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BIO/ENF-CP Drafting Group
on Developing a Guide to good practice concerning
the participation of children in the decision-making process
on matters regarding their health

GUIDE TO GOOD PRACTICE CONCERNING THE PARTICIPATION OF CHILDREN IN THE DECSION-MAKING PROCESS ON MATTERS REGARDING THEIR HEALTH

Draft Outline

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Introduction

Children have a right to participate in decisions about their lives concerning relevant issues that affect them, including but not limited to their health, education, social and democratic life, and the environment. The recognition of this, along with greater acknowledgement of children's evolving capabilities, has led to an increasing awareness that children's views must be given value in European and national policies.

The *Committee of Ministers Recommendation (2012)2 on the participation of children and young people under the age of 18*[1] establishes guidelines on the implementation of active and meaningful child participation, including by promoting the establishment of safeguards for the participation of children in healthcare. Importantly, it defines child participation as "a process where children and young people have the right, the means, the space, the opportunity and, where necessary, the support to freely express their views, to be heard and to contribute to decision-making on matters affecting them, their views being given due weight in accordance with their age and maturity". To promote and facilitate the implementation of the CM Recommendation, concrete steps have been taken by involving children in the organisation's work and supporting member states in creating national frameworks to incorporate such approach in their standard policy-making practice. The current Council of Europe Strategy for the Rights of the Child (2016-2021)[2] and the upcoming one (2022-2027) both display child participation as a priority area and have encompassed the consultation of children in several member states to include their views. The Council of Europe has also developed several practical tools, such as a Child Participation Assessment Tool (CPAT)[3] and a Handbook on children's participation for professionals working for and with children[4], including professionals in the health sector. These tools are being widely used, including in the framework of co-operation projects.

The child-friendly health care approach, rooted in the United Nations Convention on the Rights of the Child (UNCRC) and promoted by the Council of Europe Guidelines on child-friendly health care[5], establishes participation of children in their own health care, and in the development of health systems and policies as among the essential elements required to ensure children's access to health care and optimal health outcomes. Children's rights, needs and resources have to be placed at the centre of health care activities, taking into account their family and social environment. Policies to deliver child-oriented services based on child-specific developmental needs and evolving capacities are to be promoted, ensuring children's participation at every level of decision making, in accordance with their age and degree of maturity. This implies their being informed and consulted and given the opportunity to also take part in social decision-making processes on health care issues, including the assessment, planning and improvement of health care services.

Aim of the guide

The guide will be based on children's right to participate in decision-making processes regarding their health, implementation principles of Article 12 of the UNCRC (and its General Comment) in compliance with Oviedo Convention and its relevant Additional protocols.

Acknowledging the need to recognise the evolving nature of the decision-making capacity of children also in biomedical field and matters regarding their own health, the Guide aims at:

[1] Council of Europe CM Recommendation (2012)2 on the participation of children and young people under the age of 18.

[2] Council of Europe Strategy for the Rights of the Child (2016-2021)

[3] https://www.coe.int/en/web/children/child-participation-assessment-tool

[4] Council of Europe Handbook on children's participation "Listen – Act – Change" (2020) https://rm.coe.int/publication-handbook-on-children-s-participation-eng/1680a14539

[5] Council of Europe guidelines on child-friendly health care (2011) https://rm.coe.int/guidelines-of-the-committee-of-ministers-of-the-council-of-europe-on-c/16808c3a9f

- Identifying principles and concepts, relevant for the biomedical field, governing the right to participation;
- Clarifying the rights, responsibilities and interests of the child, legal representatives, and healthcare professionals;
- Presenting good practices in involving children in medical decision making giving due weight to child views.

Target group

This guide will target health professionals and will be accessible to children's legal representatives (e.g., parents) and other stakeholders, such as public health decision makers.

Background

The UNCRC Committee's General comment N.12, clearly specifies that children, including young children, should be included in decision-making processes, in a manner consistent with their evolving capacities. They should be provided with information about proposed treatments and their effects and outcomes, including in formats appropriate and accessible to children with disabilities. Furthermore, the introduction in some countries of a fixed age at which the right to consent transfers to the child should be encouraged. Thus, "children above that age have an entitlement to give consent without the requirement for any individual professional assessment of capacity after consultation with an independent and competent expert". However, it is strongly recommended that "States parties ensure that, where a younger child can demonstrate capacity to express an informed view on her or his treatment, this view is given due weight" [6].Physicians and health-care facilities should also provide clear and accessible information to children on their rights concerning their participation in paediatric research and clinical trials. They have to be informed about the research, so that their informed consent (defined as assent in many guidelines and texts relevant for research) can be obtained in addition to other procedural safeguards.

