



# ASBAI's position on vaccination of children aged 5 to 11 years against COVID-19 with the Comirnaty/Pfizer/BioNTech vaccine – 12/27/2021

*Posicionamento da ASBAI sobre a vacinação de crianças de 5 a 11 anos contra a COVID-19 com a vacina Comirnaty/ Pfizer/BioNTech – 27/12/2021*

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## ABSTRACT

The Brazilian Association of Allergy and Immunology (ASBAI) is totally in favor of immunization against COVID-19 in individuals between 5 and 11 years old, for the protection not only of this group, but also of their cohabitants. The vaccination of children, once its efficacy and safety has been demonstrated, is essential for controlling the circulation of the virus and protecting individuals whose vaccine response may not occur efficiently, such as the immunocompromised and the elderly. The immunization of people between the ages of 5 and 11 must be a fundamental public health strategy to control the pandemic that has been plaguing us since March 2020 with all its serious consequences for public health and the economy.

**Keywords:** COVID-19 vaccines, immunization, child.

In August 2020, the National Institute of Health for Women, Children and Adolescents Fernandes Figueira (IFF/Fiocruz), pointed out relevant issues to face the consequences of the COVID-19 pandemic on the health of children and adolescents in Brazil. Since the beginning of the pandemic, we have observed

## RESUMO

A Associação Brasileira de Alergia e Imunologia (ASBAI) se manifesta totalmente favorável à imunização contra a COVID-19 em indivíduos entre 5 e 11 anos, para a proteção não somente deste grupo, mas também de seus conviventes. A vacinação de crianças, demonstrada sua eficácia e segurança, é fundamental para o controle da circulação do vírus e proteção de indivíduos cuja resposta vacinal pode não ocorrer de modo eficiente, como os imunocomprometidos e idosos. A imunização de pessoas entre 5 e 11 anos deve ser uma estratégia de saúde pública fundamental para o controle da pandemia que nos assola desde março de 2020 com todas as suas graves consequências para a saúde pública e a economia.

**Descritores:** Vacinas contra COVID-19, imunização, criança.

fewer symptomatic infections and cases of severe illness and deaths from COVID-19 in children and adolescents, compared to other age groups.<sup>1</sup>

Cases by age reported to WHO from December 30 2019 to October 25 2021 showed that children under 5 years old are 2% (1,890,756) of global reported cases,

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and 0.1% (1,797) of reported global deaths. Older children and younger adolescents (age range 5 to 14 years) account for 7% (7,058,748) of reported global cases, and 0.1% (1,328) of reported global deaths. Deaths in all age groups under 25 years accounted for less than 0.5% of reported global deaths. In Brazil, almost half of Brazilian children and adolescents who died from COVID-19 in 2020 were under 2 years of age; one third of deaths up to 18 years of age occurred among children under 1 year of age and 9% among babies under 28 days old.<sup>2</sup>

Since April 2020, in several countries in Europe, North America and even in Brazil, cases of children and adolescents with a new clinical presentation associated with COVID-19, characterized by a late and severe inflammatory condition, called Pediatric Inflammatory Multisystem Syndrome temporally associated with COVID-19 (PIMS-TS) or Multisystem Inflammatory Syndrome in Children (MIS-C), adapted to Portuguese as Pediatric Multisystem Inflammatory Syndrome (SIM-P). The main findings of this syndrome include: persistent fever, gastrointestinal symptoms (abdominal pain, nausea, vomiting), bilateral non-purulent conjunctivitis, signs of dermatological/mucocutaneous inflammation, in addition to frequent cardiovascular involvement. The most severe cases present with shock requiring hemodynamic support and, sometimes they can progress to death. In Brazil, surveillance of SIM-P cases associated with COVID-19 was officially implemented on July 24, 2020, supported by the case definition criteria standardized by the World Health Organization (WHO) and, since then, 1,377 cases have been reported. in all federative units, with a total of 84 deaths, corresponding to 6.1% of cases.<sup>3</sup>

