

Pediatric COVID-19 Vaccination: A Description of Adverse Events or Reactions Reported in Kansans Aged 6 to 17

Anna Tri¹, Kale Mills, B.S.², Kari Nilsen, Ph.D.^{2,3}

¹Wichita State University, Wichita, KS

²University of Kansas School of Medicine-Wichita, Wichita, KS

³Department of Family & Community Medicine

Received Aug. 18, 2022; Accepted for publication Oct. 3, 2022; Published online Nov. 28, 2022
<https://doi.org/10.17161/kjmvoll5.18431>

ABSTRACT

Introduction. There have been widespread concerns about the safety of the COVID-19 vaccines, particularly when it comes to pediatric populations, and it is important to provide information for parents and guardians to make informed decisions. This study sought to identify the adverse events or reactions (AERs) associated with the COVID-19 vaccines in Kansans aged 6 to 17.

Methods. The U.S. Department of Health and Human Services' "Vaccine Adverse Event Reporting System" (VAERS) database was searched from May 11, 2021, to April 30, 2022, for AERs related to COVID-19 vaccines in adolescents ages 6 to 17. Results were grouped by vaccine manufacturer and patient gender.

Results. A total of 159 individuals reported 409 AERs, with an average of 2.6 per person (± 1.7 ; median = 2; range 1 to 10). Females ($n = 95$) reported 237 AERs, with an average of 2.5 each (± 1.7 ; median = 2; range 1 to 8), while males ($n = 64$) reported 172 AERs, with an average of 2.7 each (± 1.8 ; median = 2; range 1 to 8). The most common adverse event associated with Pfizer[®] vaccination was syncope/fainting.

Conclusions. COVID-19 vaccines have undergone intensive monitoring and safety regulations since the onset of the coronavirus. With over 591 million doses administered, there was compelling evidence that the COVID-19 vaccines are safe and effective. Informing the public about the potential AERs of the COVID-19 vaccines in children can help to alleviate vaccine hesitancy and strengthen vaccination confidence.

Kans J Med 2022;15:390-393

INTRODUCTION

In December 2019, the first case of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection, colloquially known as "coronavirus 19" or "COVID-19", was seen in China.¹ The virus rapidly spread throughout the first few months of 2020, becoming a worldwide pandemic, with the first case in the United States reported on January 20, 2020. Due to the rapid spread and virulent nature of the SARS-CoV-2 virus, a national campaign to develop a vaccine in the U.S. ensued. The United States Food and Drug Administration (FDA) declared an emergency use authorization (EUA) for the first COVID-19 vaccine on December 11, 2020. This vaccine was manufactured by Pfizer-BioNTech (Pfizer[®]) and had an efficacy rate of up to 95%.² This vaccine was first given an EUA for those persons aged 16 and older and subsequently given emergency approval for children ages 5 to 15 by October 29, 2021.³

The Pfizer[®] vaccine requires two doses given three weeks apart for all age groups. For children who are moderately or severely immunocompromised, the U.S. Centers for Disease Control and Prevention (CDC) recommended that they receive a total of four doses of the Pfizer[®] vaccine.⁴ This would include a primary series of three doses and an additional booster shot.⁵ On December 18, 2020, the FDA granted an EUA for a second COVID-19 vaccine developed by Moderna[®] Therapeutics, the National Institute of Allergy and Infectious Diseases (NIAID), and Biomedical Advanced Research and Development Authority (BARDA).⁶ The Moderna/NIAID/BARDA (Moderna[®]) vaccine was authorized for persons aged 18 and older and requires two doses to achieve an efficacy rate of 94.1%.⁷ The FDA granted one more EUA for Johnson & Johnson's Janssen[®] (J&J) single dose COVID-19 vaccine on February 27, 2021, for persons 16 and older.⁸ The J&J vaccine has a slightly lower efficacy rate at 66.3%.⁹

These three vaccines continue to be monitored and serious adverse events or reactions (AERs) that occur after administration are reported by health care providers through the U.S. Department of Health and Human Services' "Vaccine Adverse Event Reporting System" (VAERS). VAERS is co-managed by the FDA and CDC, and accessible through the public resource WONDER (Wide-ranging ONline Data for Epidemiologic Research). The VAERS defines serious AERs as:

*Death; a life-threatening adverse event; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; a congenital anomaly/birth defect; an important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above; cases of multisystem inflammatory syndrome; cases of COVID-19 that result in hospitalization or death.*¹⁰

Individuals can submit their AERs directly to VAERS online or report to their health care provider or vaccination manufacturer, who are mandated to report the AERs to VAERS.¹⁰ These reports cannot be used accurately to determine if a vaccine directly caused the reported AERs, however, the VAERS system can be utilized to detect unusual patterns ("safety signals") that are monitored regularly by VAERS staff.

