



Considerations regarding **consent** in vaccinating children and adolescents **between 6 and 17 years old**



INTRODUCTION

Around the world, immunization programmes are increasingly including, in their national immunization schedules, vaccines that target age groups beyond infancy and early childhood. This document is aimed at programme managers who are planning to introduce vaccines for older children and adolescents aged between 6 and 17 years.¹

It provides information that should be considered when preparing guidance notes on the consent process, or for clarifying questions from the health workers who provide the vaccinations. The document is all the more important because this population group may present for vaccination without an accompanying parent or legal guardian.

1. According to the Convention on the Rights of the Child (1989), childhood ends upon reaching 18 years of age. In most countries in the world, this is often considered the age at which legal adulthood, the age of majority, is reached.



THE PRINCIPLES OF CONSENT AND ASSENT

CONSENT

Consent is the principle wherein individuals must give their permission before receiving a medical intervention or procedure. According to the laws and regulations in place in most countries, consent is required for a range of medical interventions or procedures, from a simple blood test to organ donation, and including vaccinations. In only very few, well-described circumstances, such as life-threatening emergencies, may consent be waived. Consent derives from the principle of autonomy and forms an important part of medical and public-health ethics, as well as international law.² For consent to be valid, it must be informed, understood and voluntary, and the person consenting must have the capacity to make the decision.

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LEGAL AGE OF CONSENT

In most country's legal systems, the legal age of consent tends to coincide with the age of majority. This is 18 years in most countries. It follows, therefore, that a child or adolescent in the age group 6 to 17 years cannot provide consent to vaccination and so consent is normally required from their parent or legal guardian.

ASSENT

Assent refers to the process of children's and adolescents' participation in the decision-making on vaccination (or other medical interventions). Assent is not regulated in law like consent, and is sometimes referred to as a moral obligation closely linked to good practice in dealing with patients. International law provides strong support for children's rights to participate in decisions about their health and health care, and also in the planning and provision of health services relevant to them and based on their evolving capacity.³

In a growing number of countries, the age of consent for medical interventions is set below the age of majority. This allows adolescents to provide consent for specific interventions, such as access to contraceptives or HIV testing. Some countries have fixed the age of consent specifically to allow HPV vaccination at 12 years.

2. Convention on the Rights of the Child, General Comment No. 4 (CRC/C/GC/4, 1 July 2003) and No. 15 (CRC/C/GC/15, 17 April 2013).

3. CRC/C/GC/4, 1 July 2003 states that "adolescents need to have a chance to express their views freely and their views should be given due weight, in accordance with article 12 of the Convention."

COMMON APPROACHES FOR OBTAINING CONSENT FOR VACCINATION

Current practices of obtaining informed consent for vaccination vary among countries, but can be broadly categorized into three approaches.

1. A formal, written consent process is used, particularly in middle- and high-income countries that have a higher percentage of literate populations and a longer history of providing vaccination to older age groups.⁴ Vaccination of this target group may be delivered through school health services. Health authorities inform the parents about the vaccination and written consent from the parent is required to opt-in, i.e. give permission for the older child/adolescent to be vaccinated. Alternatively, a written form is used to allow parents to express non-consent (or refusal) to vaccination of their child. This is known as an opt-out procedure.

2. A verbal consent process, whereby consent is given verbally by the parent after being duly informed about the vaccination. However, this approach can only be used when parents accompany the child to the vaccination.

3. An implied consent process by which parents are informed of imminent vaccination through social mobilization and communication, sometimes including letters directly addressed to the parents. Subsequently, the physical presence of the child or adolescent, with or without an accompanying parent at the vaccination session, is considered to imply consent. This practice is based on the opt-out principle and parents who do not consent to vaccination are expected implicitly to take steps to ensure that their child or adolescent does not participate in the vaccination session. This may include not letting the child or adolescent attend school on a vaccination day, if vaccine delivery occurs through schools.

