

# LEGAL AND ETHICAL ISSUES AROUND COVID-19 VACCINATION CONSENT IN ITALIAN CHILDREN FROM 12 YEARS OF AGE

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## INTRODUCTION

In Europe, there are currently two vaccines against COVID-19 recommended by the European Medicines Agency (EMA) for children aged 12 and older: Spikevax (Moderna) and Comirnaty (Pfizer-BioNTech). At the moment, about half of European countries have decided to age 12 as the minimum age for vaccination against COVID-19. In addition to Italy, France, Spain, Austria, Slovenia, Hungary, Czechia, Slovakia, Denmark, Switzerland, Romania, Bulgaria, Lithuania, Latvia and Estonia. Others (Germany, UK, Netherlands, Belgium, Sweden, Finland) recommend vaccination only for children in textual conditions facing COVID-19 or living with frail people. The Italian Medicines Agency (AIFA) has approved the extension of the therapeutic indications for Comirnaty on May 31 and for Spikevax on July 29, 2021.

The various scientific societies in Italy (SIPPS, SIP) agreed in favor of vaccinating children from 12 years old. However the problem of informed consent to COVID-19 vaccination in minors is absolutely emerging, in Italy as well as in other countries (Heuerman, 2021). According to national and international conventions, he should be informed, listened to and must participate in the co-decision process regarding medical treatment. Achieving a “triple” medical-parent-child therapeutic alliance is the main goal at this time of the pandemic, but this is not always possible (Morgan, 2021). The main key legal and ethical issues on the matter are represented below.

**Keywords:** Minors, COVID-19 Vaccination, Informed Consent, Italian System

### Vaccination as a Conscious Choice

As a rule, the choice to vaccinate a minor must have the consent of both parents (Katz, 2016). This is a decision concerning the health of the minor whose responsibility must be exercised by the person exercising parental authority. This applies both to families where the parents are married, cohabiting or legally separated or divorced. In the circumstance of the absence of the parents, a “tutore” (article 357 of civil code) who will make this decision in the interest of the minor must be appointed. Since this is a medical treatment, the healthcare vaccinator must acquire a real informed consent in line with the final decision. The degree of involvement in the decision and the value of the opinion expressed by the minor will vary (law n. 219/2017) according to the age of the minor and his/her effective degree of discernment (the mental capacity of a minor to fully appreciate the medical act to which he/she will be subjected with all possible consequences) (Diekema, 2020). Although the current Italian legislation does not allow the active participation of minors (especially 12-year-olds) in choices related to their health, the health system should empathize with the minor to ensure thoughtful and shared solutions (Fedeli, 2021).

## The Relevant Legislation Regarding Minors

Since this is a medical treatment, we must not limit ourselves to following the principle of supporting the inclinations/aspirations of the minor, but we have to obtain a real informed consent in line with the final decision (Comitato Nazionale per la Bioetica - CNB -, 1992). The general rules contained in the international charters, to which the Italian system still refers, are listed below.

a) New York Convention on the rights of the child of 20 November 1989 (law n. 176/1991). The article 24 states: “States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures: (a) To diminish infant and child mortality; (b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care”.

b) Strasbourg Convention of 25 January 1996. The article 3 – Right to be informed and to express his or her views in proceedings – states: “A child considered by internal law as having sufficient understanding, in the case of proceedings before a judicial authority affecting him or her, shall be granted, and shall be entitled to request, the following rights: a to receive all relevant information; b to be consulted and express his or her views; c to be informed of the possible consequences of compliance with these views and the possible consequences of any decision”.

c) European Charter of Fundamental Rights of 2012. The article 24 states: “Children shall have the right to such protection and care as is necessary for their well-being. They may express their views freely. Such views shall be taken into consideration on matters which concern them in accordance with their age and maturity”.

d) Regulation of the EU Council of 25 June 2019 on jurisdiction, the recognition and enforcement of decisions in matrimonial matters and the matters of parental responsibility, and on international child abduction. The article 21 - Right of the child to express his or her views - states “1. When exercising their jurisdiction under Section 2 of this Chapter, the courts of the Member States shall, in accordance with national law and procedure, provide the child who is capable of forming his or her own views with a genuine and effective opportunity to express his or her views, either directly, or through a representative or an appropriate body. 2. Where the court, in accordance with national law and procedure, gives a child an opportunity to express his or her views in accordance with this Article, the court shall give due weight to the views of the child in accordance with his or her age and maturity”.

