Very brief historical considerations about the process of vaccination of children and adolescents against COVID-19 in Brazil

Brevíssimas considerações históricas sobre o processo de vacinação de crianças e adolescentes contra a COVID-19 no Brasil

Breves consideraciones históricas sobre el proceso de vacunación de niños y adolescentes contra la COVID-19 en Brasil

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According to the World Health Organization (WHO), overweight and obesity can be defined as the abnormal or excessive accumulation of fat, which can be harmful to health.[1] These public health problems have acquired pandemic proportions, where approximately, 4 million people die each year as a result of or from complications related to.[1,2]

In this way and, according to estimates, obesity since 1975 around the world has almost tripled and, in 2016, more than 1.9 billion adults who were 18 years of age or older were overweight and of these, more than 650 million were obese.[2] Obesity has a high prevalence in Europe and the United States (USA), generating an incidence greater than 40%.[3,4]

Currently, obesity and Covid-19 are considered global pandemics, and for some researchers, obesity can strongly aggravate the impacts on people affected by this viral disease. Covid-19, who have a high body mass index (BMI), are at greater risk than those who are not serious.[3,4]

Obese patients who develop Covid-19 and who have a high BMI have a greater need for treatment in an Intensive Care Unit (ICU) and the use of mechanical ventilation (MV), as a form of support for those who are unable to develop respiratory incursions of spontaneously.[5,6] In addition to obesity, metabolic syndrome (MS) can cause damage to various organs of the body, stimulating their irregular functioning, when faced with a high degree of stress in which the patient finds himself, during the your treatment.[5,6,7]

Aiming to provide greater technical and scientific quality to the process in question, as well as to contribute to the strengthening of national public health, on December 3, 2021, ANVISA gathered a group of experts whose goal was to deal with vaccines to be available for application and immunization with children of the Brazilian nation.[4,5,6]

EDITORIAL

Interested in continuing the process initiated with ANVISA, PFIZER on 12/06/2021 responded to the proposed technical requirements, and on 12/10 /2021 An important meeting was held with representatives of various societies and medical associations with the requesting multinational pharmaceutical company.[4,5,6]

In a large and enlightening document, signed by three (03) important entities of health professionals, namely the Brazilian Society of Immunology (SBIm), the Brazilian Society of Infectious Diseases (SBI) and the Brazilian Society of Pediatrics (SBP), presented their position on the vaccination process with the immunobiological "Pfizer/BioNTech", to be developed among children aged between 5 and 11 years, presenting themselves as favorable to its accomplishment.[7,8] It is important to clarify although, in this document, based on what is published in the international scientific literature, the existence of researches that were currently in phase 1/2 and also in 3 were exposed, being the same implemented with children belonging to this age group.[7 ,8]

These researches have shown that, after the application of two (02) doses of the "Comirnaty" vaccine, in a presentation with 10 µg (that is, 1/3 of the presentation used in adolescents and adults), children who had between 5 -11 years, developed an antibody response, characterized as neutralizing at concentrations similar to those observed in adolescents and adults aged 16 to 25 years, thus verifying the fulfillment of the previously proposed criteria for demonstrating non-inferiority.[7,8] Another issue of fundamental importance presented in this document is related to the orientation that this immunobiological should not be administered to children who are immunocompromised, and the expansion of its use is also indicated, making it part of the National Plan of Operationalization of Vaccination against COVID-19 (PNO).[7,8]

In this context, ANVISA on 12/16/2021 authorized the availability of the vaccine produced by Pfizer for children aged 5 to 11 years, signaling to the MS its position on this national public health issue.[4,5,6] Another important A noteworthy fact, as a way of better understanding this historical process of making the vaccination process available for children aged between 5 and 11 years old in Brazil, was the "Public Consultation" organized and carried out by the MS, aiming to better clarify the population about this issue. important action in public health.[9]

It was organized and implemented by the Extraordinary Secretariat to Combat COVID-19 (SECOVID) of the MS, and it is open for access by the whole of society, during the period from 12/23/2021 to 01/02/2022.[9] The importance of the aforementioned "Public Consultation" was to better inform, in addition to knowing the existing doubts of the Brazilian population, about the process of vaccination of children aged between 5 and 11 years, in order to obtain greater subsidies to society for the best and better decision-making process.[9]

