O MUNDO DA SAÚDE

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Events supposedly attributable to COVID-19 vaccination in children from a family health strategy

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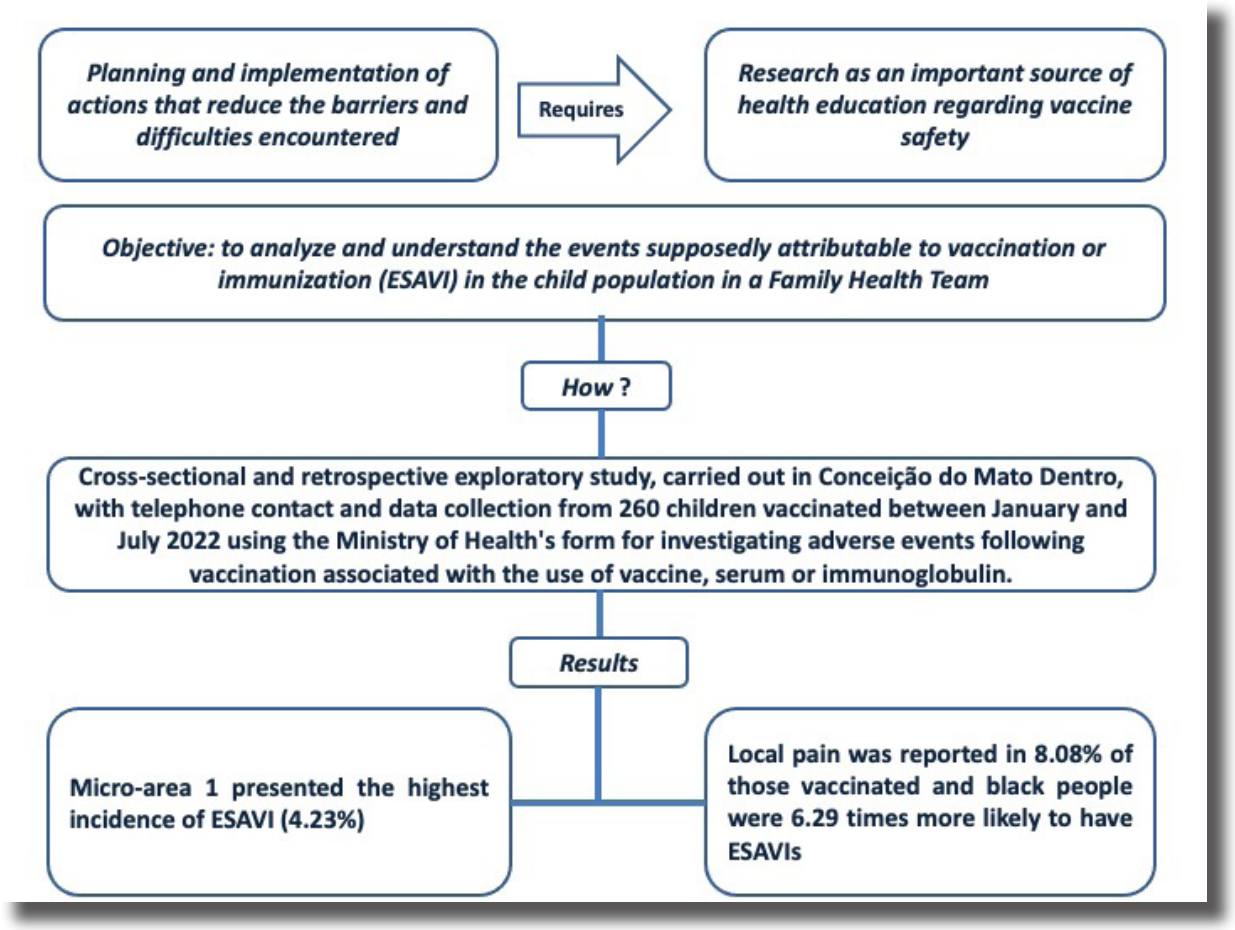
Graphical Abstract