It is worth mentioning that the COVID-19 diagnosis, in addition to the risk of severe disease and SIM-P, is also associated with a greater risk of the occurrence of different other conditions, such as myocarditis, pericarditis, cardiac arrhythmias, demyelinating diseases, encephalitis, syndrome Guillain-Barré syndrome, facial paralysis, myasthenia gravis, cerebral hemorrhages, acute renal failure, deep vein thrombosis, acute myocardial infarction and pulmonary embolism. Children and adolescents may also have prolonged clinical manifestations known as “long-term COVID-19”, or post-COVID-19 syndrome,<sup>9</sup> post-acute sequelae of SARS-CoV-2 infection, but the frequency and characteristics of these diseases are still under investigation.<sup>4,5</sup>

Therefore, although the disease is milder in children when compared to adults and the elderly, it is important to emphasize that serious illness and deaths occur and that the presence of underlying diseases and comorbidities can contribute to the risk of different serious manifestations related to COVID-19.

Below we show that, although the number of cases is proportionally much smaller, these numbers are significant and would in no way be within an “acceptable” level.<sup>6</sup> Table 1 shows the number of deaths (1,207) in children under 18 years of age in 2020, with figures for different age groups.<sup>7</sup>

In Table 2, we can compare the available data from Brazil and the world, comparing the lethality of the disease in young people and adolescents, in addition to the available data on “severe” adverse reactions to the Comirnaty vaccine (released by ANVISA for children aged between 5 and 11 years) It becomes evident that the risk of dying from COVID in this age

**Table 1**

Number of cases and deaths from COVID-19 in Brazil

COVID by age group	Notified deaths in Brazil in 2020 (< 18 years old)	Case fatality rate in Brazil in 2020 (%) (< 18 years old)
> 5 and < 18 years	525	44.3%
< 5 years	71	5.9%
< 2 years	156	12.9%
< 1 years	335	27.8%
< 1 month	150	9.1%
Total	1,207	

group is between 10,000 and 20,000 times greater than the risk of having an adverse reaction to the vaccine.<sup>8-10</sup>

### Efficacy and immunogenicity

Consistent data on the efficacy, immunogenicity, safety and tolerability of Comirnaty vaccine in patients aged 5 to 11 years are derived from a phase 2 and 3 study, involving approximately 2,268 participants, carried out in the USA, Finland, Poland and Spain, using two doses (of 10 µg) of a product with a concentration of 50 µg/mL, with an interval of three weeks.<sup>11</sup>

Efficacy was assessed through protection against symptomatic infection and production of neutralizing antibodies. It was identified that the vaccine was 90.9% effective against symptomatic infections, and that the response of production of neutralizing antibodies was as satisfactory as that observed in individuals between 16 and 25 years of age.<sup>11</sup>

We emphasize that the efficacy of two doses of the vaccine for children under five years has not yet been demonstrated in studies carried out by Pfizer.<sup>12</sup>

### Safety

Among the 1,518 children vaccinated and the 750 who received placebo, no serious adverse events attributable to vaccination were observed. In addition, data from the US Centers for Disease Control describing adverse event reports in 5,126,642 vaccinated children (including 2,014,786 with the second dose) identified an incidence of 1.58 serious

adverse events per 100,000 vaccinated children, with the most frequent serious events being fever, vomiting, chest pain and elevation of C-reactive protein. Fourteen cases with mention of myocarditis were reported, with eight cases meeting the standardized case definition (6 with the second dose and 2 with the first dose), representing an incidence of 0.04 cases of myocarditis per 100,000 first doses, and 0.29 cases of myocarditis per 100,000 second doses.<sup>12</sup>

Severe allergic reactions such as anaphylaxis can occur after any vaccine, including COVID-19 vaccines. The estimated rate of anaphylaxis for all vaccines is 1 in 1,000,000 doses applied, which is considered a rare event.<sup>13</sup> Regarding vaccines against COVID-19, the observation of anaphylaxis in the first days of mass vaccination with the PFIZER vaccine in the US and UK, led to an estimated occurrence of 0.5 cases: 100,000 doses (or 0.0005%). However, with the increasing of immunization, the CDC has estimated the prevalence of anaphylaxis at 0.37 cases: 100,000 doses.<sup>14</sup>

To date, we have not identified case reports of anaphylaxis in patients aged 5 to 11 years who received the PFIZER vaccine in countries that have already started immunization in this age group.

