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***Bioethical reflections
on Covid - 19 vaccines
in children aged 5-11 years***

18th February 2022



Presidenza del Consiglio dei Ministri

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Presidenza del Consiglio dei Ministri



**BIOETHICAL REFLECTIONS ON COVID-19 VACCINES IN
CHILDREN AGED 5-11 YEARS**

18 February 2022

Presentation

The ICB, after various documents on the pandemic, considered it important to intervene on the recently authorised paediatric vaccination for children 5-11 years of age. As part of an in-depth study of the medical aspects, relative to the epidemiological data on the development of the disease and the data on the safety and efficacy of vaccinations at international and national level for the 5–11-year-old-group, the ICB highlights the favourable relationship of benefits compared to risks.

In particular, the Committee stresses that, given the risks posed by the disease and the possible consequences, vaccinating children is primarily aimed at protecting their health, for direct benefits, considering both physical health (the prevention of serious illness and death from Covid-19) and well-being on the psycho-social level (the possibility of safely continuing schooling and socialisation).

In addition to the direct benefits there are indirect benefits that must be added, the protection of the members of the family with whom the children live, especially in the case of the elderly and vulnerable people who cannot be vaccinated as well as limiting the "circulation" of the virus and achieving community immunity more rapidly.

The Committee considers it important to explain to children, even using age-appropriate resources (including comics, cartoons, and television characters), the need for attentive and preventive health behaviours through vaccinations. Stressing the importance of setting up specific vaccination sites for children with attractive games and graphics, bearing in mind that interesting initiatives have also been taken in schools, which can be the preferred location to vaccinate children, given that school is the most familiar place after home to a child and this can *make the child feel safe, protected, and live this experience as if it were part of their routine*.

Finally, the Committee stresses the importance of informed consent in which the wishes of parents are expressed. Informed consent in paediatrics for young children, for vaccination choices, is left to the competent reflection of the physician regarding assessment of the child's health conditions and provision of complete and clear information to parents in the context of the therapeutic alliance. In this phase, paediatricians are therefore responsible for extensive work on information and persuasion, as well as monitoring the progress of vaccinations in 'real life', throughout the territory and in hospitals.

The Committee recommends that parents take decisions considering the best interests of the minor and the protection of their frail family members, as well as protection of the community; it urges institutional communication, scientific associations and societies and the paediatricians themselves to continue to provide clear and transparent information on the balance of the benefits and risks of the vaccine; it calls for the careful monitoring of *fake news*; it hopes for the organization of vaccination campaigns in schools.

The opinion was drafted by the President Prof. Lorenzo d'Avack and by Profs Mario De Curtis, Cinzia Caporale, Silvio Garattini and Laura Palazzani, with the contributions of Profs. Lucio Romano, Luca Savarino, Grazia Zuffa and Marianna Gensabella.

The document was unanimously approved by those present on February 18, 2022, by Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Bruno Dallapiccola, Antonio Da Re, Lorenzo d'Avack, Mario De Curtis, Riccardo Di Segni, Gianpaolo Donzelli, Mariapia Garavaglia, Marianna Gensabella, Laura Palazzini, Lucio Romano, Massimo Sargiacomo, Luca Savarino, Lucetta Scaraffia, Monica Toraldo di Francia and Grazia Zuffa.

Prof: Carlo Calafiore, Silvio Garattini, Assunta Morresi, absent from the plenary session, subsequently assented.

Prof. Pitch, absent at the time of the voting, subsequently abstained.

Despite their not having the right to vote assent was given by: Prof. Carlo Petrini, the delegate for the President of the National Institute of Health; Dr. Giovanni Maga, the delegate for the President of the National Research Council; Dr. Carla Bernasconi, the delegate for the President of the National Federation of the Orders of Italian Veterinarians; Dr. Maurizio Benato, the delegate for the President of the National Federation of MDs and Dentists Colleges

President of ICB

Prof. Lorenzo d'Avack

Premise

Vaccines have proven highly effective in containing the pandemic and protecting people's health, especially from severe illness. Given that research is underway to identify effective therapies against Covid-19 even in children, the vaccine remains for the moment the only weapon we have to prevent the serious outcomes of the disease. In this context, a bioethical reflection on the vaccination of young children becomes important.