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Abstract

COVID-19 in children can progress to more severe forms of the disease, such as severe acute respiratory syndrome and pediatric multisystem inflammatory syndrome. This study aimed to analyze Events Supposedly Attributable to Vaccination or Immunization (ESAVI) in the pediatric population. It was an exploratory, cross-sectional, and retrospective study conducted in the municipality of Conceição do Mato Dentro. Data were collected via telephone for 260 children vaccinated between January and July 2022 using the Ministry of Health's adverse events investigation form associated with the use of vaccines, serums, or immunoglobulin. Microarea 1 had the highest occurrence of ESAVI (4.23%); local pain was reported by 8.08% of vaccinated individuals, and Black children were 6.29 times more likely to present ESAVI. Promoting vaccine safety for COVID-19 has a crucial role in maintaining vaccination coverage rates and reducing illness rates.

Keywords: COVID-19. Breakthrough Infections. Vaccination. Immunization. Immunization Programs. COVID-19 Vaccines.

INTRODUCTION

COVID-19 is a systemic infectious disease caused by the SARS-CoV-2 virus, which, due to its rapid transmission capacity and high hospitalization rates, is considered a public health issue[1]. At the end of January 2020, the World Health Organization (WHO) declared the COVID-19 pandemic a global health emergency of international concern, mobilizing the world in the search for effective treatments against the virus, which intensified the search for vaccines at an unprecedented speed[2].

With some vaccines already authorized in the country, the COVID-19 immunization campaign began in January 2021, starting with priority groups and later expanding to the adult population. The immunization of the pediatric population in Brazil started in January 2022 with the Comirnaty® (Pfizer/BioNTech) vaccine authorized for children aged 5 years and older. Shortly after, in the same month, the CoronaVac® (Butantan/Sinovac) vaccine was granted emergency use approval for children aged 6 years and older, excluding immunocompromised individuals[3].

Specifically regarding COVID-19 in the pediatric population, studies have shown that mortality and severity rates are low, with cases typically presenting mild flu-like symptoms or even being asymptomatic[4]. However, more severe forms can occur in this population, such as pediatric multisystem inflammatory syndrome (MIS-C) and long COVID[5].

In this context, it is important to highlight the need for post-vaccination adverse event surveillance to standardize and systematize events in pursuit of safe vaccination. The definition of an Adverse Event Following Immunization (AEFI) is any undesirable medical occurrence temporally associated with vaccination, which may be an adverse or unintended event[3]. The Ministry of Health in Brazil followed the Pan American Health Organization (PAHO/WHO) in adopting new terminology for AEFI, now referred to as Events Supposedly Attributable to Vaccination or Immunization (ESAVI) for the Americas. This terminology emphasizes the uncertainty regarding the causal relationship between the adverse event and the vaccine. It also distinguishes vaccination from immunization, defining the former as the process of administering the vaccine, while the latter refers to the response generated by the vaccinated individual[3].

In the scenario of the recent introduction of a vaccine for the population, pharmacovigilance of ESAVI is of utmost importance, as any severe sign or symptom manifesting in an individual who has received an immunobiological is considered an event[6]. Therefore, it is understood that not all events following vaccine administration result from

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the vaccine itself or the vaccination process. The physiological state of the individual and concurrent illnesses at the time of vaccination may be associated with the event and could overlap with the signs, symptoms, or findings in the vaccinated person.

Despite concerns regarding AEFI related to vaccines, the events reported in both clinical trials and pharmacovigilance data occur rarely and at a frequency far lower than the benefits of vaccination[7]. Moreover, studies show results indicating that the benefits of immunization outweigh the risks associated with it[8].