## Divergent will between Parent and Child

Possible differences of will with one or more parents can easily occur (Silverman, 2019). Obviously, it is necessary first of all to proceed with every attempt at agreement between the minor (with a capacity for discernment) and the parent, through correct communication with the vaccinator or, even before, with the family doctor, called to guide the entire family unit towards the best choice to be made for the minor, both from a clinical-health perspective and from an ethical and social point of view.

Failed every attempt, a first way would be to activate the local social services to initiate an appeal with the competent Court. Similarly, the procedure could be activated by contacting the “garante per l’infanzia e l’adolescenza” (law n. 112/2011).

Another way could be to apply to the Juvenile Court which will appoint a special “curatore”, who will support the child's petition against the parents (law n. 149/2001). By the way, the Italian legislative system, in the matter of “Forfeiture of parental authority over children”, says that “The judge can void parental authority when the parent violates or neglects responsibilities or abuses this power with grave prejudice to the child” (article 330 civil code).

The orientation of the Italian jurisprudence on vaccination (compulsory and not) is 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 shared scientific data that demonstrate the effectiveness of health treatment, the tutelary judge (article 344 of civil code) can temporarily suspend the parent's decision-making capacity against the vaccine, regardless of whether the same parents are together or separated/divorced. If this *modus operandi* is also prospected for COVID-19 vaccination, the “no-vax” position of the parent/s (against the will of the child) will hardly be accepted by the judges.

The CNB (2021) has also recently expressed its opinion on the matter, arguing that “If the will of the great minor to get vaccinated is in contrast to that of his parents, the Committee believes that the adolescent must be heard by medical staff with pediatric skills and that his will must prevail, as it coincides with the best interest of his own health and public health. For adolescents suffering from pathologies and falling within the categories identified by the Ministry of Health ... for whom vaccination is recommended, the obligation of parents (legal representatives) to guarantee their children the best interest is even more relevant; it is important to have recourse to the clinical ethics committee or an ethics space and, as extrema ratio, to the tutelary judge. In the case of the adolescent who refuses vaccination in face of a parental consent, the Committee considers that it's important and desirable to inform the adolescent that the vaccination is in the interest of his health, the health of neighboring people and public health ... The CNB believes it is appropriate that in the circumstances of conflict between the parties, the will is certified in order to explain their respective positions with the utmost clarity, also in order to better identify the conflicts in an attempt to recompose them”.

### **The Incapable Minor Hospitalized**

A particularly delicate issue is that of vaccinations for minors who are totally or partially unable to determine themselves, guests in assisted healthcare residences. Regarding the consent, the recent decree law n. 1/2021, later modified by law n. 6/2021, has defined specific aspects. The article 5 of the aforementioned decree (“Demonstration of consent to the health treatment of the anti COVID-19 vaccine for incapacitated subjects hospitalized in assisted health structures”) provides that incapable subjects, hospitalized in health structures, express their consent to health treatment for anti COVID-19 vaccinations through their own “tutore”, “curatore”, “amministratore di sostegno” or “fiduciario” (as required by law n. 219/2017), which governs informed consent and advance provisions for treatment. If these figures are missing or unavailable for at least 48 hours, the law provides that the temporary function of “amministratore di sostegno”, for the sole purpose of expressing consent to the administration of the vaccine, is assumed by the medical director or other doctor of the health facility where the minor is being treated.

If the minor or persons entitled to give consent refuse the administration of the vaccine, the medical director or other doctor of the facility can appeal to the tutelary judge, asking to be authorized to vaccinate if there are not clinical contraindications.

### **CONCLUSION**

The problem of consent to the medical treatment of the minor and in particular that of the administration of COVID-19 vaccine has raised and always raises difficulties of application. The consent to the vaccination in the minor must take into account the maturity of the subject, his ability to understand the information relating to the benefits and risks of the treatment and cannot ignore the involvement in the choice of both parents. In the event of a clear conflict between the interests of the minor and the wishes of the parents, the legal system provides for the intervention of a specialized judge who can provide the useful tools (appointment of a substitute) to ensure that the best interests of the minor are respected.

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