From December 11, 2020 to May 13, 2021, the AERs reported in persons aged 18 and older in Kansas revealed that only 0.00068% of all COVID-19 vaccine doses given were associated with an AER.¹¹ The most common AERs associated with the three vaccines included fatigue/tiredness, tingling/itching, fever, hives, and muscle/joint pain. Furthermore, no report extrapolated from the VAERS system in Kansas provided a sufficient causal link between a COVID-19 vaccine and death. In contrast, there have been over 841,000 cases of COVID-19 and 8,970 deaths logged in Kansas due to COVID-19.¹² Nationally, there have been 1,257 deaths reported due to COVID-19 in individuals between the ages of 6 to 18.¹³ Moreover, instances of long COVID-19 in children who suffer from morbidity post COVID-19 infection have been reported significantly in the U.S., however, exact numbers of incidence or prevalence were unknown.

Given the potential risks associated with COVID-19 infection in children and the sensitive nature associated with vaccine uptake in the

country, it was important to give individuals and parents the knowledge they need to make informed decisions about COVID-19 vaccines. There have been widespread concerns about the safety of the COVID-19 vaccines, particularly when it comes to pediatric vaccine administration. This study sought to shed light on the current state of adverse events associated with the COVID-19 vaccines approved for use in ages 6 to 17 in Kansas with the hope that parents may use this as a guiding resource when it comes to COVID-19 vaccine safety.

METHODS

The VAERS database was searched from May 11, 2021 to April 30, 2022, for AERs related to the three COVID-19 vaccines in adolescents ages 6 to 17. The study team chose this time period as it was the time period when this age group was given FDA approval up until the date children five and under were given approval. Results were grouped by vaccine manufacturer, whether the impacted patient resided in Kansas, patient age and gender, and included information on AER description, as well as any relevant or available data regarding labs, current illnesses, AERs after prior vaccinations, medications at time of vaccination, and medical history and/or allergies. The full description of the search strategy is available from the authors upon request. This study was approved by the University of Kansas School of Medicine Institutional Review Board as non-human subject research.

Data Screening. The search identified 292 separate patient entries in VAERS. The initial data file was screened by two of the authors (AT and KN) for entries that needed to be removed. One hundred and twenty-seven entries were removed for seven reasons: a COVID-19 diagnosis (four removed), an appendicitis diagnosis (one removed), report of improper vaccine storage (six reported), incorrect dosage given (40 removed), report of unapproved underage administration (70 removed), entries that were not COVID-19 vaccine related (six removed), and duplicate entries (two removed). The breakdown of the screening criteria by vaccine manufacturer is shown in Table 1. Of the initial 292 entries, 129 were removed for a total of 163 VAERS entries to be coded by the research team.

Table 1. VAERS COVID-19 vaccine entry data screening procedure.

	Pfizer®	Moderna®	J&J	Total
Initial Cases	246	37	9	292
Cases Removed				
Removed for COVID-19 diagnosis; no AER noted	4	0	0	4
Appendicitis diagnosis; no AER noted	1	0	0	1
Improper storage; no AER noted	6	0	0	6
Incorrect dose given; no AER noted	40	0	0	40
Underage administration; no AER noted	29	35	6	70
Not vaccine related; No AER noted	6	0	0	6
Duplicate entry removed	1	1	0	2
Total Removed	87	36	6	129
Final Cases	159	1	3	163

Data Coding. Each VAERS entry was screened by one of the three authors, coded by another, and reviewed by the third, with a rotating list of entries for each author, ensuring that each entry was seen and checked by all three members of the authorship team. Any entries that were unclear were resolved by discussion. Each identified AER that appeared two or more times was coded into a separate category, for a total of 43 identified categories of AERs related to the COVID-19 vaccines. Sixteen category names utilized wording obtained from the side effects listed on the information sheets provided by the manufacturer for each vaccine.^{14,15} The additional 26 categories were named based on medical and lay terms for the AER identified (i.e., diaphoresis/cold sweats). Additionally, there was a category named “other” for 22 individual entries that did not fall into the identified AER categories. Within all 43 categories, there were a total of 409 separate AERs reported. Table 2 shows the AER categories identified with the breakdown of number of coded entries in each.

Data Analysis. Descriptive statistics were used to describe AERs reported by vaccine manufacturer (Pfizer®, Moderna®, and J&J) and gender (male and female). Traditional statistical analyses were not performed beyond calculating the inter-rater reliability, as this is a purely descriptive study of reported AERs and causal inferences are unable to be performed due to the nature of the VAERS system.