Thus, considering research as an important source of health education regarding vaccine safety, analyzing and understanding ESAVI in the pediatric population assisted by the Family Health Strategy (FHS) becomes crucial to contribute to the planning and implementation of actions that reduce barriers and challenges encountered. In this context, the importance of this investigation is highlighted, aiming to analyze ESAVI in the pediatric population assisted by an FHS unit in the city of Conceição do Mato Dentro, Minas Gerais.

METHOD

This was an exploratory, cross-sectional, and retrospective study conducted in the territory of a Family Health Strategy (FHS) located in the urban area of Conceição do Mato Dentro, Minas Gerais. The exploratory, cross-sectional, and retrospective nature of the study is justified by its preliminary and investigative approach, aiming to map and understand specific phenomena or characteristics within a given context, even with limited or unconsolidated information. It is cross-sectional due to the method's ability to analyze phenomena within a specific period, providing a comprehensive view of the current health context, enabling an analysis of the present state, and identifying possible patterns or prevalent characteristics during the studied period. The retrospective aspect is justified by the use of historical data to understand past conditions and their repercussions in the present. This approach allows the analysis of prior events, such as health actions and epidemiological indicators, to identify trends and factors influencing the current situation in the FHS region. The choice of this approach also considers the availability of secondary data, such as service records, patient files, or medical histories, which are essential for constructing a broader perspective.

Segundo According to data from the Municipal Health Secretariat, the FHS is divided into six microareas, covering 3,173 registered users, of whom 352 are children aged 5 to 11 years, the age range used in this study. Data for this study were collected by the researcher and Community Health Agents (CHAs) from the Bandeirinha FHS through medical records, interviews, and municipal immunization sector records. Prior to data collection, the Vivver Sistema, Ltda., software licensed to the Municipal Government of Conceição do Mato Dentro, was used to gather the names, phone numbers, and addresses of the children's guardians, who were then invited to participate in the research. The research sample consisted of children vaccinated against COVID-19 between January and July 2022, whose parents or guardians consented to participate in the study. It is important to note that this sample definition introduces a potential selection bias, as participation was based on the guardians' consent, which may not adequately represent the target population (all vaccinated children during the period). Additionally, ef-

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forts were made to reach those who initially did not respond, and no analysis of the characteristics of non-participants was conducted, which could influence the results.

To assess ESAVI, participants were contacted by phone, and data were collected during a scheduled call. Each session lasted approximately 20 minutes, during which the Informed Consent Form (ICF) was read, and the questionnaire was completed. The data collection tool used was the Ministry of Health's form for reporting/investigating adverse events following vaccination associated with the use of vaccines, serums, or immunoglobulins. The form was used without modifications, which introduces potential information bias, as no pre-test was conducted to identify possible adaptations needed to capture the required information from the study population. However, the form is pre-validated by the Ministry of Health for this purpose and is available at: http://pni.datasus.gov.br/Download/Eapv/Ficha_EAPV_PNI070411.pdf. It is important to note that retrospective data collection, particularly through telephone interviews and medical record reviews, is subject to recall errors and inconsistencies in records, representing a limitation of the study. These issues could impact the results, as no validation or cross-checking of the data was performed in this research to mitigate such problems.

The adverse events identified in the study were classified according to the 4th edition of the Manual for Epidemiological Surveillance of Adverse Events Following Vaccination. The classification considered the type of manifestation as either local or systemic, the severity of the events distinguishing between serious adverse events, which include those requiring hospitalization, causing significant dysfunction or permanent disability, resulting in congenital anomalies or leading to death, and non-serious adverse events, which encompass any other events not meeting these criteria. Causality was also assessed, including reactions related to the product itself, such as those caused or triggered by the vaccine or its components, reactions associated with vaccine quality issues due to deviations in quality or packaging, immunization errors related to improper handling, prescription, or administration, anxiety-related immunization reactions triggered by stress or anxiety regarding the vaccination process, and coincidental events caused by other factors unrelated to the vaccine. While this classification served as a reference, the study focused on collecting socio-demographic information and ESAVI-specific data to address its objective of analyzing ESAVI in the selected sample.