Aiming to further strengthen the process of immunization and vaccination of children in Brazil, the MS on 01/27/2022 included "Coronavac" in the vaccination campaign against COVID-19 for the age group from 6 to 17 years.[4,5,6,7] Another important action developed by the MS in the child vaccination process in Brazil was the organization of "Public Hearings", on their inclusion in this immunization campaign, which was held on 01/4/2019. 2022, being headquartered at the Pan American Health Organization (PAHO), in the city of Brasília, in the Federal District (DF).[10] These public hearings were

broadcast live and on national network by Empresa Brasil de Comunicação (EBC), and society could freely participate in this process, through a channel of questions made available, aiming at greater adherence, democratization and social participation in this important activity.[10]

Below, Table 1 presents a table containing the main differences between the adsorbed inactivated COVID-19 Coronavac vaccine from Instituto Butantan for pediatric and adult use and Comirnaty Wyeth/Pfizer for pediatric use only. In this table, the characteristics of the two vaccines are presented, such as the color of the bottle cap, the age range for which the vaccine is indicated, the dose, the preparation, the route of administration and the way of use, the vaccination schedule. , dose interval, storage conditions and contraindications.

Table 1 – Differences between the Coronavac and Pfizer vaccine against COVID-19:*,**,***

	COVID-19 adsorbed vaccine (inactivated) Coronavac Butantan - PEDIATRIC and ADULT USE	**Comirnaty vaccine Wyeth/Pfizer - PEDIATRIC USE**
Bottle cap	Gray	Orange
approved age group	6-17 years old	5-11 years old
Dose	0.5 mL per dose (600 SU)	0.2 mL per dose (10 mcg)
Preparation	* Shake the vial before use. * Do not shake	* **Thawing**: If the multidose vial is stored frozen, it must be thawed before use. Frozen vials should be transferred to an environment between 2°C and 8°C to thaw. Make sure the vials are completely thawed before using. * Unopened vials can be stored for up to 10 weeks at 2°C to 8°C. *Alternatively, individual frozen vials can be thawed for 30 minutes at temperatures up to 30°C for immediate use. * Allow the thawed vial to reach room temperature and gently invert it 10 times before dilution. **Do not shake**. *Prior to dilution, the thawed dispersion may contain white to off-white amorphous and opaque particles. *** Dilute**: Thawed vaccine should be diluted in its original vial with 1.3 mL of sodium chloride 9 mg/mL (0.9%) solution for injection using a 21 gauge or narrower needle and aseptic technique. *Equalize the vial pressure before removing the needle from the vial's rubber stopper, drawing 1.3 mL of air into the empty dilution syringe. * Gently invert the diluted dispersion 10 times. **Do not shake**. * The diluted vaccine should appear as a whitish dispersion, with no visible particles. Discard the diluted vaccine if particulate matter or discoloration is observed. * **After dilution**: Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to reach room temperature before use. * Using aseptic technique, clean the bottle stopper with a single-use antiseptic swab.

		* Withdraw 0.2 mL of Comirnaty® for children between 5 and 11 years of age. Low dead volume syringes and/or needles should be used to extract 10 doses from a single vial. The low dead volume syringe and needle combination must have a dead volume of not more than 35 microliters. * If standard syringes and needles are used, there may not be enough volume to extract ten doses from a single vial. * Each dose must contain 0.2 mL of vaccine. * If the amount of vaccine remaining in the vial cannot provide a full 0.2 mL dose, discard the vial and any excess volume.
Route of administration and method of use	* V intramuscularly, in the upper arm.	* Intramuscularly, in the upper arm.
vaccination schedule	* 2 separate doses of 0.5 mL each.	* 2 separate doses of 0.2 mL each.
Interval between doses	* 4 weeks.	* 21 days (3 weeks).
Storage conditions	* Under refrigeration (2 to 8ºC). * Do not freeze. * Protect from light. * Shelf-life: 12 months.	* Refrigerated (2°C and 8°C) for a single period of up to 10 weeks, not exceeding the original expiration date (EXP). *Alternatively, the vaccine can be stored in a freezer at -90°C to -60°C. The expiry date for storage between -90°C and -60°C is printed on the vial and cartridge after "EXP". * When stored frozen at -90°C to -60°C, the vaccine can also be thawed at 2°C to 8°C or at room temperature (up to 30°C). * Once thawed, the vaccine cannot be refrozen. * Protect from light.
* **Contraindications**	* Allergy to any of the components of this vaccine. * Patients with fever, acute illness and acute onset* of chronic illness. * Do not apply to immunocompromised children.	* It should not be administered to individuals with hypersensitivity to the active ingredient or to any of the excipients of the vaccine.