Vaccines for children aged 5 to 11 years have recently been authorized in our country, while Covid 19 vaccines are currently being tested for children between 0 and 4 years of age. This document highlights in particular the importance of vaccination for the prevention of serious illness caused by SARS-CoV-2 infection in the population of children aged 5 to 11 years (approximately 3.6 million in Italy). In fact, this age group still shows low coverage rates in our country (up to 18 February, 36.4% of the population had received one dose and 26,4% had completed the vaccination cycle), if compared to those of adults and children aged 12-17 years.

The ICB, reiterates that a priority must continue to be followed in the vaccination plan according to age groups and particular frailties regardless of age - which also includes children - (as indicated in previous documents: in the motion *Vaccination urgency: bioethical aspects*, 2021; in the opinion *Covid-19 vaccines and adolescents*, 2021), it believes that Covid-19 vaccination in children can safeguard their health and help to limit the spread of the virus from a public health perspective. Almost all European countries have recommended vaccinating children aged 5 to 11 years¹.

1. Medical aspects

1.1. Clinical manifestations of SARS-CoV-2 infection in the paediatric population

The epidemiological situation has changed profoundly over the last two years. SARS-CoV-2 disease has now also become a paediatric disease². Scientific literature has confirmed that children can get sick, although they represent only 1-5% of diagnosed cases of infection.

Although most SARS-CoV-2 positive paediatric patients are asymptomatic, however, some infected with SARS-CoV-2 are at risk of developing severe illness and complications: respiratory failure, myocarditis, acute renal failure, coagulopathy and multiorgan failure.

In Italy, the latest report from the National Institute of Health has documented from the beginning of the SARS-CoV-2 pandemic to February 9, 2022, 1,352,176 cases in the age range under 12 years. Of these, 8,923 were hospitalized in ordinary wards, 167 in intensive care with 24 deaths³. In addition, in recent weeks, with the spread of the Omicron variant, even if compared to previous waves of the pandemic the clinical manifestations that require hospitalization are less severe and children are discharged more quickly, the number of infections is clearly on the rise.

¹ After the authorization of the European Medicines Agency (EMA), 23 of the 26 countries that participated in a survey recommended vaccination for children aged 5-11 years. Three countries have recommended it only to frail individuals. Germany, one of these three countries, has authorized it at the request of the parents. https://www.ecdc.europa.eu/sites/default/files/documents/Overview-of-COVID-19-vaccination-strategies-deployment-plans-in-the-EU-EEA-Jan-2022_1.pdf. The vaccine on children aged 5-11 has also been approved in the UK cf. J. WISE, Covid-19: Vaccine Will Be Offered to 5-11 Year Olds Throughout UK, *BMJ* 2022;376

² J.S. GERBER, P. A. OFFIT, COVID-19 Vaccines for Children. "Science", 2021 Nov 19; 374 (6570): 913.

³ COVID-19: sorveglianza, impatto delle infezioni ed efficacia vaccinale Report esteso ISS Aggiornamento nazionale 09/02/2022, data pubblicazione: 11/02/2022 https://www.epicentro.iss.it/coronavirus/bollettino/Bollettino-sorveglianza-integrata-COVID19_9-febbraio-2022.pdf.

Infected children are also at risk of developing the syndrome of multisystem inflammatory disease (MIS-C) and undesirable effects over time as defined with the term "Long Covid"⁴. The most recent paediatric research shows that there is an increasing percentage in the occurrence of this latter condition⁵. In addition, from a review of 35 articles on MIS-C involving a total of 783 children with a median age of 8.6 years, it appears that 68% of patients required hospitalization in an intensive care unit⁶.

1.2 Vaccination in children aged 5-11 years: safety and efficacy

It is well known that, in the past, many vaccines have been designed/adapted to children, who often respond better and with fewer side effects compared to adults.