The database was created using Microsoft Excel® 2019, version 2310, followed by the calculation of absolute and relative frequencies for the variables. An association was also investigated between the presence or absence of adverse events and the variables: sex, residence area, income, race/color, religion, mother's education level, and the vaccine received, using Fisher's Exact Test. An association was considered significant when the p-value was less than 0.05. When an association was identified, the odds ratio (OR) was calculated for a specific category within the variables compared to others to determine which variable differed significantly ($p<0.05$). Only complete data for each variable were considered for this classification, and fields with missing information were excluded from the analysis. Fisher's Exact Test was chosen to evaluate the associations between adverse events and independent variables due to its suitability for categorical data with small samples and low frequencies. A p-value of less than 0.05 indicated a statistically significant association. When associations were identified, the odds ratio was calculated to determine which variables presented a higher risk concerning the adverse event. To control for confounding variables, only complete data were used for each variable, ex-

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cluding missing fields, ensuring that analyses were conducted with valid data and avoiding distortions in the results.

The methodology used in this study has some limitations inherent to any scientific research, such as recall bias, selection bias, and information bias, as previously discussed. However, it is also important to highlight the potential for confounding bias. The chosen method analyzed a specific number of variables, but alternative methods, such as adjustments for multiple comparisons or a multivariate statistical model, could have been employed to avoid falsely significant results and address potential confounding factors. These approaches would provide more robust results and represent a recommendation for future studies.

This article is part of a master's dissertation presented to the Graduate Program in Health, Society, and Environment (PPG/SaSA) at UFVJM. It adhered to ethical principles in accordance with Resolution 466/2012 of the National Research Ethics Commission (CONEP) and was approved by the Research Ethics Committee (CEP) involving human subjects at UFVJM under opinion number 5.884.448 and CAAE 63508922.2.0000.5108.

RESULTS

This study was conducted in an FHS unit with 352 registered children. Of these, according to records from the immunization sector, 260 had vaccination records and were therefore included for evaluation of ESAVI.

Among the children who received a COVID-19 vaccine within the area covered by the studied FHS, microarea 1 showed the highest occurrence of ESAVI (4.23%), followed by microarea 4 (2.69%), microarea 2 (1.92%), and microarea 3 (0.77%). No ESAVI cases were reported in microarea 6 (Table 1). Regarding the type of manifestation, as shown in Table 2, ESAVI were classified as local manifestations and systemic manifestations.

Table 2 presents the quantifications and classifications of ESAVI, covering both local manifestations, where only localized pain was reported by the guardians of 21 children, and systemic manifestations, where the guardians reported that the children exhibited symptoms detailed in Table 2.

To better understand the manifestations reported by the children's guardians, a comparison was made between the sociodemographic variables of the studied patients and the ESAVI (Table 3), totaling 260 children. It is important to note that these data cannot be extrapolated to comparisons with the total population of the municipality due to the selection bias inherent in this study. No association was observed between ESAVI and variables such as sex, residential area, family income, religion, mother's education level, or the type of vaccine used. However, an association was observed with race/color, with Black individuals being six times more likely to experience adverse events than non-Black individuals (odds ratio: 6.29, $p<0.05$). For context, the proportion of Black and Brown individuals in the studied population was 77.0%. No differences were identified in any other social determinants within the groups.

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Table 1 - Prevalence of events supposedly attributable to vaccination described by the children's guardians, Conceição do Mato Dentro, Minas Gerais (N= 260), 2023.