Table 2. Specific AERs identified (Pfizer® only).

Syncope (fainting)	40	Loss of appetite	5
Fever	28	Redness	5
Dizziness	24	Sore throat	5
Fatigue	23	Weakness	5
Headache/migraine	23	Abdominal pain	4
Nausea	20	Body aches	4
Dyspnea (shortness of breath)	14	Numbness	4
Pallor/pale skin	14	Tachycardia (fast heartbeat)	4
Pain at injection site	13	Abnormal menses	3
Chest pain	12	Confusion	3
Muscle/joint pain	12	Cough/congestion	3
Pruritus (tingling/itching)	12	Ear pain/tinnitus	3
Diaphoresis (cold sweats)	11	Angioedema (swelling)	2
Rash	11	Arm pain	2
Vomiting	11	Bruising	3
Mental health issues	9	Diarrhea	2
Seizure	9	Eye pain	2
Vision issues	9	Hematuria (blood in urine)	2
Chills/shaking	8	Incontinence	2
Urticaria (hives)	8	Insomnia	2
Hypotension	6	Other	22
Allergic reaction	5	Total	409

RESULTS

Adverse Events or Reactions (Table 2). For ages 6 through 17 in Kansas, 209,215 individuals have been vaccinated out of 516,487 eligible adolescents for a vaccination rate of 40.5%. A total of 159 individuals reported adverse events out of the 209,215 adolescents vaccinated (0.08%). Overall, there were a total of 409 AERS reported with the Pfizer® vaccine, with an average of 2.6 per person (± 1.7), median of 2, and a range of 1 to 10. Females ($n = 95$) reported 237 AERS, with an average of 2.5 each (± 1.7 ; median of 2, range 1 to 8); while males ($n = 64$) reported 172 AERS, with an average of 2.7 each (± 1.8 ; median of 2, range 1 to 8). The most common adverse event associated with Pfizer® vaccination was syncope/fainting (Table 2). The second most common AER reported was fever ($n = 27$), followed by dizziness ($n = 24$), fatigue ($n = 23$), and headache/migraine ($n = 23$). Females were more likely to report syncope ($n = 23$), dizziness ($n = 18$), fever ($n = 13$), and headache/migraine ($n = 12$); while males were more likely to report syncope ($n = 17$), fever ($n = 14$), headache/migraine ($n = 11$), fatigue ($n = 10$), and nausea ($n = 10$).

Moderna®/NIAID/BARDA and Johnson & Johnson's Janssen® Vaccines. While the Moderna® vaccine has been approved only for ages 18 and older, there was one underage administration to a female who reported tachycardia, dyspnea, headache, fever, arm pain, and dizziness. The J&J vaccine has been approved for ages 16 and older, but three people with underage administration (two females, one male) reported the following AERS: dizziness (one female), body aches (one male, one female), headache (one male), and fever (one female).

Other Adverse Events or Reactions Reported. Overall, there were 22 AERS that were outliers, meaning they were only reported in VAERS once and they did not fall into one of the 43 identified categories. All "other" AERS were reported with the Pfizer® vaccine: cerebral venous thrombosis (blood clot), hemoptysis (coughing up blood), acute dacryoadenitis (lacrimal gland inflammation), vasculitis (inflammation of blood vessels) in both feet, autism, hypoglycemia, bump on head, subacute progressive emergence of obsessive compulsive disorder-like behaviors, methicillin-resistant staphylococcus aureus, pneumothorax (collapsed lungs), ageusia (loss of taste), Bell's Palsy, non-specified heart failure, hearing loss, vision loss, vulvodynia (vulvar pain), epistaxis (nosebleed), breast lump, pneumonia, pulmonary embolism, motor tics, and vocal tics.

DISCUSSION

Similar to a prior manuscript,¹¹ causality between adverse events and vaccination was difficult to establish. No deaths in this vaccinated cohort were seen, however, and reported serious adverse events were limited. Other studies have noted similar results.¹⁶⁻¹⁸ Notably, no reports of myocarditis were identified within our VAERS analysis, which was a point of concern for many individuals in the academic and lay community alike regarding the Pfizer® vaccine in particular.^{19,20} Of further note, some of the adverse events like syncope/fainting could be unrelated to the actual action of the vaccine and more associated with anxiety over

vaccine administration, which could trend adverse events even lower. Given these facts, this study further may enshrine the narrative that adverse events, of all levels of severity, are rare and the risk-benefit ratio was in favor of receiving a COVID-19 vaccine.