Implied consent procedures are common practice in many countries. However, when children present for vaccination unaccompanied by their parents, it is challenging to determine whether parents indeed provided consent. Therefore, countries are encouraged to adopt procedures that ensure that parents have been informed and agreed to the vaccination. Comprehensive data on whether the approach countries use to deal with consent has changed or evolved over the last decades is not available.

APPROACHES TO OBTAIN INFORMED CONSENT:

1. *Written consent*
2. *Verbal consent*
3. *Implied consent*



4. A WHO survey in 2012 in 34 selected countries from four regions on consent procedures for vaccination in 6–17 year-olds, found that approximately half of the respondent countries use written consent for vaccination in this age group.

MANDATORY VACCINATION DOES NOT ALWAYS OVERRULE THE NEED FOR CONSENT



Based on concepts of vaccines as a public good, or on public-health goals of disease elimination and outbreak control, some countries identify one or more vaccines as mandatory in law, or in their policies. Vaccination may, for example, be made a condition for entry into preschool or primary school, or to enable access to welfare benefits. Whether consent is needed for mandatory vaccination depends on the legal nature of the regulations. When mandatory vaccination is established in relevant provisions in law, consent may not be required. If the mandatory nature of vaccination is based on policy, or other forms of soft law, informed consent needs to be obtained as for any other vaccines. Some countries allow individuals to express non-consent (opt-out) and obtain an exemption for mandatory vaccines. This may come with certain conditions, like barring unvaccinated children from attending school during disease outbreaks.

SCHOOLS AND COMMUNITIES CAN AUTHORIZE, NOT GIVE CONSENT

When vaccination is carried out in schools, local or national school authorities normally authorize the intervention to take place at their premises. This authorization is needed for planning and implementing the vaccination sessions in schools. The same applies when community or traditional leaders are asked for permission for vaccination to be carried out in their communities. This authorization, however, does not imply informed consent by the individuals in that school or community.

In a legal sense, school or local welfare or other community authorities, do not have the capacity to consent to medical interventions on behalf of the children in their care. Exceptions, stipulated in local laws and regulations, may exist in defined, special situations. In some countries, there may be tension between cultural or customary practices surrounding community consent, and the formal requirements for consent in laws and regulations.

PRACTICAL CHALLENGES

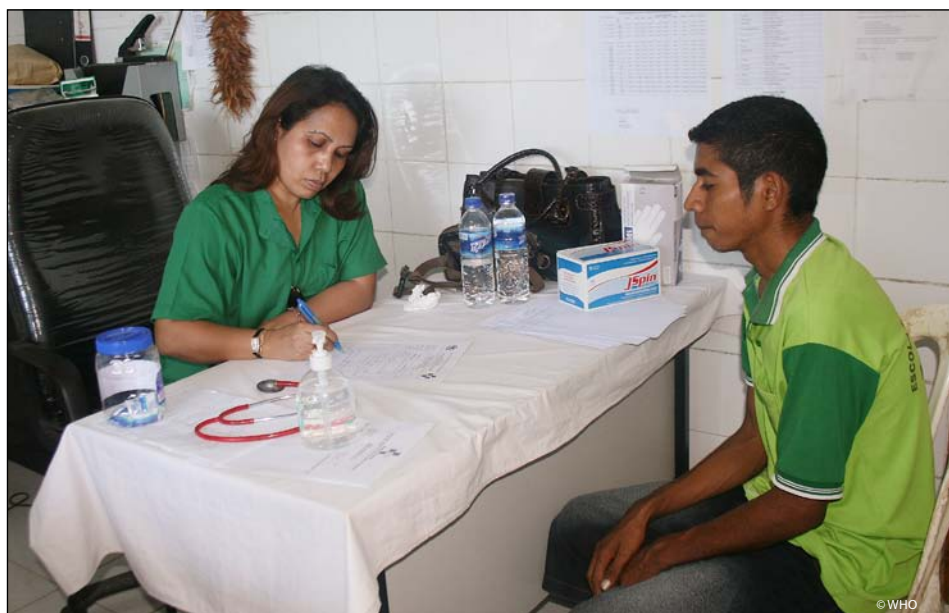
There are two main areas in which the vaccination of older children and adolescents presents challenges for the informed consent process.