The paediatric vaccine used today in the age group 5-11 years is the Pfizer-Biontech vaccine, which has the same active ingredient as that used for adults (mRNA vaccine), but in a different dosage, corresponding to only one third of the amount of active ingredient used in adults and children over 11 years of age.

In the initial clinical trial of the Pfizer-BioNTech COVID-19 vaccine in children 5 to 11 years of age, 1,517 children who received the vaccine and 751 who received placebo were followed up for a minimum of 2 months. The results indicated that the vaccine's effectiveness against symptomatic disease and its immunogenicity are similar to those reported in COVID-19 vaccine studies in adolescents and young adults. The vaccine, given when the delta variant was predominant, was shown to be effective in reducing the risk of symptomatic disease by approximately 91%⁷.

The safety of the Covid vaccine has been evaluated by regulatory agencies (FDA, the US agency, EMA, the European agency, and AIFA, the Italian agency) and the risk of serious adverse events was very rare. Local reactions were very common, mostly mild to moderate in severity and more common than in older children. Systemic events occurred more frequently after the second dose and were predominantly fatigue, headache, muscle pain, chills, fever and joint pain. Most systemic events were mild or moderate in severity. There were no cases of myocarditis or pericarditis or other serious adverse events. The relationship between benefits and risks was therefore also favourable for the 5-11 age group.

Following approval by the regulatory bodies, the vaccine has been widely used in many countries. In the USA, nearly 9 million doses were administered to children 5 to 11 years of age, in the period 3 November - 19 December 2021. There was a very low percentage (0.05%) of adverse events, which, among other things, mostly involved errors in the administration of the vaccine (incorrect preparation in 22% and incorrect dose in 16%). There were in all only 100 "severe" cases, with no permanent consequences. These also included 11 cases of myocarditis, all resolved or in the process of being resolved⁸. Current

⁴ D BUONSENSO. et al., Brief Report Preliminary Evidence on Long COVID in Children, in "Acta Paediatrica". 2021;110: 2208–2211.

⁵ Among the very young of today and future adults of tomorrow, there is a threat of Long Covid and its consequences that are currently little known. See for example LUDVIGSSON JF., *Case Report and Systematic Review suggest that children may experience similar long-term effects to adults after clinical COVID-19*, in "Acta Paediatrica". 2020; 00: 1–8.

⁶ T. RADIA et al., *Multi-system Inflammatory Syndrome in Children & Adolescents (MIS-C): A Systematic Review of Clinical Features and Presentation*, in "Paediatr Respir Rev.", 2021 Jun; 38: 51-57. 63% required the administration of vasoactive drugs, 28% respiratory assistance, 18% mechanical ventilation and 4% ECMO - extracorporeal membrane oxygenation.

⁷ E. B WALTER. et al., *Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age, January 6, 2022* "N Engl J Med" 2022; 386: 35-46; J.S. GERBER., *COVID-19 Vaccines for Children*, in "Science", 2021 Nov 19; 374 (6570): 913

⁸ The analysis was conducted by the CDCs (Centres for disease control and prevention) on the reports received by the Vaers (Vaccine Adverse Event Reporting System) surveillance system in relation to over 8.7 million vaccinations administered from 3 November to 19 December 2021.

scientific research in the paediatric field seems to be able to confirm that vaccination is well tolerated and is strongly recommended in children 5 to 11 years of age and should also be carried out in children who have previously had SARS-CoV-2 infection or disease. Children with chronic illnesses and frail children are particularly advantaged by this vaccination because they are the ones who are most at risk from the disease in terms of complications, risk of hospitalization and long-term consequences. Similarly, the data just published by AIFA in the *Annual Report on the safety of COVID 19 vaccines* confirm that the vaccine is safe for use, also in the paediatric age group⁹.

The European Academy of Paediatrics (EAP) and the European Confederation of Primary Care Paediatricians (ECPCP) have published a joint request for children to be vaccinated¹⁰.