* **Source:** ANVISA, 2021.
** The authors are faithful to the source consulted.
*** As a result of several factors, changes may occur in terms of issues related to immunobiologicals presented here.

Still in relation to the vaccine, Pfizer/BioNTech, SBIm, SBP and SBI, were totally in favor of its approval, as they understand that its benefits in the population of children aged 5 to 11 years, with the immunobiological "Comirnaty", in the current context of the pandemic infectious disease of COVID-19 and its known variants, outweigh the possible risks associated with vaccination.[11] Another parameter exposed in favor of the use of this immunobiological in children in the age group in question was that, there was a demonstration of its effectiveness of approximately 90.7% (i.e., 95%CI, 67.7 to 98.3%) in relation to the prevention of COVID-19, for at least 7 days after the application of your second dose, and for a period of period of approximately 2-3 months.[11]

In this way, the emergence of serious adverse events, which had some type of association with vaccination, was not observed in the studies and research carried out, and a reactogenicity profile classified as favorable was also verified.[11] The requesting company in question also provided ANVISA with , a safety database, consisting of two (02) follow-up cohorts of children aged 5-11 years, each of which consists of approximately 1500 vaccinated children, making it possible to identify the possible adverse events.[11]

In the context of the research, it is important to highlight that the sample universe constituted can be classified as limited, that is, approximately two thousand five hundred (2,500) volunteers, who are being monitored, in addition to the follow-up time if constitute while relatively short, aiming to carry out the determination of safety over the long term.11 On the other hand, we have at present the quantity superior of five million (5,000,000) of doses already applied, of this vaccine in children who are in the age group 5-11 years with the United States of America (USA) and other nations, in relation to data classified as pharmacovigilance, not revealing the presence of adverse events of no concern.[1,2,3,11]

According to some researchers, a relationship between COVID-19 was found with regard to what is known today as Pediatric Multisystem Inflammatory Syndrome (SIM-P), and it was verified that it is of potential severity in this age group.[2,3,7, 8,11] SIM-P is constituted as a disease classified as rare, severe, in which children with COVID-19 more easily tend to develop an inflammatory process, which affects different organs of the body, conditions being more easily reported in these patients to cardiovascular disease, chronic lung disease (including asthma), immunosuppression, and obesity.[12]

Checking the issue of vaccination of children against COVID-19, it was possible to verify that, in Europe, at least twenty-three (23) nations have already approved or have already started the immunization/vaccination process in people belonging to the pediatric age group against the Covid-19, as is the case in Germany, Austria, Belgium, Croatia, Cyprus, Denmark, Slovakia, Spain, Estonia, Finland, France, Greece, Netherlands, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Portugal, United Kingdom United Kingdom, Czech Republic and Sweden.[1,2,3] In this way, it is understood the importance of the immunization and vaccination process aimed at children and adolescents, with regard to the fight and control of COVID-19 and its variants, as a way of enhancing national public health.

The need to carry out hygiene and prophylaxis care in the fight and prevention of COVID-19 and its variants must be remembered, such as the systematic hand washing process, the use of gel alcohol, the use of masks, in addition to respect regarding the social distancing of all members of society. In this sense, we are forced to agree with the words of the Greek philosopher Aristotle (384-322 BC), when he defended in his reflections and analyzes that "through information I acquire knowledge, and knowledge allows me to act, make decisions with freedom, while others do it out of fear."