### Benefits of vaccinating children

Although the percentage of serious illness among pediatric cases is small, if the number of infections in this age group increases, the number of children who will become seriously ill will proportionally increase. Data from studies in adolescents suggest that vaccination with BNT162b2 (Comirnaty/Pfizer) in children 5 to 11 years old is likely to prevent most

**Table 2**

COVID-19 fatality rate in Brazil and worldwide and serious adverse reactions from the Comirnaty vaccine

COVID-19 by age group	Case fatality rate in Brazil in 2020 (%)	Lethality rate in the world (%)	Serious reactions from the Comirnaty vaccine (%)
Severe conditions due to the disease			
< 29 years	1.5%	0.50%	
> 6 and < 19 years	0.3%		
Total	2.90%	1.15%	0.000158%

hospitalizations and deaths. While pediatric studies have not evaluated whether vaccines will reduce transmission of SARS-CoV-2, data from studies in vaccinated adults suggest that vaccinated children are likely to transmit smaller amounts of the virus for a shorter time. Thus, vaccinating children 5 to 11 years of age has the potential to reduce transmission of the virus between family members, schools, and communities.<sup>15,16</sup>

### International experience

The debate on the need and appropriateness of instituting an immunization program against COVID-19 in children took place around the world.<sup>11,18</sup>

The strategy to adopt the vaccination of children must consider the epidemiological scenario of each country and the individual and collective benefits of immunization. There are important issues to consider when vaccinating children and adolescents that go beyond the direct health benefits of the recipient. The proposal is that the high vaccine coverage can contribute to the reduction of SARS-CoV-2 transmission in this age group and, therefore, reduction of transmission to adults, the elderly and immunocompromised people. In addition, mitigating interruptions in children's educational and sports activities, maintaining safety and well-being are indisputable benefits to be considered.

Considering all these data, the following countries have already approved the immunization of children aged 5 to 11 years old against COVID-19 with the PFIZER vaccine:

- United States (FDA), approval on October 29, 2021<sup>19</sup>;
- Canada (HC), approval on November 19, 2021<sup>20</sup>;
- European Community (EMA), approval on November 25 2021<sup>21</sup>;
- Australia (TGA), approval on December 5 2021<sup>22</sup>;
- Singapore (HSA), approval on December 10 2021<sup>23</sup>;
- Switzerland (Swissmedic), December 10, 2021<sup>24</sup>;
- United Kingdom (MHRA), approved on December 22 2021<sup>25</sup>.

### Approval by ANVISA

After evaluating the benefits and risks, following analysis protocols used by several international

agencies with a similar function, ANVISA granted emergency authorization for the Pfizer-BioNTech COVID-19 vaccine for use in children aged 5 to 11 years on December 16 of 2021.<sup>26</sup>

### Conclusion

In view of the data presented, the Brazilian Association of Allergy and Immunology (ASBAI) is totally in support of immunization against COVID-19 of individuals between 5 and 11 years old, for the protection not only of this group, but also of their cohabitants. The vaccination of children, once its efficacy and safety has been demonstrated, is essential for controlling the circulation of the virus and protecting individuals whose vaccine response may not occur efficiently, such as those who are immunocompromised.

Therefore, ASBAI considers that a public consultation is not appropriate, since the indication of immunization of people between 5 and 11 years old should not be a matter of opinion, but a fundamental public health strategy for controlling the pandemic that plagues us since March 2020 with serious economic, social, emotional consequences and effects on individual and collective health.

