

SHORT COMMENTATORY

Covid-19 vaccination for children in India: Queries and Clarifications regarding consent.

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ABSTRACT

The Government of India initiated the COVID-19 vaccination for children in the age group of 15 -18 years on January 3rd 2022. Although this was a much-awaited phase of vaccination, the parents, health care workers and the organizations dispensing the vaccines had many doubts and concerns regarding consent and liability for adverse effects, especially in this age group. There are no clear cut guidelines issued by the Ministry of Health & Family Welfare, Government of India on this subject. In this article, we elaborate on the various aspects of consent, particularly consent for vaccination, which is being followed in our country. By analyzing the related sections in the Indian Penal Code and prevalent practices in our country regarding consent, we endeavour to answer frequently encountered questions.

Keywords: Consent; Vaccine; Children; India; Law

Introduction

Consent literally means "agreement or permission." Consent is legally valid if it is granted freely and voluntarily, without fear, favour, force, or fraud, and with a thorough knowledge of the purpose and dangers involved [1]. Consent is the legal manifestation of the idea that everyone has the right to make decisions that impact their well-being. In the fields of medical research and treatment, consent plays a major part in doctor-patient/subject interaction. It has wide humanitarian as well as legal connotations.

For all practical purposes, consent can be divided into:

- **Express consent:** when given verbally or by writing.
- **Implied consent:** consent that is inferred from a patient's actions.

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Examples of such consent are when an adult patient of sound mind voluntarily

- Accepts the treatment, puts forward his arm to take the injection.
- Co-operates with the physician, carries on his instructions, even though he has not given consent in words.
- Calls a physician to his house, implying his consent for treatment.
- When an emergency operation has to be undertaken to save the patient's life or while that patient is unconscious, its consent is implied^{1,2}.

Consent in the Indian Law system:

According to Section 13 of the Indian Contract Act (1872), the term 'Consent' has been defined as 'two or more persons are said to consent when they agree upon the same thing in the same sense'. This definition was more applicable to the transactions/interactions between two or more parties/ individuals regarding mutual contracts with no direct application in the medical field³.

Consent has never been defined legally for the purpose of medical sciences. However, Section 90 of the IPC mentions what does not constitute consent. It describes consent in a negative term. It states, a consent given by a person under the fear of injury, or under a misconception of facts, or because of unsoundness of mind, intoxication, or a child under the age of 12 years (unless the contrary appears from the context), who is incapable to understand the nature and consequences of the consented act, is no consent⁴.

Section 90 IPC also regulates the operations of Section 87, 88 & 89 IPC.

Section 87 IPC: A person >18years of age can give valid consent to suffer any harm, which may result from an act not intended or not known to cause death or grievous hurt.

Section 88 IPC: A person can give valid consent to suffer any harm which may result from an act, not intended or not known to cause death, done in good faith & for its benefits.

Section 89 IPC: A child under 12 years of age & an insane person cannot give valid consent to suffer any harm which may result from an act done in good faith & for its benefit. The consent of the parent/guardian should be taken⁴.

Consent & COVID-19 Vaccination in India:

Before delving into the issue of consent in COVID-19 vaccination, we need to look at the current practices about other vaccinations for children in our country. The immunization program in India for children was started way back in the year 1978 and was later modified as UIP (Universal Immunization Programme)⁵. The vaccines covered under this scheme are administered either orally or as injectables. Being a National Program, the law provides consent in these cases and therefore informed express consent of the child /parent is not mandatory⁶.

The Government of India (GoI) started COVID-19 vaccination for children in the age group of 15-18 years from 3rd January 2022. The Ministry of Health and Family Welfare, GoI approved 'Covaxin' to be administered to children as this was the only vaccine listed for EUL (Emergency Use Listing). The vaccination guidelines mention that the beneficiaries can register for the same by booking an appointment either online (CoWIN portal) or by onsite registration⁷.

Global Scenario

The World Health Organization (WHO) approved vaccination of healthy children above 5 years of age and adolescents as per the national vaccination strategies of individual countries⁸.

In the United States of America (USA), consent for vaccinating children and adolescents is different for different states. Parental consent for immunizations is a standard practice in 43 states. Self-consent is sufficient for adolescents to receive hepatitis B vaccination in nine states as a part of promoting and encouraging healthy sexual practices. Most states require consent for vaccination services provided to adolescents⁹. However, there is no Federal law making informed consent mandatory before vaccination.

The recommendations of the American Academy of Paediatrics regarding consent for vaccination are:

- In infants & young children: Informed permission of the parents is required.
- In older school-age children: Informed permission of the parents, as well as patients assent, is required.
- In adolescents & young adults: Informed consent of the patient is required⁹.

Pertinent issues regarding consent for vaccination in children of 12-18 years in India:

The following questions regarding vaccinating children of 12-18 years age need to be addressed:

- Can the child register online/onsite by himself/ herself without the consent of the parents?
- Should the parents be physically present when the vaccine is given to the child?
- Can the vaccine be given in the school?
- Should the Parent/Guardian sign any consent form for vaccination?
- Are there any legal repercussions in case of any adverse effects following the vaccine?

Discussion

Sections 87 and 89 of the IPC clearly mention the rules regarding consent for children <12 years and adults above 18 years. There is, however, ambiguity regarding consent for children who fall in between these two age groups that are between 12 and 18 years. From the above two sections, it can be indirectly deciphered that children between the ages of 12-18 can give consent for physical examination and non-invasive procedures. This fact is supported by many other studies which state that children above 14 years have well developed decisional skills as those of adults for making informed health care decisions¹⁰⁻¹².

In the context of the COVID-19 vaccine, since the beneficiary on their own volition registers through online/ onsite portals, this in itself can be taken as implied consent; hence informed expressed consent is not necessary. A child between 12 and 18 years can register and get vaccinated of his own volition without parental approval. Although the physical presence of the parents is not necessary for children to take the vaccine, their presence may provide additional mental support. In response to a query raised by the Supreme Court of India, the GoI stated that COVID-19 inoculation guidelines issued by the Union Health Ministry do not envisage forcible vaccination without obtaining the consent of an individual & also highlighted the fact that no person can be vaccinated forcibly against their wishes¹³.

Another major issue that needs to be addressed in this regard is the medico-legal liability in the case of Adverse Events Following Immunization (AEFI). If a causal relationship is established between vaccination and severe/fatal adverse event in children, can the organization/ Government be held legally responsible? The MoHFW, during parliamentary proceedings, had clarified that there is no provision for any form of compensation in case of adverse effects following vaccination. It also stated that pharmaceutical firms manufacturing the vaccines are accountable for any of the adverse reactions to vaccines¹⁴. Being a National Programme, conducted under the rules and regulations set by the Government, vaccinations are being administered under the norm of implied consent by various government and private organizations. Therefore the organizations dispensing the vaccine such as schools or community centres per se are not under legal liability.

Conclusion

Immunization programs for children are being implemented in India for many years & vaccinating children for COVID-19 doesn't come with a new set of rules & guidelines. Informed expressed consent is not mandatory to vaccinate children. The children in the age group of 12-18 years can register themselves through the online/onsite portal. However, the parents/guardians are advised to be physically present with the child during the process of vaccine administration, as it will boost the emotional well-being of the child.

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