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## Informed consent/assent in children. Statement of the Ethics Working Group of the Confederation of European Specialists in Paediatrics (CESP)

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**Abstract** Informed consent means approval of the legal representative of the child and/or of the competent child for medical interventions following appropriate information. National legal regulations differ in regard to the question when a child has the full right to give his or her autonomous consent. Informed assent means a child's agreement to medical procedures in circumstances where he or she is not legally authorised or lacks sufficient understanding for giving consent competently. Doctors should carefully listen to the opinion and wishes of children who are not able to give full consent and should strive to obtain their assent. Doctors have the responsibility to determine the ability and competence of the child for giving his or her consent or assent. All children, even those not judged as competent, have a right to receive information given in a way that they can understand and give their assent or dissent. This consent/assent process must promote and protect the dignity, privacy and confidentiality of the child and his or her family. Consent or assent is required for all aspects of medical care, for preventive, diagnostic or therapeutic

measures and research. Children may effectively refuse treatment or procedures which are not necessary to save their lives or prevent serious harm. Where treatment is necessary to save a life or prevent serious harm, the doctor has the duty to act in the best interest of the child. However, parents may also refuse to consent and in this case national laws and legal mechanisms for resolving disputes may be used.

**Keywords** Children · Ethics · Informed consent

### Introduction and nature of consent/assent

Informed consent means approval of the legal representative of the child or of the competent child for medical interventions following appropriate information. There are differences in national legal regulations when a child has the full right to give his or her autonomous consent. Informed assent means a child's agreement for medical procedures in circumstances where he or she is not legally authorised or has insufficient understanding to be competent to give full consent.

Consent/assent as applied to medical treatment involves more than mere agreement that a diagnostic test or a therapeutic procedure shall be done. Consent/assent is a more active process and involves a patient receiving information about the proposed procedure at a pace and a level which they can comprehend and the ability to use that information to make a voluntary choice as to whether to undergo that procedure. Consent/assent emphasises the qualities of partnership, mutual understanding, respect and trust which underline the doctor-patient relationship. An essential element in consent/assent is that informed choices are freely made without coercion or force.

The legal purpose of consent of the patient is to safeguard his or her autonomy or right to self-determination but also gives licence for the physician and others to do things to patients which would otherwise be illegal. However, doctors should also carefully listen to the

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opinion and wishes of children who are not able to give full consent and should obtain their assent. The doctor has a high responsibility because he has to determine the ability and competence of the child to give his or her consent or assent under the conditions of the national law.

Although consent/assent is often perceived as one-off event, it is better regarded as a continuing process.

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### **Ethical justifications for consent/assent**

Seeking consent/assent for medical treatment is justified by the application of traditional moral theory or principles.

Firstly, seeking a person's consent/assent respects their basic right to self-determination (autonomy). Individuals are best placed to determine what is their best interests and the only justification for infringing this right is to prevent harm to others. Secondly, obtaining consent/assent involves treating others in a way in which we would expect to be treated ourselves. The universal need to obtain consent/assent also involves treating people justly. Thirdly, obtaining consent/assent protects patients from the physical and psychological harms which may occur as a result of illness or its treatment. Fourthly, obtaining consent/assent confers benefit by encouraging active participation of individuals in investigation and treatments which are intended to restore their health. As a consequence, compliance for treatment is often improved. Wider social benefits from consent/assent include the fostering of a doctor-patient relationship which is based on partnership, mutual trust, understanding and respect.

Traditional moral theories have to do with adults who are usually regarded as sentient rational beings without having the obligation to prove it. Increasingly, doctors actively involve children in making decisions about their own health care to an extent which would have been unlikely in the past. This greater involvement implies some changes in our attitudes to the moral status of children and the moral claims which they may make on society.