In Italy, the request to promote, as much as possible, the vaccination of children 5 to 11 years of age with a reduced dose was made by the Ministry of Health, the President of the Superior Health Council, and the Technical Scientific Committee for Pandemic Management (CTS). The same recommendation also comes from various paediatric societies, including the Italian Society of Paediatrics (SIP), the Italian Society of Neonatology (SIN) and the Italian Society of Gynaecology and Obstetrics (SIGO). The SIP has pointed out that the proportion of unvaccinated children continues to be a reservoir of the virus and is therefore susceptible to relapses in schools and personal and family infections¹¹.

2. Bioethical reflections

2.1 The priority of children's health: direct and indirect benefits

Some doubts and perplexities have been raised with reference to the issue of vaccinating children: it is argued, for example, that the benefit-risk ratio for the individual child does not justify administration of the vaccine; or it is claimed that this could have some basis, but only as a public health protective measure. These are partial opinions, not supported by adequate scientific evidence, which are also problematic on the bioethical level. First of all, the most important purpose of vaccinating children is to protect their health: this is the priority that must be considered and sought in the best interests of the child. There is also a further purpose, justified on the grounds of public health: paediatric vaccination would also make it possible to limit the circulation of the virus, which is currently negatively affected by non-completion of adult vaccination.

From a bioethical point of view, the balance of benefits and risks must be measured primarily on the *direct* benefits and risks considered with respect to children's health.

In the current epidemiological and clinical picture, as reported above, it emerges that the assessment of direct benefits and risks is certainly favourable for children.

The risks for children of contracting the infection (and the negative consequences it can have in some cases, even neurological, cognitive or heart damage) are growing and the risks and consequences of vaccinations are very low. The risks of the vaccines - as

COVID-19 vaccine safety updates: Primary series in children and adolescents ages 5–11 and 12–15 years, and booster doses in adolescents ages 16–24 years, Advisory Committee on Immunization Practices January 5, 2022

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/02-COVID-Su_508.pdf. Last accessed: January 12, 2022; *COVID-19 Vaccines in Children and Adolescents*, *Committee on Infectious Diseases*, "Pediatrics", Volume 149, number 1, January 2022: e2021054332

⁹ Rapporto annuale sulla sicurezza dei vaccini anti-COVID-19 27/12/2020 - 26/12/2021

https://www.aifa.gov.it/documents/20142/1315190/Rapporto_annuale_su_sicurezza_vaccini%20anti-COVID-19.pdf.

¹⁰ <https://www.frontiersin.org/articles/10.3389/fped.2021.721257/full>.

¹¹ <https://sip.it/wp-content/uploads/2021/06/SIP-Vaccino-Covid-2-1.pdf>.

evidenced by the most accredited scientific literature - are clearly much lower than the risks of contracting the disease in a severe form with their relative consequences.

Therefore, the importance of vaccination becomes evident *primarily* given the *direct benefits for the children* themselves with regard to protection of their health.

The **direct benefits** to be considered include the following:

- Physical health benefits: prevention of severe illness, hospitalization, ICU admission and death; disease prevention and long-term negative consequences of the disease.

- Psycho-social benefits: not to be disregarded is the psycho-social damage that Covid-19 has had both on younger children, who have been affected by the moods and concerns of parents about the pandemic, as well as on older children, who as they get older, have had the opportunity to become fully aware of the pandemic, and its relative risks, but at the same time of the possibility of reducing these risks through vaccination. The vaccine therefore is beneficial for them as it constitutes an important tool for returning to a life with fewer restrictions on freedom, guaranteeing schooling and sociality, which are important elements for their education and personal growth, as well as stemming fears and stress and manifestations of regressive symptomology¹². The Italian Committee for Bioethics in its opinion *Covid-19 and children: from birth to school age* (2020) stressed the specific impact of the pandemic on the global health of young children and the main underlying bioethical aspects, with specific attention to the very first correlations existing in the maternal-foetus-neonatal unit, up to the early stages of development, such as infancy and childhood. In the context of pregnancy, childbirth and neonatal life, precaution and responsibility are specified by the ICB as essential bioethical principles in the "care relationship" in children in need of specific protection.