In a more collective dimension, measures enabling children to contribute their views and experiences to the planning and programming of services for their health and development should also been introduced[7]. This information can be obtained through, inter alia, feedback systems for children using services or involved in research and consultative processes and to develop standards and indicators of health services that respect the rights of the child.
Furthermore, respect for right of the child to be heard within education is considered as fundamental also to the realization of the right to education. Actions should be encouraged to build opportunities for children to express their views and for those views to be given due weight.

The active role of children in a participatory learning environment should be promoted, in all educational environments, including educational programmes in the early years, taking into account life conditions and prospects of the children[8].

[6] Moreover, nnational legislation or regulations shall ensure that children have access to confidential medical counselling and advice without parental consent, irrespective of the child's age, where this is needed for the child's safety or well-being. The right to counselling and advice is distinct from the right to give medical consent and should not be subject to any age limit.

[7] Their views should be sought on all aspects of health provision, including what services are needed, how and where they are best provided, discriminatory barriers to accessing services, quality and attitudes of health professionals, and how to promote children's capacities to take increasing levels of responsibility for their own health and development. See para. 100-104 https://www2.ohchr.org/english/bodies/crc/docs/advanceversions/crc-c-gc-12.pdf

[8] To include children's and their parents' views in the planning of curricula and school programmes should be important.

Another fundamental legal principle underpins the rights of the child in Europe is the "best interest" of the child, as a primary or paramount consideration (and in certain circumstances as the higher standard applicable) in all matters concerning children[9]. It is closely intertwined with the principle of "evolving capacities of the child"[10] and based upon the recognition that an adult is only in a position to take decisions on behalf of a child because of the child's lack of full legal capacity, as well as of experience and judgment. Stemming from the acknowledgement that childhood is not a single, fixed, universal experience, children require, at different stages in their lives, different degrees of protection, provision, prevention and participation. Thus, children's wishes should be considered seriously, notably in the field of healthcare and biomedical research.

It is also important to underline that the Charter of the European Association for Children in Hospital[11], by emphasising the primacy of the child's welfare and their best interest, contributed significantly to the development of patient charters and the inclusion of fundamental and social rights in national legislation relevant for the health sector (such as the right of the child to the enjoyment of the highest attainable standard of health, respect for the view of the child, right to appropriate information, right to privacy …).

Legal context

Article 5 of the Convention on Human Rights and Biomedicine (the Oviedo Convention)[12] lays down the general rule that an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given clear and suitably worded information as to the purpose and nature of the intervention as well as on its consequences and risks. Furthermore, consent may be freely withdrawn at any time. Article 6 of the Oviedo Convention specifies that where, according to national law, a minor does not have the capacity to consent to an intervention, the intervention may be carried out only with the consent of parents who have custody of the minor, his or her legal representative or any person or body provided for by law. However, as far as possible, with a view to the preservation of the autonomy of persons with regard to interventions affecting their health, Article 6, paragraph 2, second sentences states that "the opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity". This means that in certain situations which take account of the nature and seriousness of the intervention as well as the minor's age and ability to understand, the minor's opinion should increasingly carry more weight in the final decision[13]. In the specific area of research, Article 17 stipulates that research can be undertaken only if, among other conditions, "the person concerned does not object".

Regarding the recognition of a right for minors to participate in treatment and research decisions, substantial discrepancies exist between national laws. Across Europe, the statutory age at which a child is considered able to consent varies from 12 years to 18 years.

- In some countries, the legal age for consent to a medical intervention corresponds to the age of legal majority, and children and adolescents younger than this age will require authorisation from their legal representatives before an intervention can be carried out. However, some national laws recognise the need for informing minors and taking their will into account, according to their cognitive capacity.
- In other countries, children and adolescents younger than the age of legal majority can give consent without their parents' or guardians' authorisation, or they are entitled to

[9] Please refer to: PDF- The best interests of the child – A dialogue between theory and practice (coe.int)

[10] Lansdown G., The Evolving Capacities of the Child, UNICEF 2005 https://www.unicef-irc.org/publications/pdf/evolving-eng.pdf

[11] European Association for Children in Hospital *Charter of the European Association for Children in Hospital* (1986).