### References

1. FIOCRUZ. COVID-19 e Saúde da Criança e do Adolescente [Internet]. Available at: [https://portaldeboaspraticas.iff.fiocruz.br/wp-content/uploads/2021/09/Covid\\_edu\\_v2.pdf](https://portaldeboaspraticas.iff.fiocruz.br/wp-content/uploads/2021/09/Covid_edu_v2.pdf). Access: 12/22/2021.
2. FIOCRUZ. Fiocruz analisa dados sobre mortes de crianças por Covid-19 [Internet]. Available at: <https://portal.fiocruz.br/noticia/fiocruz-analisa-dados-sobre-mortes-de-criancas-por-covid-19>. Access: 12/23/2021.
3. Brasil. Ministério da Saúde. Boletim Epidemiológico Especial – Doença pelo Novo Coronavírus – COVID-19. Semana epidemiológica 45: 7/11 a 13/11/2021. Available at: [https://www.gov.br/saude/pt-br/centrais-de-conteudo/publicacoes/boletins/boletins-epidemiologicos/covid-19/2021/boletim\\_epidemiologico\\_covid\\_89\\_23nov21\\_fig37nv.pdf](https://www.gov.br/saude/pt-br/centrais-de-conteudo/publicacoes/boletins/boletins-epidemiologicos/covid-19/2021/boletim_epidemiologico_covid_89_23nov21_fig37nv.pdf). Access: 12/23/2021.
4. World Health Organization - WHO. Coronavirus disease (COVID-19): Post COVID-19 condition [Internet]. Disponível em: [https://www.who.int/news-room/questions-and-answers/item/coronavirus-disease-\(covid-19\)-post-covid-19-condition](https://www.who.int/news-room/questions-and-answers/item/coronavirus-disease-(covid-19)-post-covid-19-condition).
5. Hageman JR. Long COVID-19 or Post-Acute Sequelae of SARS-CoV-2 Infection in Children, Adolescents, and Young Adults. *Pediatr Ann.* 2021 Jun;50(6):e232-e233.
6. Yahoo!notícias. Queiroga diz que mortes de crianças por covid “estão dentro de patamar aceitável” [Internet]. Available at: <https://br.yahoo.com/noticias/queiroga-diz-que-mortes-de-criancas-por-covid-estao-dentro-de-patamar-aceitavel-171221199.html>. Access: 12/23/2021.

