highlighting how it facilitated sharing the experience with other family members (especially siblings) and that it was a source of emotional support during the stay.

There are numerous limitations to this study, as it was a pilot experience conducted in a single centre without a control group, and there was no standard reference that would allow comparing the incidence of F-PICS in the ''intervention'' group.

Nevertheless, our experience suggests that PICU diaries are a feasible initiative that should be contemplated during PICU stays, as they are very well received by families and could help prevent and cope with F-PICS by improving intrafamily communication.

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COVID-19 vaccine adverse events in a population aged 5–17 years: a study from the VAERS database

Eventos adversos en vacunas COVID-19 en una población de 5–17 años: estudio de la base de datos VAERS

Dear Editor:

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that emerged in late 2019.[1] On October 29, 2021, the Food and Drug Administration (FDA) expanded the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 mRNA vaccine to authorize its use in children aged 5–11 years to be given in 2 doses (10 μg in 0.2 mL each) 3 weeks apart.[2] Up to December 2021, only the Pfizer-BioNTech COVID-19 vaccine had been authorized for children aged 5–17 years, followed in May 2022 by authorization of a single booster for children 5 through 11 years with this vaccine. Trials for Moderna and Janssen vaccines are underway in this age group, and adverse events (AEs) in these trials or in the context of off-label use could have been reported to the Vaccine Adverse Event Reporting System (VAERS) database of the United States.[3] Our study focused on the safety of the COVID-19 vaccines approved in the United States for children aged 5–17 years based on the AEs notified to the VAERS.

We conducted an observational descriptive study by reviewing AE reports related to the Pfizer/Biotech, Moderna, and Janssen vaccines registered in the VAERS database from the dates the vaccines were first approved through December 1, 2021. The VAERS database, available through its webpage (https://vaers.hhs.gov/data.html), contains voluntary reports of health care providers and patients as well as mandated manufacturer reports of adverse events after vaccination. The VAERS database codifies up to 5 symptoms for each report using the Medical Dictionary for Regulatory Activities (MedDRA) codes for preferred terms (PTs).[4] These PTs, which do not correspond to medically confirmed diagnoses, were not mutually exclusive.

We created a frequency distribution with the most commonly documented PTs stratified by age and manufacturer. We also included reports that mentioned PTs related to anaphylaxis, pericarditis, thrombotic events or death.

We found a total of 687402 AEs mentioning any of the approved COVID-19 vaccines in the VAERS database, of which 2.9% involved children aged 5–17 years. Of these children, 2820 were aged 5–11 years, 8382 12–15 years and 8659

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Table 1 Severe and frequent adverse event reports stratified by age and manufacturer.

	Age 5—11 years (n = 2820)[a]			Age 12—15 years (n = 8382)[a]			Age 16—17 years (n = 8659)[a]		
	Janssen	Moderna	Pfizer	Janssen	Moderna	Pfizer	Janssen	Moderna	Pfizer
Total AEs reported	215	1705	900	1076	3447	3859	1124	3821	3714
Death	4 (0.1%)			7 (0.1%)			17 (0.2%)		
Death	1 (0.5%)	2 (0.1%)	1 (0.1%)	1 (0.1%)	2 (0.1%)	4 (0.1%)	1 (0.1%)	6 (0.2%)	10 (0.4%)
Anaphylactic (reaction/shock)	4 (0.1%)			26 (0.3%)			32 (0.4%)		
Anaphylactic reaction	1(0.5%)	2 (0.1%)	–	3 (0.3%)	6 (0.2%)	16 (0.4%)	2 (0.2%)	16 (0.4%)	13 (0.4%)
Anaphylactic shock	1(0.5%)	–	–	–	–	1 (0.0%)	–	–	1 (0.0%)
Chills	70 (32.6%)	515 (30.2%)	182 (20.2%)	376 (34.9%)	1099 (31.9%)	824 (21.4%)	586 (52.1%)	1408 (36.8%)	1042 (28.1%)
Dizziness	49 (22.8%)	155 (9.1%)	142 (15.8%)	180 (16.7%)	531 (15.4%)	736 (19.1%)	180 (16.0%)	546 (14.3%)	752 (28.1%)
Fatigue	14 (6.5%)	193 (11.3%)	84 (9.3%)	106 (9.9%)	344 (10.0%)	384 (10.0%)	142 (12.6%)	482 (12.6%)	401 (10.8%)
Headache	19 (8.8%)	190 (11.1%)	72 (8.0%)	116 (10.8%)	343 (10.0%)	199 (5.2%)	114 (10.1%)	286 (7.5%)	222 (6.0%)
Myocarditis	–	–	–	–	4 (0.1%)	2 (0.1%)	–	–	5 (0.1%)
Pain (generalised)	32 (14.9%)	13 (0.8%)	45 (5.0%)	23 (2.1%)	37 (1.1%)	63 (1.6%)	10 (0.9%)	51 (1.3%)	46 (1.2%)
Pericarditis	–	–	1 (0.1%)	–	–	2 (0.1%)	–	1 (0.0%)	1 (0.0%)
Redness at injection site	–	144 (8.4%)	–	–	67 (1.9%)	9 (0.2%)	–	52 (1.4%)	3 (0.1%)
Pain at injection site	–	22 (1.3%)	–	20 (1.9%)	11 (0.3%)	31 (0.8%)	–	9 (0.2%)	10 (0.3%)

[a] Total reports involving COVID-19 vaccines in the given age group.

16–17 years. Out of the total reports, 52% corresponded to female patients, and 45.2% (n = 8973) involved the Moderna vaccine, 42.7% (n = 8473) the Pfizer/BioNTech vaccine and 12.1% (n = 2415) the Janssen vaccine. The most common AEs in every age group were chills, dizziness, fatigue and headache. Stratifying by age, the most frequent AEs in the 5-to-11 years age group were chills (27.2% of reports), dizziness (12.3%), fatigue (10.3%), and headache (9.9%); in the 12-to-15 years age group, chills (27.4%), dizziness (17.3%), fatigue (9.9%), and headache (7.9%); and in the 16-to-17 years age group, chills (35.1% of reports), dizziness (17.1%), fatigue (11.8%) and headache (7.2%). Anaphylactic reactions were documented in 0.31% of reports, myocarditis or pericarditis in 0.08%, and death in 0.14%. Table 1 presents details on AEs by vaccine.

These results contribute to our understanding of the frequency of AEs associated with COVID-19 vaccines in children aged 5–17 years. Using the VAERS database has its limitations, as it is a passive public health reporting system and therefore can be a source of reporting bias, for instance, increased reporting due to the media coverage of COVID-19 vaccines.[5] To date, little research has been conducted on the safety of these vaccines in the paediatric population, highlighting the need for further investigation.[6] Though causality could not be established in our study, its results suggest that currently approved COVID-19 vaccines are relatively safe in children aged 5–17 years.

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The study received no funding.

Ethical considerations

The VAERS complies with all United States Government security standards and protections concerning health information. Use of the VAERS database does not require approval by an institutional review board or informed consent.

Conflicts of interest

The authors declare that they have no conflict of interests, either financial or personal.

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