[12] CETS no. 164, Full list (coe.int)

[13] Para. 45 of the Explanatory Report to the Oviedo Convention, https://rm.coe.int/16800ccde5

> receive information and to make decisions, according to their maturity and competence in relation to the nature of the health issues concerned.[14]

Taking into account that to exercise his/her right to be heard, a child has to be capable of understanding. The notion of discernment or Decision-making capacity (DMC) is an important notion to be considered. According to national laws, the discernment or DMC can be evaluated by those who are supposed to interact with the child (notably the healthcare professionals) or can be determined by the legislator who sets a minimum age for the exercise of the right to be heard, or the discernment[15].

The right to receive information and/or to express his/her will, on the basis of the evaluation of the degree of maturity or of the capacities or of the level of development of the child is recognized in **Italy, Belgium, France, Germany, Finland, Hungary, Monaco**. The situation is more complex in Spain, where different provisions exist according to the autonomous communities' laws. In **France**, healthcare professionals do not have to obtain the parent's or guardian's consent when medical treatments are necessary to safeguard the health of a minor or when the minor expressly refuses the consultation of the holders of parental authority. In **Belgium** the minor can independently exercise their rights if he/she can be considered as being able to reasonably assess his/her interest. In **Monaco,** health professionals can be exempt from obtaining the consent of legal representatives when the minor refuses their consultation for the medical acts or treatments that can be carried out anonymously according to legal provisions in force.

The exercise of the right to receive information or to express his/her will is recognized once the child reached the minimum age set by legislators in **Austria**, **Bulgaria, Italy, Norway, Ireland, Portugal, the Netherlands, Ukraine and Denmark**. The age ranges vary from 7 to 16 years and are combined with different conditions (see Tables 1 and 2). For example, in **Norway**, the child who is able to form their own opinions has the right to receive information and give opinion from 7 years. From 12 child has the right to refuse to inform parents about his/her health and from 16 the child can give consent, unless special provisions, or where the nature of measures dictate otherwise. In **Ukraine**, children from 14 have the right to choose a doctor and treatments methods according to the doctor's recommendation. Medical treatment shall be provided upon his / her written consent as well as that of his/her legal representative. Nevertheless, since a child from 14 is required to consent to medical intervention but can receive information only from the age of 18, a normative dissonance exists. In **Italy**, the minor or the person must receive information concerning their choices with regards to their health in a way that is appropriate to their capacities, so as to being in proper conditions to express their wishes. Furthermore, not specifically for the healthcare sector, it is specified that the minor from the age of 12, or even younger where capable of understanding, has the right to be heard in all matters and procedures that concern him or herself.

In **Austria**, it is assumed that a child older than 14 years is capable of making decisions. Nevertheless, in case a child capable of making decisions gives its consent to a medical treatment, which normally induces severe and enduring physical or psychological damage, such medical treatment may only be administered if the legal representative gives his consent as well.

Table 1. Ages set by legislator to recognise the child able to take a decision

Age	Country
7	Norway *

[14] Altavilla A, Halila R, Kostopoulou M-A, Lwoff L, Uerpmann K, Strengthening children's participation in their health: the new initiative of the Council of Europe, Lancet Child Adolesc Health 2021 Feb 10. Doi: 10.1016/S2352-4642(21)00019-5

[15] Altavilla A, Summary of the survey results on children participation in decision making process regarding their health *summary commissioned by the Committee on Bioethics (DH-Bio) of the Council of Europe.

12	Netherlands (child can be associated to decisions) Italy (right to be heard not only in the healthcare sector)
14	Austria*, Ukraine *
15	Denmark (right to consent/refuse)
16	Bulgaria, Ireland*, Norway* Netherlands* Portugal (regardless of level of education literacy/cultural characteristics)
16 or judged to be Gillick competent[16]	UK & Scotland minor patients from 16 years of age or judged to be "Gillick competent" are commonly granted the right to consent to treatment but not to refuse it

**Conditions for including the child in decision process according to the age (See Table 2)*

Table 2. Conditions for including the child in decision process according to the age

Country	Conditions for including the child in decision process according to the age
Austria	Even in case a child capable of making decisions gives its consent to a medical treatment, which normally induces severe and enduring physical or psychological damage, such medical treatment may only be administered, if the legal representative gives his consent as well
Ireland	Specific conditions for treatment/diagnostic with increased risk
Netherlands	Above 16 of age the child can decide on her or his own and can also decide that the legal guardian will not be informed
Norway	From 7 or younger, if the child is able to form their own opinions, right to receive information and give an opinion From 12 right to refuse to inform parents about his/her health From 16 right to give consent unless special provisions or the nature of measures dictate otherwise
Ukraine	From 14 children must consent to medical intervention but receive information from the age of 18 (normative dissonance)

In the context of research, the respect of the wish of the minor concerned has been included in many legal frameworks. National legislations on research are essentially compliant with the provisions of the Oviedo Convention and its additional protocol on research provisions as well as, where applicable, with EU Directive 2011/20 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (with some national specificities, especially in terms of age ranges). This means that, within research, the explicit wish of a minor who is capable of forming an opinion and assessing the information referred, to refuse participation in, or to withdraw from the clinical trial, at any time, is to be respected. This principle implies that national legislations integrate the need to provide information to the child according to his/her capacity of understanding.