Variables	Absolute Frequency	Relative Frequency (%)
Microarea 1		
Reported an ESAVI*	11	4.23
Did not report an ESAVI	49	18.85
Total Children	60	23.08
Microarea 2		
Reported an ESAVI	5	1.92
Did not report an ESAVI	38	14.62
Total Children	43	16.54
Microarea 3		
Reported an ESAVI	2	0.77
Did not report an ESAVI	23	8.85
Total Children	25	9.62
Microarea 4		
Reported an ESAVI	7	2.69
Did not report an ESAVI	76	29.23
Total Children	83	31.92
Microarea 5		
Reported an ESAVI	5	1.92
Did not report an ESAVI	35	13.46
Total Children	40	15.38
Microarea 6		
Reported an ESAVI	0	0.00
Did not report an ESAVI	9	3.46
Total Children	9	3.46

Source: Research Data, 2022.
*ESAVI: Events Supposedly Attributable to Vaccination and Immunization.

Table 2 - Quantification and Classification of Events Supposedly Attributable to Vaccination or Immunization Reported by Children's Guardians, Conceição do Mato Dentro, Minas Gerais (N=260), 2023.

Variables	Absolute Frequency	Relative Frequency (%)
Local Manifestations		
Localized Pain	21	8.08
Systemic Manifestations		
Sneezing	2	0.77
Fainting	1	0.38
Rhinorrhea	1	0.38
Dry Cough	1	0.38
Generalized Urticaria	1	0.38
Vomiting	1	0.38
Fever below 39.5°C	5	1.92
Headache	3	1.15
Dyspnea	1	0.38

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...continuation - Table 2.

Variables	Absolute Frequency	Relative Frequency (%)
Chills	1	0.38
Fatigue	1	0.38
Foot Pain	1	0.38
Early Menarche	1	0.38

Source: Research Data, 2022.

Table 3 - Events Supposedly Attributable to Vaccination or Immunization Versus Categorical Variables from a Family Health Strategy in Conceição do Mato Dentro, Minas Gerais (N=260), 2023.

Variables	ESAVI		P - Value
Sex	**No**	**Yes**	***p***
Female	103	14	0.8453
Male	127	16	
Zone	**No**	**Yes**	***p***
Rural	9	0	0.2701
Urban	221	30	
***Per Capita* Income**	**No**	**Yes**	***p***
1 to 2 minimum wages	76	14	0.4399
3 to 9 minimum wages	122	12	
More than 10 minimum wages	23	4	
Less than 1 minimum wage	5	0	
Race	**No**	**Yes**	***p***
White	53	7	<0.01
Black	7	5	
Brown	170	18	
Religion	**No**	**Yes**	**p**
Catholic	146	20	0.7376
Evangelical	62	8	
Does not attend	9	0	
Escolaridade Mãe	**No**	**Yes**	**p**
Literate	2	0	0.4380
Illiterate	3	0	
Primary Education	22	5	
Secondary Education	90	15	
Higher Education	103	10	
Vaccine	**No**	**Yes**	**p**
CoronaVac®	138	20	0.5543
Comirnaty®	92	10	

Source: Research Data, 2022.

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DISCUSSION

For this study, 352 children aged 5 to 11 years, registered in a Family Health Strategy (FHS) unit in Conceição do Mato Dentro, Minas Gerais, were selected. However, data collection focused on 260 children. The reduction in this number was due to the inclusion criteria, which considered only children who had received at least one dose of a COVID-19 vaccine.

Regarding the reasons why parents and/or guardians did not adhere to pediatric vaccination, a study[9] identified that the main factors included concerns that the vaccine was still experimental, fear of adverse reactions and long-term effects, the perception that COVID-19 in children is not severe, and the belief that the risks of vaccination outweigh the benefits.

In general, as with any other vaccine, the common reactions observed with the COVID-19 vaccine in pediatrics are frequent and very similar. However, some rare and benign effects, such as myocarditis, have been reported. Myocarditis was more commonly observed in boys after receiving the second dose of the Comirnaty® vaccine. This is an extremely rare event, occurring in approximately 40 to 50 cases per 1 million doses administered. It is important to emphasize that the risk of myocarditis is significantly higher with the disease itself[10].