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### **The moral status of children**

According to Article 1 of the Declaration of Human Rights, the child must be recognised as a person with the basic rights of all human beings to be free and equal in dignity and rights. Therefore, the principal attitude or doctors must be dedicated to the respect of the life and dignity of the child as an entity of full value at each stage of development. The more children are dependent on the protection and the support of their parents and other adults because of the lower status of their development, the more the attention and empathy of doctors should be focused on the needs of children. Therefore doctors should not only concentrate on the view of parents and

must not ignore children's interests. On the contrary they, in partnership with parents, have a duty to enhance, encourage, protect and promote children's development from the dependency of infancy to the autonomy of adults.

Parents are given the ethical and legal responsibility to make decisions for children provided that they do so in the best interest of the child (United Nations Convention of Rights of the Child). However, the UN Convention, which has been ratified by all EU states and which defines the child as being a person also under the age of 18, provides a mechanism for children's views to be heard. Article 12 provides that the states "shall assure the child who is capable of forming his or her own view, the right to express those views freely in all matters affecting the child, the view of the child being given due weight in accordance with the age and maturity of the child". As a consequence, "children shall be provided with the opportunity to be heard in any judicial or administrative proceeding affecting the child directly". Whilst this does not explicitly refer to medical treatment, there is no doubt that this is what is intended. The Convention also provides that children should have access to the best available standards of health care, the right to information, the right not to be subjected to inhuman or degrading treatment and the right to privacy. Children are right owners, even if they are not able to express their rights. Everyone dealing with such rights has the duty to promote them, to give voice to them and to become a true child advocate.

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### **The role of law in disputes about consent**

As indicated above, disputes about consent/assent and refusal may require legal intervention. The role of law in ethical decision-making is to: (1) provide a framework within which to resolve difficult ethical issues, (2) provide safeguards in response to controversial issues viz (a) absolute prohibition- even with consent, e.g. circumcision, (b) procedural hurdles, e.g. regulation of fertility treatments, (3) provide a mechanism for resolving intransigent disputes fairly and (4) to protect weak and vulnerable individuals, e.g. infants.

Controversies, which may arise, are likely to relate to the age at which children and young people are regarded as competent to refuse treatment, which health care professionals believe to be in their best interests. Although it is logical to assume that if children are competent to consent to a procedure, they are also competent to refuse it, there may be difficulties with this approach. Many jurisdictions are reluctant to permit children to refuse life-saving treatment, even when they are felt to be competent to consent to it, e.g. treatment for anorexia nervosa, blood transfusions and treatment of leukaemia in Jehovah's Witnesses. The general overriding principle of law is usually that the best interests of the child or young person are a major factor in deciding what should be done. This is in keeping with

the provisions of the UN Convention on the Rights of the Child, which has been widely ratified and in decisions by the European Court of Human Rights.

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### The question of age

Under the UN Convention all children have rights irrespective of their age or maturity and these rights confer certain obligations on society and individuals in their treatment of children. The Convention does not define when the wishes of a child become determinative rather than merely need to be taken into account. Thus the Convention does not determine when children become competent to make decisions for themselves. Parents are acknowledged as being the most important decision-makers for incompetent children although there may be other complex circumstances where other agencies, e.g. the law court, may be involved.

In law, if not ethically, it has been traditional to regard competence as a function of age. Thus the age at which children may ride motor cycles, drive automobiles or drink alcohol has been defined by relevant law in European states. However this notion of age-related competence has been increasingly questioned in relation to such personal matters as making decisions about health care. This questioning has begun to find expression in national laws or their application in relation to a child's competence to consent/assent or refuse medical treatment. In EU countries, the age of majority is generally 18 years although exceptions exist. At this age any competent person is legally able to refuse treatment as well as consent to it.

Younger children may, according to laws of individual states, be able to consent to treatment especially if they have enough maturity and ability to understand the benefits and risks of the proposed treatment and its alternatives. The concept of a "mature minor" has been introduced by some authorities to include groups of children whose age ranges in most EU countries from 14 to 18 years and who are often regarded as being mature enough to give their own consent to treatment. In some countries the age at which children are considered to be potentially competent is even lower. In some jurisdictions competent minors can give their consent without the involvement of parents, assuming the decision is beneficial for the adolescent and he/she does not want the parents involved.