One troublesome note in our study was that 38.3% of original adverse event entries ($n = 110$) were screened out due to vaccine administration to underage individuals, or the incorrect dosage was given. These issues were concerning given research is still underway regarding the safety of these vaccines in certain pediatric populations. Furthermore, the J&J COVID-19 vaccine, as of the completion of this project, has not been approved and is not recommended for individuals under 18 years of age, and nine individuals in our study received that vaccine. In this regard, research and quality improvement studies may be needed to reduce the amount of vaccine administration errors seen with the rollout of the COVID-19 vaccines, due to the potential negative health outcomes of such errors.

Given the small number of children who have received a COVID-19 vaccination in Kansas, the main issue at hand was addressing the concerns that individuals and their families have regarding vaccine uptake. A survey by the Kaiser Family Foundation reported that only 27% of parents of 5 to 11 year olds across the country were keen to immunize their child for COVID-19.²¹ Furthermore, a recent study found that a cohort of parents felt that vaccine side effects were the most significant factor associated with COVID-19 vaccine hesitancy.²² A main underlying concern that likely gives rise to the hesitancy associated with concerns of vaccine side effects was the fact that COVID-19 vaccines are relatively novel. A 2021 study by Trojano and colleagues found that the most observed reasons for refusal of COVID-19 vaccination were concerns about safety/thinking that a vaccine produced in a rush is too dangerous.²³ These two concerns of safety and novelty often were equated to each other, and more research may be needed on the appropriate ways to educate individuals to make informed decisions when it comes to COVID-19 vaccinations. As with our prior manuscript,¹¹ it is the hope that this study can be used as a valuable resource for those who are unsure about receiving a COVID-19 vaccine themselves or allowing their children to be vaccinated.

Limitations. The Pfizer® vaccine was approved for adolescents five and older, however, our study focused on persons aged 6 to 17 due to limitations in the VAERS self-reported age categories. Additionally, VAERS is a passive reporting system, which means that anyone can report adverse events or reactions to the system. There was no guarantee that all AERS were reported, nor can any definitive link be established between the AER reported and the vaccine administered. Underreporting of AERS was also a possibility as some may not consider a particular adverse event important enough to report.

CONCLUSIONS

Currently, COVID-19 vaccines are only authorized for use in adults, adolescents, and children ages 6 to 11. Children under the age of five were the last remaining group in the U.S. pending full FDA approval for COVID-19 vaccination. COVID-19 vaccines have undergone intensive monitoring and safety regulations since the onset of the coronavirus, and with over 616 million doses administered in the U.S.,²⁴ there is compelling evidence that the COVID-19 vaccines are

to receive the COVID-19 vaccine could be a major step towards achieving herd immunity and mitigating the spread of the virus. The CDC, FDA, and healthcare providers agree that COVID-19 vaccines can help protect children against severe COVID-19 disease.^{2,7,9,25-27}

With over 66% of the U.S. population fully vaccinated, along with other relief efforts, the effects of COVID-19 slowly are starting to diminish. Public health experts, elected officials, and healthcare professionals should take heed to provide reliable information to the public to encourage vaccine uptake.²⁸ Informing the public about the potential AERs of the COVID-19 vaccines in children can help to alleviate vaccine hesitancy and provides an additional source of information to strengthen vaccination confidence.

ACKNOWLEDGEMENTS

The authors thank the Kansas Department of Health and Environment for their help in accessing vital vaccine related data, as well as the VAERS operated and maintained for public use by the U.S. Centers for Disease Control and Prevention and the Food & Drug Administration.

