

Presidenza del Consiglio dei Ministri



ANTI-COVID-19 VACCINES AND ADOLESCENTS

29 July 2021

Presentation

The Italian Committee for Bioethics (ICB), while reiterating that priority in the vaccination plan must continue to be given according to age group and particular fragilities, believes that the anti-Covid19 vaccination of adolescents can safeguard their health and help contain the spread of the virus from a public health perspective, particularly in view of their returning to school.

The Committee stresses that the anti-Covid 19 vaccination of adolescents requires new and different attention and age-appropriate forms of communication, on the part of Institutions and physicians. It highlights the importance of the information addressed to parents, which must be tailored according to the age of the adolescent, paying particular attention to the balance of risks and benefits, different from those of adults and the elderly. The information must also be given to adolescents, hopefully by means of an information sheet before vaccination, in order for them to be able to participate in an informed manner. This information must be accompanied by awareness-raising actions and the educating of parents and teachers, with the activation of specific initiatives in schools. It is important to listen to adolescents and to value their right to express their choice, in relation to their capacity for discernment.

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 with the best interests of his/her psycho-physical health and of public health. For adolescents with diseases and who fall into the categories identified by the Ministry of Health (in an updated list), for which vaccination is recommended, the duty of the parents (legal representatives) to guarantee the best interests of their child becomes even more pressing; it is important to have recourse to the clinical ethics committee or to an ethical space and, as *extrema ratio*, to the tutelary judge.

In the case of adolescents who refuse to be anti-Covid 19 vaccinated despite parental consent, the Committee considers it important and desirable for these adolescents to be informed that vaccination is in the interest of their own health, the health of the people around them and of public health. Lastly, it seems, however, right, from a bioethical point of view, not to proceed with compulsory vaccination in the absence of a law expressly requiring it, but to put in place appropriate measures to safeguard public health.

The ICB deems it appropriate in the event of conflict between the parties, that their wishes should be certified in order to explain with the utmost clarity their respective positions, also with a view to better identify the differences in an attempt to reconcile them.

From a bioethical point of view, although vaccination has not been made compulsory, in the absence of a law expressly requiring it, the moral and civil duty to get vaccinated remains, as authoritatively emphasized by President Mattarella.

The opinion was drafted by the President Lorenzo d'Avack, by the Deputy Vice President Vicar Laura Palazzani, with a working group made up of Profs Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Antonio Da Re, Mario De Curtis, Paola Di Giulio, Gianpaolo Donzelli, Mariapia Garavaglia, Silvio Garattini,

Assunta Morresi, Lucio Romano, Luca Savarino and with the wide participation of all the members of the Committee.

The opinion was unanimously approved by those present: Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Bruno Dallapiccola, Antonio Da Re, Lorenzo d'Avack, Mario De Curtis, Gianpaolo Donzelli, Silvio Garattini, Mariapia Garavaglia, Marianna Gensabella, Assunta Morresi, Laura Palazzani, Tamar Pitch, Lucio Romano, Massimo Sargiacomo, Monica Toraldo di Francia.

Profs: Carlo Caltagirone, Maurizio Mori, Riccardo di Segni, Luca Savarino, Grazia Zuffa, absent from the plenary session, subsequently assented.

Despite their not having the right to vote assent was given by: Dr. Carla Bernasconi, the delegate for the President of the National Federation of the Orders of Italian Veterinarians; Dr. Amedeo Cesta, the delegate for the President of the National Research Council; Prof. Carlo Petrini, the delegate for the President of the National Institute of Health.

Dr. Maurizio Benato, the delegate for the President of the National Federation of MDs and Dentists Colleges, absent from the plenary session, subsequently assented.

Prof. Lorenzo d'Avack
President of the ICB

The ICB intends to highlight how recent circumstances have led to the extend anti-Covid 19 vaccination to adolescents included in the age group 12-17 years (so-called mature minors). And although the ICB reiterates, in line with its previous Opinions and Motions (*Vaccines and Covid-19: ethical aspects on research, cost, and distribution*, 2020 and *Vaccination urgency: bioethical aspects*, 2021), that priority in the vaccination plan must continue to be given according to age groups, and, irrespective of age, according to particular fragilities involving important risk factors,¹ it acknowledges that the anti-Covid 19 vaccination of adolescents can safeguard them from possible damage deriving from the infection (despite not having contracted serious forms of the disease) and help to contain the expansion of the virus from a public health perspective².

Moreover, as is well known, adolescents also get infected and in turn infect others. The first advantage of vaccination consists in: helping to slow down the spread of the pandemic and therefore to improve the health situation of the population. Secondly, the vaccine is an important tool for protecting adolescents, considering the direct, indirect and psycho-social risks involved. Thirdly, vaccinating adolescents can provide greater protection for both their families and the communities in which they participate. Furthermore, by means of the *green pass*, vaccinated adolescents can have greater freedom of movement and assembly (for example, travelling, going to cinemas, concerts, theatres, attending gyms, etc.).