Competence has often been associated with cognitive capacity, rationality and age. However, it is now regarded to be also a function of a child's experience of the illness in question. For example a 12-year-old adolescent with a second relapse of leukaemia has a unique experience of the illness on which to base his or her decisions about future treatment. Very young children may have a clear understanding of death although they may lack understanding of the likely effect of their death on their families. In any case, doctors should always question themselves if the child is mature enough to give consent

or assent. However, valid consent/assent requires not only competence but also the adequate information and the obtaining of the consent/assent without duress or constraint.

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### Assessing competence

Competence is the ability to perform the task in question. In this case, it involves the ability to make decisions about health care. Whether a child may make such decisions, depends on the national law and on the judgement of the doctor on the developmental skills of the child to be able to make autonomous decisions. The child therefore needs to show that he or she can (1) understand the information which is given to them, (2) believe that information applies to them, (3) use the information to make a free choice and (4) make the choice in question.

Competence depends on the context which may involve the physical surroundings of the child. It also depends on the relationship between the child, the parents and the health professionals and must be seen within the child's experience of their illness. Competence also varies over time and with the state of the illness. For example a child who is in severe pain may not be competent to make decisions which they could otherwise make.

Broadly speaking, children need to show understanding of the nature of their illness, why treatment is necessary, understanding of the treatment which is proposed and what risks are entailed and understanding of the implications of treatment or non-treatment on themselves or on their families. The more impact a treatment is likely to have, the greater understanding they will need to demonstrate, especially if they wish to refuse it. There is a complex relationship between competence and information. It would be difficult for a child to be competent if they had not been adequately informed. Therefore, all children, even those not judged as competent, have the right to receive information given in the way they can understand and to give their assent or dissent.

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### Information

It is doubtful if fully informed consent/assent is ever possible. Therefore the information which needs to be divulged needs to be adequate in quantity and quality.

#### Quality of information

It is most important that all information should be in conformity with the capacity of the child to understand. Language and communication should be adapted to the capacity of the child to understand and make decisions. Both parents and children should have sufficient time and space to reflect upon the information which has been given to them to use it to make a choice. For special cases e.g.

cardiac, oncological and other diseases, clinical centres usually provide supporting written information. Additional drawings which illustrate medical interventions are useful means of information. However, the personal and lingual communication between the doctor and the parents and child-patients is mandatory for the informed consent/assent process.

The content of information which needs to be given should include the following:

1. What is going to be done?
2. Why is it going to be done?
3. What is the intended outcome?
4. What are the benefits and risks of the treatment proposed?
5. What are the alternatives including benefits and risks?
6. What will happen if nothing is done?

These questions deal in broad terms with the quality of information which should be given. They do not consider how much information should be given.

#### Quantity of information

Previously, professionals revealed as much information as they thought was necessary; this often provided insufficient information. The minimum information which should be provided is that which a reasonable or average parent or child might want in order to make a decision about whether to undergo a procedure in similar circumstances. A more stringent standard is to provide the information which this individual parent or child might actually require to make the decision in question. Whatever standard is chosen there is a duty to answer all questions that the child or parents may have unless the doctor feels that to do so would be so harmful that he or she feels that it cannot be given. These circumstances are exceptionally rare. Without sufficient information neither children nor parents can be competent to make decisions.

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#### Voluntariness

The consent/assent process must promote and protect the dignity, privacy and confidentiality of the child and his or her family. The consent/assent must be obtained without forced or undue influence and should not take place under duress. There may be circumstances, e.g. an acute emergency, where time constraints apply. The power imbalance in the doctor-patient relationship can also be a factor in reducing voluntariness.

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#### In what situations is informed consent/assent necessary?