Non-accompanied persons

Older children and adolescents may attend a vaccination session without a parent. This situation arises when vaccination is school-based, but may also occur when adolescents visit a health facility to be vaccinated without their parents. In such situations, obtaining consent from parents before vaccination becomes a challenge, and careful planning is needed to enable them to provide consent prior to the vaccination of their child. This is especially true for school-based vaccination programmes. Countries that use implied consent for childhood vaccination, consider the parent bringing the child for vaccination as an expression of informed consent. To allow parents to express consent, when vaccination of their child takes place in their absence, special procedures need to be put in place. Planning for vaccination must take into account the informed consent process. If written consent (or non-consent) is required for school-based vaccination, sufficient time needs to be allowed for the consent forms to be provided to parents and to be returned to the school prior to the vaccination session.

Evolving capacities of the child

The capacities of older children and adolescents evolve towards independent decision-making as they mature. This principle of “evolving capacity” outlined in the Convention on the Rights of the Child (Art. 5),⁵ combined with the obligation to “respect the views” (Art. 12) and securing the “best interests of the child” (Art. 3), implies that older children and adolescents should have a say in the consenting process. Formally, this is known as “assent”, which is interpreted as a moral obligation



on the part of the health worker to ensure that the child/adolescent agrees to the intervention. While the views of the child/adolescent and parents on vaccination will concur in most situations, sometimes they may be different. A parent may want their adolescent to be vaccinated but the adolescent refuses, or the reverse when the adolescent wants to be vaccinated but the parent does not give permission. It is important that health workers understand the rights of parents and children in such cases, and are able to weigh these rights based on guiding principles that govern such situations in the country context.⁶ She/he also needs to know, and apply the correct procedure to follow, according to national or local laws and regulations.

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5. Convention on the Rights of the Child. UNGA resolution 44/25 (1989).

6. Convention on the Rights of the Child, General Comment No. 4, 2003 (CRC/GC/2003/4) states: “Before parents give their consent, adolescents need to have a chance to express their views freely and their views should be given due weight, in accordance with article 12 of the Convention. However, if the adolescent is of sufficient maturity, informed consent shall be obtained from the adolescent her/himself, while informing the parents if that is in the ‘best interest of the child’ (Art. 3)” (para. 32–33).



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EXCEPTIONAL SITUATIONS AND EMANCIPATED MINORS

Specific situations, living conditions or status of children and adolescents, may affect informed consent.

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Among others, these may include certain groups like orphans, child-headed households, adolescents living on the streets or married adolescents. In some of these cases, when the parent or legal guardian is absent, such children are considered emancipated children or minors. Specific regulations may govern consent in such situations.

● **In some countries**, laws and regulations are in place that identify school- or social-services officials as appointed guardians for children and adolescents not living with their parents,

including adolescents in boarding school. This is also called “third party consent”. In such cases, these third parties can provide consent for medical care, including vaccination of specific, individual children.

● **In some African countries**, with many HIV/AIDS orphans and child-headed households, the oldest child as of a specific age (e.g. 16 years of age), is empowered by law to consent to medical interventions for themselves and their younger siblings.

CONSENT AND IMMUNIZATION COVERAGE

A common concern is that consent procedures affect vaccine acceptance and coverage. When comparing data from countries using written consent and those using informal, verbal or implied consent processes, comparable levels for vaccination can be seen in both settings. This suggests that the association between the informed consent procedure that a country uses, and actual levels of immunization coverage, is not strong. Other factors, such as accessibility, acceptance and cost of vaccines, have been seen to have more impact on coverage. A study in the United States of America, which compared vaccination coverage among states in the country with mandatory hepatitis B and varicella

vaccination for 13 year-olds, found that more liberal opt-out exemption policies were associated with 5% lower coverage.⁷ Another country that had introduced HPV vaccination using written, opt-in consent forms for parents, had lower coverage initially but coverage levels improved when it switched to a written, opt-out procedure. While better advance planning with the opt-in form could have contributed to better coverage levels, the experience confirms evidence from other fields, like HIV,⁸ national organ-donation programmes and behavioural economics,⁹ which suggests that opt-out procedures are associated with higher coverage levels than opt-in approaches.