[16] Adolescents from 16 years of age or children considered "Gillick competent" (no age limit), that is, those who demonstrate "sufficient understanding and intelligence … to fully understand what is proposed" and have "sufficient discretion to… make a wise choice …" can provide consent to treatment. However, a refusal can be overruled if treatment is considered to be in the child's best interest. Gillick competency derives from the Gillick v West Norfolk and Wisbech AHA Case (1986), where the court's ruling stated that "whether or not a child is capable of giving the necessary consent will depend on the child's maturity and understanding and the nature of the consent required. The child must be capable of making a reasonable assessment of the advantages and disadvantages of the treatment proposed, so the consent, if given, can be properly and fairly described as true consent". Ruhe K M, Wangmo T, Badarau D O, Elger B S, Niggli F , Decision-making capacity of children and adolescents—suggestions for advancing the concept's implementation in pediatric healthcare Eur J Pediatr. 2015 Jun;174 (6): 775-82.

In most European countries[17], the written consent of both parents in addition to the child's own assent or consent is required following different conditions. The new EU Regulation 536/2014 on clinical trials is significantly progressive with respect to 'dissent' of the child and include a definition of assent.

In this context, it should be important to elucidate notions of informed consent in relation to information, assent and decision-making competence (DMC).

The informed consent process implying information, consent, assent and Decision Making Capacity (DCM)

Informed consent

The Informed Consent is the decision, taken freely after being duly informed of the nature, significance, implications and risks of an intervention (including all medical acts, in particular interventions performed for the purpose of preventive care, diagnosis, treatment, rehabilitation or research) by any person capable of giving consent or, where the person is not capable of giving consent (minors), by his or her legal representative.

The three central elements necessary for informed consent are the information, the decision-making capacity (DMC) and the voluntariness. The voluntariness represents the absence of undue influence on the decision-making process including fear, pain, false beliefs, or incorrect information).

Information

The patient's consent is considered to be free and informed if it is given on the basis of objective information from the responsible health care professional as to the nature and the potential consequences of the planned intervention or of its alternatives, in the absence of any pressure from anyone. Information on the risks involved in the intervention or in alternative courses of action must cover not only the risks inherent in the type of intervention contemplated, but also any risks related to the individual characteristics of each patient, such as age or the existence of other pathologies. Requests for additional information, also according to circumstances, made by patients must be adequately answered. Moreover, this information must be sufficiently clear and suitably worded. The child must be put in a position, through the use of terms he or she can understand, to weigh up the necessity or usefulness of the aim and methods of the intervention against its risks and the discomfort or pain it will cause[18].

Information should be targeted at different age groups and abilities, making sure that time is given to fully inform children about their condition. This includes discussions as to what is happening to them, what treatments are proposed, what options are available, implications of all the options, side effects of treatments, and likelihood of pain and discomfort. Information and explanations are given in age-appropriate language, in a way that is consistent with the child's understanding, giving children the opportunity to ask questions and explore their concerns and deal with them honestly and fully. Children should be given time to consider what they want, making clear to the child that his/her concerns will be taken seriously when decisions are being made. If a decision is made against the child's wishes, it should always be explained to the child why that decision has been made and how all efforts will be made to take account of his/her fears or concerns. Policies on consent and confidentiality should be developed making sure that all relevant staff, as well as children are aware of them[19].

[17] Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, France, Germany, Italy, Lithuania, Malta, Netherlands, Norway, Portugal, Romania, Sweden. Lepola P. et al., Informed consent for paediatric clinical trials in Europe, Arch Dis Child, 2016 (0), 1-9.

[18] Oviedo Convention Explanatory Report https://rm.coe.int/16800ccde5

[19] Lansdown G, Every child's right to be heard: a resource guide on the UN Committee on the Rights of the Child general comment no. 12.

The provision of adequate information in a manner that facilitates understanding is a central element. It influences paediatric patients' comprehension and information-processing skills and thereby the decision-making capacity (closely linked to the notion of competence). However, informing patients appropriately about treatment or procedures is independent of the presence of DMC [20] The notion of DMC should be clarified also with regard to the competence.