Consent or assent is required for all medical care, for preventive, diagnostic or therapeutic measures and research. Usually it is necessary to obtain express con-

sent in which an individual is specifically asked to consent/assent to the procedure in question, e.g. appendectomy for acute appendicitis. Consent may be implied when an individual presents themselves or is presented for a procedure to which general agreement has been agreed or implied. For example, a child's presentation by a parent for immunisation as a result of a letter of invitation is often taken as being implied consent/assent for this procedure. Nevertheless, information about benefits and risks should be regarded as mandatory.

Consent may be written or verbal. Written consent provides some kind of record that the procedure has been discussed but may have no more legal force in some countries than verbal consent. Nevertheless, it is essential to provide a written account of the information which is being given to obtain consent. Assent may be given verbally.

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#### In what circumstances is consent/assent unnecessary?

Medical treatment may take place without consent/assent when the indication to intervene overrides the practicalities of obtaining consent/assent. Doctors need to satisfy themselves that either the child's life would be in danger or there is a serious risk to the physical or mental health of the child if treatment is not given. A doctor has a duty to act in the child's best interest and would need to show that is what he or she had done. It would be wise to have the written support of a colleague that the child's life would be in danger if treatment were not given. A record of the steps taken to try to obtain consent/assent should be kept. In most circumstances parents would be available to give consent but if they refuse to do so, e.g. in the case of a child who requires a blood transfusion but whose parents are Jehovah's Witnesses, then legal intervention may be necessary if there is sufficient time to do so.

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#### Refusal of treatment

It is logical to assume that a child who is competent to assent to treatment is also able to refuse treatment even if doctors feel that it is in the child's interest. However, thus is not necessarily the case in law whose function in this instance is to protect the child or others from harm.

Children may refuse treatment or procedures which are not necessary to save their lives or prevent serious harm, e.g. blood tests or minor dental procedures. Attempts should be made to persuade them that the procedure is in their best interests but in general, the treatment should be postponed until the child is able to agree to it.

Where treatment is necessary to save life or prevent harm, the doctor has a duty to act in the best interest of the child. In these circumstances the consent of the parents is usually obtained and in law is often regarded

as sufficient. However, parents may also refuse to consent and in this case national laws and legal mechanisms for resolving the dispute may be used.

Children may also refuse treatment if mental illness renders them incompetent to consent/assent to treatment which is otherwise in their best interest, e.g. an adolescent with anorexia nervosa who refuses feeding support. Although treatment may proceed with parental consent or by invoking appropriate medical health legislation, it is good to listen carefully to children and explain to them why their wish to refuse treatment is going to be overruled. Very rarely children may consent to treatment which is in their best interest but also dangerous or experimental and to which their parents refuse. If they are competent to understand fully the nature and purpose of what is involved, then their choice should generally be respected.

Many disputes about consent/assent and refusal can be resolved by devoting time and energy to discussions with parents and children by perhaps involving advocates, religious advisers etc. However, in cases where resolution cannot be achieved, the appropriate legal steps are taken. Such documentation should include clear justification as to why a child's right might be infringed.

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## Research

Research involving children is important in terms of the benefits which it may provide to both individual children, children in general and to society. However, all research must fulfill strict ethical criteria and must be subject to valid consent/assent. All research proposals should be subject to evaluation by research ethics committees/review boards which will usually require that:

1. The research proposed will answer a valuable scientific question.
2. The research needs to be done in children.
3. The research has a favourable risk-benefit ratio.
4. A written information leaflet will be given.
5. A written consent will be obtained.
6. Adequate time is provided for consent.
7. Withdrawal of consent may occur at any time without any consequences for patients or parents.
8. The person obtaining consent/assent will be the person who is carrying out the research project.

Studies suggest that children over 9 years of age can understand quite complex metabolic projects but

national and international law on this matter are often unclear.

In general children should give their consent/assent to be involved in research also when the parents have given consent. This is especially so if children are involved in projects which carry no tangible benefit to them e.g. the provision of blood samples to obtain controlled data of normal population value.

Guidelines for the process of obtaining informed consent/assent in biomedical research involving children are laid down by a separate document of the ethics working group of the CESP.

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