7. Olshen E et al (2007). The impact of state policies on vaccine coverage by age 13 in an insured population. *Journal of Adolescent Health*. 40;5:405–411.

8. Baisley K et al (2012). Uptake of voluntary counselling and testing among young people participating in an HIV prevention trial: comparison of opt-out and opt-in strategies. *PLoS One*. 7(7):e42108.d.

9. Kahneman D. *Thinking, fast and slow*. New York: Farrar, Strauss and Giroux;2011.

PROGRAMMATIC CONSIDERATIONS

Immunization programmes planning to amend or introduce new consent procedures for the vaccination of older children and adolescents, are encouraged to consider the following.

- Informed consent is required for medical interventions, including vaccination.
- Where parental consent is required, health workers should allow older children and adolescents to provide assent to the vaccination.
- Understanding the benefits and risks of vaccination is a central aspect of informed consent and assent. Hence, communication strategies and materials need to cater not only to parents but also to older children and adolescents. The level of information provided to the child should be compatible with their evolving mental capacities and with the level of their mental maturity.
- Making changes to consent procedures for vaccination requires a clear and well-targeted communication strategy to ensure public acceptance.¹⁰ In countries where written consent is not common practice in routine vaccination, the community may associate written consent with research. In particular, communities may interpret the introduction of a new vaccine in combination with a new informed consent process, as an experiment.
- Resource requirements (materials, planning and time) for written consent, particularly for active opt-in approaches, are often higher than for other consent strategies.
- Evidence suggests that consent procedures based on opt-out approaches are likely to result

in higher acceptance of an intervention, than using opt-in.

- Increasingly, vaccines are part of integrated approaches¹¹ and may be delivered alongside other health interventions, such as deworming. Hence, there may be a need to harmonize consent procedures that are currently used for different interventions and establish a single, common, informed consent procedure.

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10. For example, using the principles from: Communication for development. Strengthening the effectiveness of the United Nations. UNDP; 2011.

11. For example, WHO guidance note on: Comprehensive cervical cancer prevention and control: a healthier future for girls and women. Geneva: WHO; 2013.

COUNTRY RESPONSIBILITY

To ensure that national immunization programmes use informed consent procedures that are programmatically feasible and in line with national and local laws and regulations, as well as international human rights principles, vaccination programmes and regulatory agencies are encouraged to:



- collect information about the (legal) requirements for informed consent for medical interventions (including age of consent and assent) at national, subnational and institutional levels;
- collect information on public-health laws, including provisions related to mandatory vaccinations and relevant non-compliance measures;
- collect information about authorization processes in institutions involved in vaccinating older children, such as educational establishments;
- become familiar with international human rights principles and rights of parents and children, and the implications for informed consent process, when vaccinating older children and adolescents;
- develop an informed consent procedure that is adapted to the local situation, to the capacity of the health system and, if relevant, school system, in a way that optimizes use of resources and public-health outcomes while respecting the rights of individuals;
- provide guidance to, and build the capacity of health workers to implement, informed consent procedures for vaccination and deal appropriately with any special situations.¹²

12. CRC/C/GC/15 (17 April 2013) states: “it is therefore essential that supportive policies are in place and that children, parents and health workers have adequate rights-based guidance on consent, assent and confidentiality.”

FOR FURTHER INFORMATION

- Convention on the Rights of the Child available at: <http://www.ohchr.org/en/professionalinterest/pages/crc.aspx>.
- Informed consent procedures for vaccinating non-accompanied children and adolescents. Background document, World Health Organization (2013).
- Adolescent HIV testing, counselling and care – Implementation guidance for health providers and planner. World Health Organization, 2013. Section on ‘Informed consent and HIV testing’ available at: http://apps.who.int/adolescent/hiv-testing-treatment/page/Informed_consent_and_HIV_testing

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