Based on the most recent epidemiological and scientific studies, the anti-Covid 19 vaccine has also been shown to be safe and effective for adolescents³, although there have been rare short-term adverse events, which resolve quickly⁴.

Furthermore, a safe return to school is one of the major reasons which further justify the anti-Covid vaccination for adolescents, also in order to protect those who cannot be vaccinated due to their fragility.

The ICB underlines that, compared to adults, the anti-Covid 19 vaccination of adolescents requires new and different attention and age-appropriate forms of communication on the part of institutions and physicians, differentiating between the communication addressed to adults and communication addressed to mature minors, taking into account those who are already close to the age of majority and are able to give their consent or dissent to vaccination with greater awareness. It is also necessary that the choice of vaccine to be administered should be made on the basis of adequate scientific, epidemiological and clinical

¹ In addition to the professional categories outlined in the vaccination plans.

² The health authorities of countries that have already vaccinated a large part of the population, even among the very young, such as Israel and the United States, have verified that the protection of young people, and therefore also of adolescents, is of primary importance as part of the strategy of containment of the virus. D. GLIKMAN, M. STEIN, E.S. SHINWELL, *Vaccinating Children and Adolescents against Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) - the Israeli Experience*, "Acta Paediatrica", 2021 Jun 22.

³ R.W. FRENCK et al., *Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescent*. May 27; NEJMO.

⁴ https://www.epicentro.iss.it/coronavirus/bollettino/Bollettino-sorveglianza-integrata-COVID19_9-giugno-2021.pdf- M. MARSHALL, et al., Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID-19 Vaccination, <https://pediatrics.aappublications.org/content/pediatrics/early/2021/06/04/peds.2021-052478.full.pdf>. The forms of myocarditis are close to those expected, they are mild and can be resolved quickly.

reasoning paying particular attention to specific conditions of the developmental age, from the point of view of the benefit/risk ratio. The importance of the information for parents is also highlighted, which needs to be highly comprehensive, updated and tailored according to the age of the minor.

The information, given in an environment suitable for the reception of these adolescents, is to be imparted by medical personnel with specific paediatric expertise and communication skills, in a proportionate manner in accordance with their age and level of maturity, understood as cognitive and emotional development, on the physical, psychological and social level⁵. The communication methods specified by the ministerial recommendations on the implementation of the anti-Covid19 vaccination strategy in adolescents will be followed. There must be a simplification of the medical technical language and a clarification of the fundamental elements, so that even the adolescent can participate and be involved with parents in a conscious way in the choice of vaccination⁶.

The ICB emphasises how information to parents should highlight the following elements regarding the risks and benefits.

a) Risks and benefits must take into account the adolescent's clinical condition. The extreme importance of providing medical history before vaccination of the child should also be clarified to parents, urging them to carefully consider the adolescent's condition, also taking into account the psychological aspects of emotionality or anxiety, given the particular vulnerability of this age group.

b) In general, as already highlighted, the direct benefits far outweigh the possible risks, considering the hypothetical adverse effects following vaccination in the face of the serious consequences induced by the infection and the Covid-19 disease⁷. Any new variants, sensitive to current vaccines, which could even impact young people, must also be taken into consideration.

c) The indirect benefits relate to controlling the transmission of the virus, in particular to the limitation of the development of new variants, even more aggressive than the current ones, and to individual responsibility and solidarity in contributing to the health of the community. Community immunity can in fact be achieved all the more easily the more widespread vaccination is within the susceptible population.

⁵ Age and maturity are essential dimensions to verify the ability of minors to participate in decision-making: these are objective and subjective factors that must be verified on a case-by-case basis to identify the minor's ability to understand and decide.

⁶ Even Law no. 219 of 2017 (art. 3) states that the minor must "receive information on the choices relating to their health in a manner consistent with their abilities in order to be able to express their will".

⁷ *Statement Following CDC ACIP Meeting from Nation's Leading Doctors, Nurses and Public Health Leaders on Benefits of Vaccination*, <https://services.aap.org/en/news-room/news-releases/aap/2021/statement-following-cdc-acip-meeting-from-nations-leading-doctors-nurses-and-public-health-leaders/>, realized 23 June 2021: "We strongly encourage everyone age 12 and older who are eligible to receive the vaccine under Emergency Use Authorization to get vaccinated, as the benefits of vaccination far outweigh any harm"; "Especially with the troubling Delta variant increasingly circulating, and more readily impacting younger people, the risks of being unvaccinated are far greater than any rare side effects from the vaccines". Position of the Italian Society of Paediatrics on the Covid vaccination strategy for the paediatric and adolescent age group (21 June 2021) <https://sip.it/wp-content/uploads/2021/06/SIP-Vaccino-Covid-2-1.pdf>.

