64.4 per 100,000 vs. 190.0 per 100,000).

After accounting for patient's prior COVID-19 infection, race, social vulnerability index (SVI), and census region of residence, the protective effect of receiving a COVID-19 bivalent vaccine remained.

COVID-19 ED Visit Rates by Vaccine Status and Age Group

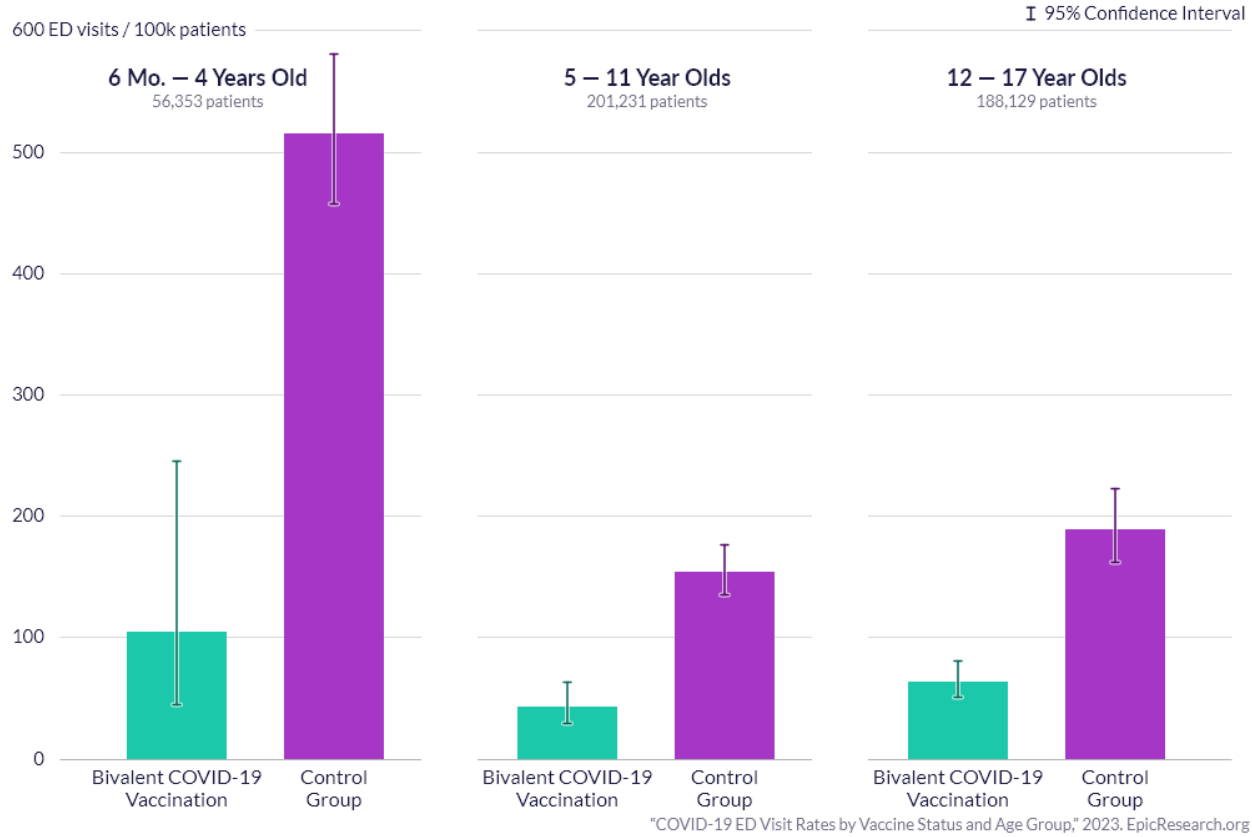

Figure 1. COVID-19-related emergency department visit rates per 100,000 pediatric patients stratified by vaccine status and age group.

Because COVID-19-related hospital admissions were so infrequent in both the vaccinated group and the control group (91 admissions across all age groups and vaccination statuses during the study period), we were unable to identify a significant difference in the rate of hospitalization between the two groups.

These data come from Cosmos, a HIPAA-defined Limited Data Set of more than 190 million patients from 203 Epic organizations including 1,176 hospitals and more than 25,300 clinics, serving patients in all 50 states and Lebanon. This study was completed by two teams that worked independently, each composed of a clinician and research scientists. The two teams came to similar conclusions.