- Also, to be considered among the primary direct benefits for children is that, after Covid-19 vaccination, the routine immunization schedule can be resumed (unfortunately there are many data on the suspension of non-Covid-19 vaccinations¹³) as well as ensuring, more easily, any suspended paediatric care¹⁴, due both to the overloading of health facilities and the fear of parents that attending such health facilities could lead to getting infected with the virus.

In addition to the direct benefits there are **indirect benefits** that must be added, those regarding the protection of the community, with particular *focus* on family members and the people with whom the child comes into contact, as mentioned below.

- Reducing the risk of transmission among the child's family and household members, especially in the case of the elderly and vulnerable people who cannot be vaccinated.

- Contributing to slowing down the spread of the epidemic and limiting its impact because it reduces, but does not eliminate, the likelihood that the vaccinated child will infect adults or, specifically, the elderly with whom the child comes into contact (a situation of particular relevance in Italy where, given the configuration of the family unit, children frequently have close contact with elderly relatives)

- Attending school more regularly, allowing the resumption of the normal rhythm of family life.

- Limiting the "circulation" of the virus, helps to attain community immunity more rapidly.

¹² A study in this regard was conducted by the Giannini Gaslini Institute and the University of Genoa. See also ICB, *Covid-19 and Children: from Birth to School Age*, 23 October 2020

¹³ <https://www.epicentro.iss.it/vaccini/covid-19-riduzione-attivita-vaccinale>

¹⁴ <https://sip.it/2020/11/26/covid-gli-effetti-indiretti-sui-bambini-salta-prevenzione-aumentano-diseguaglianze-e-disagi-psicologici-a-rischio-i-diritti/>.

2.2 Allocation of resources

The ethical problem raised by the WHO of the allocation of vaccine resources arises especially with reference to low-income countries¹⁵, is it right to allocate vaccines to children, a group which has little exposure to serious or lethal forms of SARS-CoV-2 infection, to the detriment of more exposed groups?

This question would have reason to be if, as in the past, vaccination resources were genuinely scarce, which it is not the case. In addition, the number of vaccines necessary to immunize children and adolescents is a marginal quantity compared to the amount of supplies needed to immunize low-income countries. The problem of supplying low-income countries can be solved if there is a solidaristic intention of the higher-income countries as well as a commitment of the pharmaceutical industry itself towards them¹⁶. The WHO has spoken out against bilateral agreements between vaccine-producing states and has proposed the mechanism of Covax (The People's Vaccine)¹⁷, which is certainly perfectible but in principle entirely justified. Therefore, discussions for these reasons regarding access to vaccines for children seem unjustified.

2.3. Informed parental consent

Another aspect that is being discussed in this period is the decision to vaccinate a child requiring the consent of both parents. Given the number of parents who are uncertain whether to make their children run even the slightest risk with vaccination, it is possible to hypothesize that the tension of divergent viewpoints between parents, disputes have already been brought before the courts with reference to adolescent children, will also regard children under 12 years of age.

Regarding the vaccination of adolescents in some cases, divergent viewpoints have emerged between the adolescents themselves and their parents. The judgments¹⁸, in line with the general case law on vaccinations, favoured administering the vaccine, because it protects personal health, and therefore the interest of the minor, and in addition community health that is based on the principle of solidarity. The judges' decisions confirm what was written by the Italian Committee for Bioethics in the opinion *Covid-19 vaccines and*

¹⁵ WHO, *Interim Statement on Covid-19 Vaccination for Children and Adolescents*, 24 November 2021: "However, the benefits of vaccinating children to reduce the risk of severe disease and death are much less than those associated with vaccinating older adults. Countries with few or no vaccine supply constraints should consider the issues of global equity when making policy decisions about vaccinating children and adolescents. Any guidance on vaccine use prioritization, including booster dose policy, cannot ignore the current, on-going profound inequities in global vaccine access. While higher-income countries expand their vaccination programmes to adolescents, children, and, in some countries, booster doses to a large proportion of their populations, many lower-income countries still lack sufficient vaccine supply to offer a primary vaccination series to their highest priority-use groups, including older adults and health care workers who comprise only a small proportion of their populations" <https://www.who.int/news/item/24-11-2021-interim-statement-on-covid-19-vaccination-for-children-and-adolescents>.