The ICB also emphasises the importance of adequate information for adolescents.

a) It is desirable for the Ministry of Health to make a clear, simple and effective form easily available, especially *online*, including the information sheet that must be given to the adolescent at the vaccination site, with specific information, possibly activating a Question-and-Answer service and also indicating to young people professional figures and accredited reference sites.

b) It is also essential to explain to adolescents the need to find a correct balance between individual freedom and the enjoyment of public places; the importance of safety protocols should be highlighted, respecting the indications of effective measures to protect from the risk of contagion even those who have not been able to be vaccinated and those already vaccinated but who lack sufficient immune responses even in the face of variants of the virus. Certainly, more worrying are the mass events and gatherings of many people in open places or, worse still, in closed places in the absence of any rules.

c) Information to adolescents about Covid-19 and vaccination must be accompanied by awareness-raising actions and the education of parents and teachers, with the welcome activation of specific initiatives in schools, which highlight the importance of vaccination not only for the protection of individuals but also of solidarity in protecting the community.

The legal solution embodied in Law n ° 219/2017 the 'participation' and 'involvement' in choices, proportionately to age and maturity, in line with international documents (e.g., the Oviedo Convention), is certainly also a path of ethical relevance, which stimulates case-by-case evaluation and to dialogue with the adolescent.

Certainly, the adolescent's point of view must be listened to and considered: listening to the minor is a consolidated principle in many settings. The need to affirm and value the right of minors to express their own preferences in relation to their capacity for discernment must be ethically shared: adolescents, even vulnerable ones, are able to assume their responsibilities in accordance with their personal life plan.

If the mature minor's wishes to get vaccinated were to contrast with those of the parents opposed to vaccination, the Committee believes that the adolescent should be heard by the medical personnel and the minor's wishes should prevail over parental dissent, as their wishes coincide - according to current scientific indications and with the exception of particular health situations for which vaccination is not recommended - with the best interests of his/her psycho-physical health and of public health.

For adolescents with diseases and who fall into the categories identified by the Ministry of Health (in an updated list), for which anti-Covid 19 vaccination is recommended, the duty of the parents (legal representatives) to guarantee the best interests of the child becomes even more pressing. Should the parents refuse the vaccination, considered as clinically relevant by the doctor, or should there be disagreement between the parents, it is evident that even in these cases - as in general where there are disagreements between doctors, guardians, minors - it would be desirable and valuable, before appealing to the judge, to have recourse, where possible, to a clinical ethics committee, (Law n ° 219/2017,

art. 3 paragraph 5), which offers advice for the clarification and possible resolution of differences. Another opportunity could be the discussion of the different opinions by those involved with experts, within an ethical space.

In the case of adolescents who refuse to be anti-Covid 19 vaccinated despite parental consent, the Committee considers it important and desirable for these adolescents to be informed by medical staff in the manner recommended above, that vaccination is in the interest of their own health, the health of the people around them and public health. The Committee is aware that even in certain age groups the protection of personal health and above all the principle of solidarity may not be fully understood or its related implications; it believes, however, that these arguments may, if necessary, be examined in depth and evaluated together with the adolescent.

Lastly it seems, however, right, from a bioethical point of view, not to proceed with compulsory vaccination in the absence of a law expressly requiring it, but to put in place appropriate measures to safeguard public health, such as, for example, remote attendance of remote teaching activities, as well as recreational activities, the use of swab tests which should be free, at least for minors.

The ICB deems it appropriate in these situations of disagreement between the parties, that their wishes should be certified in order to explain with the utmost clarity their respective positions within the family and in relations with the doctor, also with a view to better identify the differences in an attempt to reconcile them.

Recommendations

In view of the general considerations on adolescents, the vaccine and Covid-19, the Committee recommends:

1. Speeding up the immunization of adolescents with sufficient doses. Immunization is also a tool that allows adolescents to regain their freedom, after the harsh period of restrictions due to the pandemic, with sufficient margins of safety, in light of recent scientific findings, and to act responsibly also towards public health.

2. In the epidemiological framework of variants with the possibility of new risks, urging adolescents, even those already vaccinated, to respect the limitations that persist, in order to prevent the virus from circulating again, given the epidemiological picture of the variants, with the possibility of new risks.

3. Obtaining the informed consent of the parents, evaluating the balance of risks and benefits in relation to the age of the minor.

4. Providing adequate information to minors, in a manner proportionate to their capabilities, by means of an information sheet, with a view to their conscious participation in vaccination.

5. Bearing in mind that information given to minors on Covid-19 and vaccinations is to be accompanied by awareness-raising actions and the education of parents and teachers, with the welcome activation of specific initiatives in schools and elsewhere, on the meaning of individual personal protection but also of solidarity in protecting the community.