REFERENCES

- U.S. Centers for Disease Control and Prevention. CDC Museum Covid-19 Timeline. January 5, 2022. www.cdc.gov/museum/timeline/covid19.html. Accessed July 2, 2022.
- U.S. Food and Drug Administration. FDA takes key action in fight against COVID-19 by issuing emergency use authorization for first COVID-19 vaccine. October 29, 2021. www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19. Accessed July 2, 2022.
- U.S. Food and Drug Administration. FDA authorizes Pfizer-BioNTech COVID-19 vaccine for emergency use in children 5 through 11 years of age. October 29, 2021. www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age. Accessed July 2, 2022.
- Priß BM. Current state of the first COVID-19 vaccines. *Vaccines (Basel)* 2021; 9(1):30. PMID: 33429880.
- U.S. Centers for Disease Control and Prevention. COVID-19 vaccines for people who are moderately or severely immunocompromised. July 20, 2022. www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html. Accessed August 2, 2022.
- U.S. Food and Drug Administration. FDA takes additional action in fight against COVID-19 by issuing emergency use authorization for second COVID-19 vaccine. December 18, 2021. www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid. Accessed July 2, 2022.
- Haynes BF. A new vaccine to battle COVID-19. *N Engl J Med* 2021; 384(5):470-471. PMID: 33378607.
- U.S. Food and Drug Administration. Janssen COVID-19 vaccine. May 5, 2022. www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine. Accessed July 2, 2022.
- U.S. Centers for Disease Control and Prevention. Johnson & Johnson's Janssen COVID-19 vaccine overview and safety. July 2, 2022. www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html. Accessed July 23, 2021.
- U.S. Department of Health and Human Services. Department of Health and Human Services, Public Health Service Food and Drug Administration/ Centers for Disease Control and Prevention Vaccine Adverse Event Reporting System (VAERS) CDC WONDER Online Database. <https://vaers.hhs.gov/data.html>. Accessed May 13, 2022.
- Mills K, Tri A, Nilsen K. The COVID-19 vaccines: A description of adverse events of reactions reported in Kansas. *Kans J Med* 2022; 15:39-47. PMID: 35371387.
- Kansas Department of Health and Environment. COVID-19 cases in Kansas. <https://www.coronavirus.kdheks.gov/160/COVID-19-in-Kansas>. Accessed July 2, 2022.
- Hause AM, Baggs J, Marquez P, et al. COVID-19 vaccine safety in children aged 5-11 years - United States, November 3-December 19, 2021. *MMWR Morb Mortal Wkly Rep* 2021; 70(5152):1755-1760. PMID: 34968370.

¹⁴ Pfizer. Fact sheet for healthcare providers administering vaccine. July 2, 2022. <https://labeling.pfizer.com/ShowLabeling.aspx?id=16073&format=pdf>. Accessed July 23, 2022.

¹⁵ U.S. Food and Drug Administration. Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19). June 17, 2022. <https://www.fda.gov/media/153714/download>. Accessed August 6, 2022.

¹⁶ Hause AM, Gee J, Baggs J, et al. COVID-19 vaccine safety in adolescents aged 12-17 years - United States, December 14, 2020-July 16, 2021. *MMWR Morb Mortal Wkly Rep* 2021; 70(31):1053-1058. PMID: 34351881.

¹⁷ Klein NP, Lewis N, Goddard K, et al. Surveillance for adverse events after COVID-19 mRNA vaccination. *JAMA* 2021; 326(14):1390-1399. PMID: 34477808.

¹⁸ Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine. *New Engl J Med* 2020; 383(27):2603-2615. PMID: 33301246.

¹⁹ Marshall M, Ferguson ID, Lewis P, et al. Symptomatic acute myocarditis in 7 adolescents after Pfizer-BioNTech COVID-19 vaccination. *Pediatrics* 2021; 148(3):e2021052478. PMID: 34088762.

²⁰ Dionne A, Sperotto F, Chamberlain S, et al. Association of myocarditis with BNT162b2 messenger RNA COVID-19 vaccine in a case series of children. *JAMA Cardiol* 2021; 6(12):1446-1450. PMID: 34374740.

²¹ Hamel L, Lopes L, Sparks G, et al. KFF COVID-19 Vaccine Monitor: October 2021. October 28, 2021. <https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-october-2021/>. Accessed July 20, 2022.

²² Ruggiero KM, Wong J, Sweeney CF, et al. Parents' intentions to vaccinate their children against COVID-19. *J Pediatr Health Care* 2021; 35(5):509-517. PMID: 34217553.

²³ Troiano G, Nardi A. Vaccine hesitancy in the era of COVID-19. *Public Health* 2021; 194:245-251. PMID: 33965796.

²⁴ U.S. Centers for Disease Control and Prevention. CDC Covid Data tracker. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total. Accessed September 24, 2022.

²⁵ U.S. Centers for Disease Control and Prevention. Safety of COVID-19 Vaccines. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html>. Accessed September 24, 2022.

²⁶ U.S. Food and Drug Administration. Covid-19 Vaccines. <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>. Accessed September 24, 2022.

²⁷ Ransone SN Jr. Family physicians urge all eligible children and adults to get vaccinated against COVID-19. March 8, 2022. <https://www.aafp.org/news/media-center/statements/family-physicians-urge-all-eligible-children-and-adults-to-get-vaccinated-against-covid-19.html>. Accessed September 24, 2022.

²⁸ Thunström L, Ashworth M, Finnoff D, Newbold SC. Hesitancy toward a COVID-19 vaccine. *Ecohealth* 2021; 18(1):44-60. PMID: 34086129.

Keywords: vaccination, adverse drug events, COVID-19 vaccines, vaccine refusal, Kansas