An analysis of the six microareas of the evaluated FHS revealed that 11.54% of the guardians reported the occurrence of ESAVI. The highest number of reports was observed in microarea 1 (4.23%), while no cases were reported in microarea 6. Similar findings were observed in a study[11] conducted in northeastern Brazil , where 6.3% of children aged 2 to 10 years presented ESAVI, and in another study6 in a municipality in Santa Catarina, where the overall ESAVI rate in the studied population was 13.9%.

A large proportion of adverse reactions to vaccines is related to the toxicity of the immunizing agent, often occurring as part of the immune response to the vaccine antigen and considered normal. Toxicity refers to the harmful or damaging effects a substance can have on the body due to its interaction with biological systems. In the context of vaccines, toxicity is generally associated with the immune system's reaction to the antigen present in the vaccine, which can cause temporary symptoms such as fever, localized pain, or malaise. These symptoms are largely transient and part of the body's defense process. However, there is low public acceptance of any adverse sign, often leading to refusal of subsequent doses due to fear of potential side effects[12].

Among the ESAVI reported by the children in this study, most were localized manifestations, with localized pain being the most commonly reported symptom. Supporting these findings, research[13] indicated that localized pain was also the most common symptom reported in their studies by 64.57% and 25.3% of vaccinated participants, respectively, showing that localized manifestations are a common type of occurrence after immunization. These manifestations can be attributed to differences in the application technique, vaccine temperature, and injection speed[14].

Although the present study did not specify ESAVI for each vaccine used, another study[15] reported that injection site pain was the most prevalent event in children who received the CoronaVac® vaccine, occurring in 9% of cases. For other vaccines, localized pain was not the most prevalent event.

Regarding the safety of the vaccines used in the study population, while ESAVI were not categorized by vaccine type, research on the prevalence of adverse events following vaccination with CoronaVac® and Comirnaty® found that 20% of participants experienced mild or moderate reactions with CoronaVac®, and similarly, 25% of participants experienced non-severe adverse events in phase III trials for Comirnaty®[15].

Data from a study conducted by Chinese experts indicated that most adverse reactions to COVID-19 vaccination are mild to moderate, with the most common being pain, redness, and swelling at the injection site, as well as fever, headache, nausea, diarrhea, fatigue, and limb pain[16].

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In terms of systemic manifestations, these accounted for 7.64% of the reported ESAVI. Systemic reactions involve multiple systems and typically progress rapidly following vaccine administration. These include fever, malaise, muscle pain, headache, or loss of appetite, though they are not always severe[17]. In a study conducted in Paraná, researchers observed that the percentage of systemic adverse events was higher than those found in the present study. The incidence rates for headache, fever, and myalgia were 16.3%, 32.16%, and 30.4%, respectively[18].

Regarding reports of manifestations such as fever, cough, and sneezing found in this study, these were also the most common symptoms identified in research conducted in Indonesia with children aged 6 to 11 years, though in higher proportions: 5.2%, 11.8%, and 9.2%, respectively. Generally, low-grade fever is the primary systemic adverse event observed in children under 5 years of age[19].

As for the report of vomiting by one participant, another study[20] similarly found only one case of vomiting following COVID-19 vaccination. This manifestation is often associated with non-anaphylactic allergic reactions, which can be triggered by substances in the vaccine, such as non-human proteins, preservatives, or stabilizers[21].

Headache was another systemic manifestation reported in this study, occurring in 1.15% of the children. Previous research[19] identified headache as the primary symptom affecting children over 5 years old after vaccination. However, this event typically resolves quickly and tends to be less frequent after the second dose.

It is important to emphasize that vaccines undergo rigorous testing by manufacturing institutions and the health systems of the countries where they will be administered. Approval and commercialization occur only after thorough analysis and authorization through stringent clinical trials (phases I, II, and III). The final phase (phase IV) occurs after approval and commercialization, aiming to detect adverse events that were not identified or recorded in earlier phases[17].