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References

1. BBC News. Brasil. Vacinação de crianças: os 39 países que aprovaram imunização de menores de 12 anos contra covid. Disponível em: [https://www.bbc.com/portuguese/internacional-59151980]. Acesso em: 29 jan 2022.
2. Lima EJ da F, Faria SM de, Kfouri R de A. Reflexões sobre o uso das vacinas para COVID-19 em crianças e adolescentes. Epidemiologia e Serviços de Saúde. 2021;30(4):e2021957. doi: https://doi.org/10.1590/S1679-49742021000400028.
3. Oviedo N, Carvalho G. COVID-19 em Pediatria: O muito que ainda não se sabe!. Gaz Med. (Portugal).2020;7(2):192-198.
4. Brasil. Agência Nacional de Vigilância Sanitária. Assuntos. Portos, aeroportos e fronteiras. Coronavírus. Linha do tempo. Disponível em: [https://www.gov.br/anvisa/pt-br/assuntos/paf/coronavirus/linha-do-tempo]. Acesso em: 29 jan 2022.
5. Brasil. Agência Nacional de Vigilância Sanitária. COVID-19. Anvisa alerta para diferenças entre as vacinas para crianças. O objetivo é favorecer a vacinação segura das crianças contra Covid-19. Disponível em: [https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2022/anvisa-alerta-para-diferencas-entre-as-vacinas-para-criancas]. Acesso em: 28 jan 2022.
6. Brasil. Governo Federal. Ministério da Saúde. Assuntos. Notícias. 2022. Janeiro. Covid-19. Ministério da Saúde inclui Coronavac na vacinação de 6 a 17 anos. O intervalo entre a primeira e segunda dose será de 28 dias; imunizante não será aplicado em imunocomprometidos da faixa etária. Disponível em: [https://www.gov.br/saude/pt-br/assuntos/noticias/2022/janeiro/covid-19-ministerio-da-saude-inclui-coronavac-na-vacinacao-de-6-a-17-anos]. Acesso em: 29 jan 2022.
7. Sociedade Brasileira de Imunologia. Sociedade Brasileira de Infectologia. Sociedade Brasileira de Pediatria. Posicionamento SBIm/SBI/SBP sobre a vacinação de crianças de 5 a 11 anos contra a Covid-19 com a vacina Pfizer/BioNTech – 20/12/2021. Disponível em: [https://www.sbp.com.br/fileadmin/user_upload/carta-divulgacao-sbim-sbi-sbp-anvisa.pdf]. Acesso em: 19 jan 2022.
8. Brasil. Agência Nacional de Vigilância Sanitária. Informações Técnicas. Anvisa alerta os profissionais de saúde sobre as diferenças no processo de vacinação contra a covid-19 em crianças. Disponível em: [http://antigo.anvisa.gov.br/informacoestecnicas13?p_p_id=101_INSTANCE_WvKKx2fhdjM2&p_p_col_id=column1&p_p_col_pos=1&p_p_col_count=2&_101_INSTANCE_WvKKx2fhdjM2_groupId=33868&_101_INSTANCE_WvKKx2fhdjM2_urlTitle=anvisa-alerta-os-profissionais-de-saude-sobre-as-diferencas-no-processo-de-vacinacao-contra-a-covid-19-emcriancas&_101_INSTANCE_WvKKx2fhdjM2_struts_action=%2Fasset_publisher%2Fview_content&_101_INSTANCE_WvKKx2fhdjM2_assetEntryId=6385266&_101_INSTANCE_WvKKx2fhdjM2_type=contente]. Acesso em: 28 jan 2022.
9. Brasil. Governo Federal. Ministério da Saúde. Acesso à Informação. Participação Social. Consultas Públicas 2021. Consulta Pública para esclarecimentos quanto à vacinação de crianças de 5 a 11 anos. Aberta durante o período de 23 de dezembro de 2021 a 02 de janeiro de 2022. Secretaria Extraordinária de Enfrentamento à Covid-19 - SECOVID. Disponível em: [https://www.gov.br/saude/pt-br/acesso-a-informacao/participacao-

social/consultas-publicas/2021/consulta-publica-para-esclarecimentos-quanto-a-vacinacao-de-criancas-de-5-a-11-anos]. Acesso em: 29 jan 2022.
10. Brasil. Governo Federal. Ministério da Saúde. Acesso à Informação. Participação Social. Audiências Públicas 2022. Audiência Pública sobre a inclusão de crianças de 5 a 11 anos na campanha de vacinação contra COVID-19. Disponível em: [https://www.gov.br/saude/pt-br/acesso-a-informacao/participacao-social/audiencias-publicas/2022/audiencia-publica-sobre-a-inclusao-de-criancas-de-5-a-11-anos-na-campanha-de-vacinacao-contra-covid-19]. Acesso em: 19 jan 2022.
11. Sociedade Brasileira de Pediatria. Posicionamento SBIm/SBI/SBP sobre a vacinação de crianças de 5 a 11 anos contra a Covid-19 com a vacina Pfizer/BioNTech. Disponível em: [https://www.sbp.com.br/imprensa/detalhe/nid/posicionamento-sbimsbisbp-sobre-a-vacinacao-de-criancas-de-5-a-11-anos-contra-a-covid-19-com-a-vacina-pfizerbiontech/]. Acesso em: 29 jan 2022.
12. Organização Pan-Americana de Saúde. Início. OMS publica diretrizes sobre tratamento de crianças com síndrome inflamatória multissistêmica associada à COVID-19. Disponível em: [https://www.paho.org/pt/noticias/23-11-2021-oms-publica-diretrizes-sobre-tratamento-criancas-com-sindrome-inflamatoria]. Acesso em: 31 jan 2022.

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