References

1. Coronavirus (COVID-19) update: FDA authorizes updated (bivalent) COVID-19 vaccines for children down to 6 months of age. U.S. Food and Drug Administration. Accessed May 2, 2023. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-updated-bivalent-covid-19-vaccines-children-down-6-months
2. Coronavirus (COVID-19) update: FDA authorizes Bivalent Pfizer-BioNTech COVID-19 Vaccine as booster dose for certain children 6 months through 4 years of age. U.S. Food and Drug Administration. Accessed May 2, 2023. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-bivalent-pfizer-biontech-covid-19-vaccine-booster-dose

3. Coronavirus (COVID-19) update: FDA authorizes Moderna and Pfizer-BioNTech Bivalent COVID-19 vaccines for use as a booster dose in younger age groups. U.S. Food and Drug Administration. Accessed May 2, 2023. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-bivalent-covid-19-vaccines
4. Coronavirus (COVID-19) update: FDA authorizes Moderna, Pfizer-BioNTech bivalent COVID-19 vaccines for use as a booster dose. U.S. Food and Drug Administration. Accessed May 2, 2023. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use

Data Definitions

Term	Definition
Study period	Patients aged 6 months to 4 years at the time of vaccination who were vaccinated between 12/14/22 and 2/24/23. Patients aged 5 to 11 years at the time of vaccination who were vaccinated between 10/13/22 and 2/24/23. Patients aged 12 to 17 years at the time of vaccination who were vaccinated between 9/7/22 and 2/24/23.
Study population	Patients aged 6 months to 17 years who had no COVID-19 infection between 90 days prior to and 14 days after their vaccination event.
Flu vaccination	Immunization with CVX codes 160, 205, 135, 197, 171, 186, 158, 150, 161, 166, 149, 155, 185, 141, 140, 231, 200, 201, 202, or 168. With no history of any COVID-19 vaccination.
Bivalent COVID-19 vaccination	Immunization with CVX codes 229, 230, 519, 300, 301, 302 or 520.
Any COVID-19 vaccination	Immunization with CVX codes 207, 208, 210, 211, 212, 213, 217, 218, 219, 221, 225, 226, 229, 230, 300, 301, 302, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, or 520.
COVID-19 infection	A diagnosis with ICD-10-CM codes U07.1, J12.81, or J12.82 or a positive lab with a LOINC codes 94306-8, 94307-6, 94308-4, 94309-2, 94310-0, 94311-8, 94312-6, 94313-4, 94314-2, 94315-9, 94316-7, 94500-6, 94502-2, 94509-7, 94510-5, 94511-3, 94532-9, 94533-7, 94534-5, 94536-5, 94558-4, 94559-2, 94565-9, 94639-2, 94640-0, 94641-8, 94642-6, 94643-4, 94644-2, 94645-9, 94646-7, 94647-5, 94660-8, 94745-7, 94746-5, 94756-4, 94757-2, 94758-0, 94759-8, 94760-6, 94763-0, 94764-8, 94765-5, 94766-3, 94767-1, 94819-0, 94822-4, 94845-5, 95406-5, 95409-9, 95425-5, 95521-1, 95522-9, 95608-6, 95823-1, 95824-9, 95826-4, 96091-4, 96094-8, 96120-1, 96121-9, 96122-7, 96123-5, or 96448-6.
Emergency department (ED) visit	Emergency department encounter for a COVID-19 infection within 90 days of vaccination event.
Vaccination event	Date of flu vaccination or bivalent COVID-19 vaccination.

Table 1: ED Visit Rates by Vaccine Status and Age Group

Age group	Exposure	Count	Rate per 100k	Low CI	High CI
6 months-4 years	Bivalent COVID-19 Vaccine	4,757	105.1	44.9	245.8
	Control	51,596	515.5	457.3	581.1
5-11 years	Bivalent COVID-19 Vaccine	61,892	43.6	30.0	63.5
	Control	139,339	155.0	135.7	177.1
12-17 years	Bivalent COVID-19 Vaccine	108,620	64.4	51.0	81.4
	Flu Vaccine	79,509	190.0	162.0	222.7