Regarding early menarche, reported in one child after receiving a COVID-19 vaccine, no robust studies have been found on this subject. A preliminary report conducted with women of reproductive age who received a COVID-19 vaccine dose noted menstrual irregularities, including changes in flow quantity or cycle duration, either increasing or decreasing. However, it was observed that these irregularities resolved spontaneously in approximately half of the cases within two months, without clinically relevant consequences[22].

It is worth noting that no association was found between categorical variables such as the child's sex, area of residence, income, or parents' education level and ESAVI. Conversely, a study[23] on reported adverse events indicated a slight predominance of ESAVI in females, though it could not be concluded that females are more affected.

Regarding residence, studies suggest that living in rural areas, lower socioeconomic levels, and lower education levels are statistically significantly associated with vaccine hesitancy due to fear or lack of knowledge about adverse events, though not necessarily with the occurrence of such events[24].

Regarding the race of the respondents, the significant association between being Black and experiencing ESAVI contradicted studies that identified White individuals as the predominant group in post-vaccination adverse events[25]. It is important to consider that Brazil is a multicultural and multiethnic country shaped by the presence of diverse races and ethnicities. In the religious context, this study found no association between being a regular attendee of Catholic or Evangelical churches and reporting ESAVI. The population of the municipality does not fully represent Brazil's demographic composition, which suggests that a more comprehensive approach considering social inequality would enhance future studies.

Concerning the association between receiving the Comirnaty® or CoronaVac® vaccine, the study found no significant relationship between adverse events and these vaccines. This reaffirms that the vaccines offered by the

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National Immunization Program (PNI) are safe and underwent all pre-clinical and clinical study phases (I, II, and III) to ensure their safety and efficacy before being introduced[26].

A study conducted by researchers in China demonstrated that the CoronaVac® vaccine is safe and immunogenic in children and adolescents aged 3 to 17 years. Another study in the United States involving the Comirnaty® vaccine in adolescents aged 12 to 15 years showed a favorable safety profile, produced a stronger immune response than in young adults, and was highly effective against COVID-19[27].

To date, evidence from studies on both vaccines has shown highly satisfactory immunogenicity post-vaccination and high effectiveness against SARS-CoV-2 infection and COVID-19. These findings highlight the benefits and contributions of vaccination in promoting children's health, with the advantages of vaccination in this population outweighing the associated risks[28].

Although this study has limitations, such as incomplete data for some participants and the fact that reports were collected weeks after vaccination—potentially introducing recall bias that could distort the results, especially for less severe or subjective adverse events—the findings demonstrated that ESAVI were of low prevalence and predominantly local, aligning with the related literature. This investigation is considered essential to provide more information to the community and healthcare professionals within the local healthcare network about vaccine adverse effects. It can support actions aimed at reducing vaccine hesitancy, addressing specific myths about COVID-19 vaccines, and combating misinformation. These efforts can lead to concrete strategies for health education, particularly since children are important vectors of outbreaks and transmission to patients more vulnerable to severe COVID-19.

For future studies, it would be beneficial to delve deeper into the topic to bring more elements into the discussion, specifically examining whether the proximity of an FHS service within its coverage area could be a potential strategy for reducing vaccine hesitancy. Furthermore, including qualitative perspectives, such as interviews with parents and guardians, could enrich the discussion by offering a broader view of vaccination perceptions, recognizing that decisions about vaccination are often influenced by cultural and emotional factors.

CONCLUSION

This study identified a small proportion of ESAVI in the pediatric population studied, with most adverse events being local and classified as mild, consistent with findings reported in the literature.

Confirming and promoting the safety of COVID-19 vaccines plays a crucial role in maintaining vaccination coverage rates and sustaining low illness rates.

It is within this context that the present study is situated. It is believed that disseminating these findings can support health education initiatives and efforts to combat misinformation and fake news related to COVID-19 vaccines.

CRediT author statement

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All authors have read and agreed to the published version of the manuscript.

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