7. World Health Organization - WHO [Internet]. Global surveillance for COVID-19 caused by human infection with COVID-19 virus. Available at: <https://www.who.int/publications/i/item/global-surveillance-for-covid-19-caused-by-human-infection-with-covid-19-virus-interim-guidance>. Access: 12/23/2021.
8. United States Food and Drug Administration - FDA. Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) [Internet]. Available at: <https://www.fda.gov/media/144413/download>.
9. United States Food and Drug Administration - FDA. Pfizer-BioNTech COVID-19 Vaccine. Available at: <https://www.fda.gov/emergency-preparednessandresponse/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine>.
10. Interim Report – Children 5 to <12 Years of Age: A Phase 1, Open-Label Dose-Finding Study to Evaluate Safety, Tolerability, and Immunogenicity and Phase 2/3 Placebo-Controlled, Observer-Blinded Safety, Tolerability, and Immunogenicity Study of a SARS-CoV-2 RNA Vaccine Candidate Against COVID-19 In Healthy Children and Young Adults Número de Protocolo: C4591007.
11. Su JR; Vaccine Safety Team; CDC COVID-19 Vaccine Task Force. Adverse events among children ages 5-11 years after COVID-19 vaccination: updates from v-safe and the Vaccine Adverse Event Reporting System (VAERS) – Dec 13, 2021 [Internet].
12. Pfizer.com [Internet]. Pfizer and Biontech provide update on ongoing studies of Covid-19 Vaccine. Available at: [www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-ongoing-studies-covid-19](http://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-ongoing-studies-covid-19). Access: 12/23/2021.
13. McNeil MM, Weintraub ES, Duffy J, Sukumaran L, Jacobsen SJ, Klein NP, et al. Risk of anaphylaxis after vaccination in children and adults. *J Allergy Clin Immunol*. 2016;137:868-78.
14. Woodworth KR, Moulia D, Collins JP, Hadler SC, Jones JM, Reddy SC, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5-11 Years - United States, November 2021. *MMWR Morb Mortal Wkly Rep*. 2021 Nov 12;70(45):1579-83. doi: 10.15585/mmwr.mm7045e1.
15. Olson SM, Newhams MM, Halasa NB, Price AM, Boom JA, Sahni LC, et al.; Overcoming COVID-19 Investigators. Effectiveness of Pfizer-BioNTech mRNA Vaccination Against COVID-19 Hospitalization Among Persons Aged 12-18 Years - United States, June-September 2021. *MMWR Morb Mortal Wkly Rep*. 2021 Oct 22;70(42):1483-8. doi: 10.15585/mmwr.mm7042e1.
16. Moss WJ, Gostin LO, Nuzzo JB. Pediatric COVID-19 Vaccines: What Parents, Practitioners, and Policy Makers Need to Know. *JAMA*. 2021 Dec 14;326(22):2257-8. doi: 10.1001/jama.2021.20734.
17. Zou X, Cao B. COVID-19 vaccines for children younger than 12 years: are we ready? *Lancet Infect Dis*. 2021 Dec;21(12):1614-5. doi: 10.1016/S1473-3099(21)00384-4.
18. Saxena S, Skirrow H, Wighton K. Should the UK vaccinate children and adolescents against covid-19? *BMJ*. 2021;374:n1866. doi: 10.1136/bmj.n1866.
19. United States Food and Drug Administration - FDA. FDA Authorizes Pfizer-BioNTech COVID-19 vaccine for emergency use in children 5 through 11 years of age [Internet]. Available at: <https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age>. Access: 12/18/2021.
20. Government of Canada - Health Canada. Vaccines for children: COVID-19 [Internet]. Available at: <https://www.canada.ca/en/public-health/services/vaccination-children/covid-19.html>. Access: 12/18/2021.
21. European Medicines Agency - EMA. Comirnaty COVID-19 vaccine: EMA recommends approval for children aged 5 to 11 [Internet]. Available at: <https://www.ema.europa.eu/en/news/comirnaty-covid-19-vaccine-ema-recommends-approval-children-aged-5-11>. Access: 12/22/2021.
22. Australian Government - Department of Health. TGA provisionally approves Pfizer COVID-19 vaccine for 5 to 11 years-olds [Internet]. Available at: <https://www.health.gov.au/news/tga-provisionally-approves-pfizer-covid-19-vaccine-for-5-to-11-year-olds>. Access: 12/22/2021.
23. Government of Singapore - Health Sciences Authority - HSA. HSA extends the use of comirnaty COVID-19 vaccine by Pfizer-BioNTech to children of ages 5 to 11 [Internet]. Available at: [https://www.hsa.gov.sg/announcements/press-release/pfizercomirnaty\\_children](https://www.hsa.gov.sg/announcements/press-release/pfizercomirnaty_children). Access: 12/22/2021.
24. Swissmedic - Swiss Agency for Therapeutic Products. Swissmedic approves COVID-19 vaccine from Pfizer/BioNTech for children aged 5 to 11 years [Internet]. Available at: <https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-19/covid-19-impfstoff-pfizer-biontec-kinder-5-11-jahren-genehmigt.html>. Acessado em 12/23/2021.
25. GOV.UK. UK regulator approves use of Pfizer/BioNTech vaccine in 5- to 11-year-olds [Internet]. Available at: <https://www.gov.uk/government/news/uk-regulator-approves-use-of-pfizerbiontech-vaccine-in-5-to-11-year-olds#:~:text=A%20new%20age%2Dappropriate%20formulation,it%20is%20safe%20and%20effective>. Access: 12/23/2021.
26. ANVISA – GGMed. Parecer Público de Avaliação do Medicamento – Aprovação [Internet]. Available at: [https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2021/copy\\_of\\_PPAM511anosPfizer2.pdf](https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2021/copy_of_PPAM511anosPfizer2.pdf). Access: 12/23/2021.

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