¹⁶ S PAGLIANI, Covid-19, vaccinazione pediatrica sotto la lente, <https://www.scienza.inrete.it/articolo>, 2021-09-15.

¹⁷ The COVAX partnership, of which Gavi, the Vaccine Alliance, the World Health Organization (WHO), UNICEF and the Coalition for Epidemic Preparedness Innovations (CEPI) are part, aims to share competencies, experiences and set up a unique vaccine distribution network. The aim is to counter vaccine nationalism and guarantee everyone a vaccine against COVID-19. In: <https://unric.org/it/che-cose-covax/>

¹⁸ Court of Parma, judgment of 11 October 2021; Court of Monza, decree 22.07.21; Court of Arezzo, order 09.09.21. Moreover, the jurisprudence regarding vaccine health treatments is consistent in the belief that where there is a concrete danger to the life or health of the minor (due to the severity and spread of the virus) and there are scientific data that the health treatment is effective, the judge may suspend the capacity of the opposing parent for the time being (see among others Court of Milan 17/10/2018; Court of Appeal of Naples 30/08/2017; Court of Rome 16/02/2017)

adolescents (2021) which gave importance to these cases of vaccination disagreement between parents and minor children, supporting the priority consideration of the health needs of adolescents for their own good and that of the community¹⁹.

Informed consent in paediatrics for young children has an ethical importance which can be considered unique. In fact, to speak of obtaining informed consent in paediatrics, by the doctor who will have to vaccinate the child does not correspond to what is generally required in the medicine of the mature minor or adult.

While bearing in mind that the doctors' dialogue with minors 5-11 years of age cannot take place in the same form as with adolescents, it is still considered necessary for children below 12 years of age to have, within the limits of their capacity for discernment, the opportunity to be heard by doctors.

The wishes and decision of the parents, if in agreement, will always prevail. However, in the event that the doctor, to the best of his/her knowledge and belief, believes that the child's medical history, being medically particularly fragile, calls for particularly urgent vaccination albeit against the parents' wishes, the dispute could be left to the decision of the tutelary judge.

For these aspects, the consultation - not mandatory - of an independent ethics committee for clinical practice could prove to be truly important, because alongside the parents or the guardian, it would carry out an additional function of protecting the child's health and it could facilitate dialogue between the parties.

Therefore, the rule that adolescents should be listened to and express their preferences in relation to their capacity for discernment is, in the paediatric age group, difficult to achieve until the development of the child allows for understanding, voluntariness, participation in decision making. Informed consent in paediatric practice for young children, regarding vaccination choices, is left to the competent reflection of the doctor, to evaluate the health conditions of the child, and to the understanding and discussion of these reasons by the parents in the context of the therapeutic alliance. In this phase, paediatricians are therefore responsible for extensive work on information and persuasion, as well as monitoring the progress of vaccinations in '*real life*', throughout the territory and in hospitals.

There are many countries which, while currently excluding mandatory vaccination for minors, entrust paediatricians with the task of correctly communicating the benefits of *routine* vaccines and Covid-19 vaccines. This will be a fundamental element for the success of the vaccination campaign for very young children. This work of providing information appears to be a fundamental weapon in the fight against *fake news*²⁰ which must be conducted both in the context of public communication with the contribution of traditional *media*, *social media*, and with information campaigns in schools. In this context, ethical space could play a significant role, as expressed in the recent opinion *Vulnerability and care in community welfare. The role of the ethical space for a public debate* (2021).

In this phase of the pandemic, mutual protection between parents and children cannot prescind the need for the former to be vaccinated in any case, to reduce the risk of contagion and prevent reported adverse events. From current data, 69% of children up to 4 years of

¹⁹ Should the mature minor's wishes to be vaccinated conflict with those of the parents, the Committee believes that the adolescent needs to be heard by medical personnel with paediatric expertise and that the minor's wishes should prevail, as they coincide - according to current scientific indications and with the exception of specific health conditions for which vaccination is not recommend - with the best interests of his/her psycho-physical health and public health.

²⁰ Fake News. Ministero della Salute.

<https://www.salute.gov.it/portale/nuovocoronavirus/archivioFakeNewsNuovoCoronavirus.jsp?lingua=italiano&area=nuovocoronavirus&fakeNewsArchivio.page=4>; Nic Fleming. Fighting coronavirus misinformation *Nature*, Vol 583: 2 July 2020 <https://media.nature.com/original/magazine-assets/d41586-020-01834-3/d41586-020-01834-3.pdf>.

age admitted to intensive care units have unvaccinated parents²¹. Perhaps the protection of children's health could be a further reason to encourage vaccine-hesitant parents to get vaccinated. Certainly, it emerges strongly that the responsibility of those who do not get vaccinated also falls negatively on their children, exposing them to higher risks. It is assumed that parents who have accepted to be vaccinated themselves will also accept vaccination for their children, based on established scientific evidence and data provided by paediatricians. But in the case of unvaccinated parents, it will be important to urge them to make a choice that does not necessarily have to be aligned with their own personal convictions, because it is not a choice for them, but a choice for the children, therefore it is rooted in the parental responsibility to take care of the minor.

2.4. How to vaccinate

It is important to explain to children, even using age-appropriate resources (including comics, cartoons, and television characters), the need for attentive and preventive health behaviours through vaccinations, the use of masks and physical distancing, where possible. The initiative that has led to the setting up of specific vaccination sites for children, with attractive games and graphics, is certainly commendable.

Interesting initiatives have also been taken in schools²², which, in addition to being the place where the importance of vaccinations can be highlighted, constitute the preferred location to vaccinate children. School is the most familiar place after home to a child and this can *make the child feel safe, protected, and live this experience as if it were part of the routine*. The same vaccine-hesitant parents could be persuaded to have their child vaccinated after seeing that classmates, after being vaccinated, did not have any problems and in any case, they can compare themselves to other parents.

Recommendations

The Committee:

1= given that the ICB considers vaccination for 5-11-year-old children to be essential, it deems it important to underline, in support of parents called on to make decisions for their children, that the goal of vaccination consists in respecting the interests of minors to safeguard their health; it also reiterates the importance of the additional purpose of the protection of frail family members who are at risk and cannot be vaccinated and live together or have frequent contact with the minors themselves, as well as the general protection of public health;

2= urges institutional communication at national and regional level, associations and scientific societies in the paediatric field and paediatricians to strengthen their commitment to provide clear and transparent information to parents on the balance of the benefits and risks of the vaccine, undoubtedly recommending its administration, and highlighting primarily the protection of health of the child who receives it;

3= considers it particularly important to disclose, by means of constantly updated communication, pharmacovigilance data relating to the age group 5-11 years;

²¹ These data are from the Association of Italian Paediatric Hospitals (AOPI), which has activated a weekly monitoring system for Covid patients - children and adolescents - hospitalized in both the medical area and critical area.

²² The Puglia Region, in agreement with the Department of Health Policies, the Covid Control Room and the provincial school offices, has decided that vaccines for children from 5 to 11 years of age can be administered directly in schools, in the presence of their parents. *The health system and civil protection system will contribute to the organization of vaccination sessions in the institutions that will be identified in agreement together with the school offices. This organization will also make use of the support of freely chosen paediatricians and the prevention departments of the ASL.*

4= hopes for a strengthening of careful monitoring of *fake news*, which has always been circulating, on the issue of vaccines for children;

5= considers it appropriate to involve television media (through cartoons or games) as well as *social networks* in programs and initiatives to make known, also to children, the benefits of vaccines and the data relating to the impact of SARS-CoV-2 on children, mobilizing authoritative experts capable of communicating in a way appropriate to age and *target* audience; it is particularly important for similar programs and initiatives to be implemented within schools;

6= hopes that vaccination campaigns will be organized in schools to increase the number of vaccinated children.



Presidenza del Consiglio dei Ministri

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