DMC versus Competence

DMC is defined as a person's cognitive ability to manipulate information in order to reach a decision[21].Competence refers to the authority of a person to transform such choices into legally binding decisions within the limitations of the law[22]. As such, competence is usually used as a legal concept, while DMC is a clinical construct and a criterion and a necessary requirement for legal competence [23].

Whereas adult persons are presumed to have legal capacity unless the presence of DMC is rebutted[24], children lack capacity. Therefore, they cannot provide legally valid consent to medical treatment. As already underlined, to treat a minor patient, authorisation from a parent or a guardian is required. However, some national legislations acknowledge that the ability to make healthcare decisions may be present in older children and thus give limited decision-making rights to those who fulfil standards of DMC[25].

While legal capacity and DMC are two distinct concepts, an inconsistent use of terminology as well as unclear conceptualizations can be found in the literature and in practice[26]. This may partly stem from the close relationship between the two[27] and from differences in the use of these terms across countries[28]. In paediatrics, however, it seems important to keep these two terms clearly apart because, although children do not generally have the right to make legally binding decisions, they participate in the decision process (may consent) to treatment if they demonstrate DMC.

DMC and legal capacity are close concepts, but they are not interchangeable, and possessing DMC does not automatically lead to having competence in minors. This becomes evident when turning to jurisdiction in the UK where minor patients from 16 years of age or judged to be

[20] British Medical Association (2000) Involving children and assessing a child's competence. In: British Medical Association (ed) Consent, rights and choices in health care for children and young people. BMJ Books, London, pp 92–pp 103.

[21] Grisso T, Appelbaum PS (1998) Why competence is important: the doctrine of informed consent. In: Grisso T, Appelbaum PS (eds) Assessing competence to consent to treatment: a guide for physicians and other health professionals. University Press, Oxford, pp 1–15.

[22] Spaak T, The concept of legal competence. The IVR Encyclopeadia of Jurisprudence, Legal Theory, and Philosophy of Law, May 2005.

[23] Bielby P (2005) The conflation of competence and capacity in English medical law: a philosophical critique. Med Healthc Philos 8:357–369

[24] Lo B, Assessing decision-making capacity. JLME (1990) 18:193–201.

[25] Alderson P (2007) Competent children? Minors' consent to health care treatment and research. Soc Sci Med 65:2272–2283

[26] Appelbaum PS (2007) Assessment of patients' competence to consent to treatment. New Engl J Med 357: 1834–1840; Ruhe K M, Wangmo T, Badarau D O, Elger B S, Niggli F, Decision-making capacity of children and adolescents—suggestions for advancing the concept's implementation in pediatric healthcare Eur J Pediatr. 2015 Jun;174 (6): 775-82.

[27] Bielby P (2005) The conflation of competence and capacity in English medical law: a philosophical critique. Med Healthc Philos 8:357–369

[28] Legal competence and clinical decision-making capacity are used in the US, legal capacity and decision-making competence in the UK [12, 13], occasionally, also the term competency can be found [15, 60, 64]). See Berg J (1996) Constructing competence: formulating standards of legal competence to make medical decisions. Rutgers L Rev 48:351–395; Bielby P (2005) The conflation of competence and capacity in English medical law: a philosophical critique. Med Healthc Philos 8:357–369; Brook G (2000) Children's competency to consent: a framework for practice. Paediatr Nurs 12:31–35;

Gillick competent are commonly granted the right to consent to treatment but not to refuse it (e.g. UK, Scotland)[29].

Consent versus Assent

A distinction between consent and assent is also relevant. In particular, assent is considered a means to account for the developmental nature of decision-making abilities in children [30]. Whereas consent presumes DMC and thus the right to make a final choice, assent acknowledges children's active involvement in healthcare and recognizes that their decision-making abilities are developing [31]. Hence, capacity to assent represents a lower level of DMC given that appreciation and reasoning criteria are not applicable. If a child is considered capable of assent, his or her assent should be sought in addition to parental permission[32].

The notion of assent, introduced by the Declaration of Helsinki[33] and mentioned in the WHO-CIOMS[34] and ICH-E11[35] guidelines, was introduced into the EU legal framework only with Regulation 536/2014[36]. Nevertheless, States which ae bound by this framework, still have a large margin within which to manoeuvre in applying this principle, possibly leading to some disparities, especially with multinational trials.

The new Regulation is significantly progressive with respect to 'dissent' of the child. While Directive 2001/20/EC notes that dissent of the child has to be 'considered', the new Regulation now expects it to be 'respected': 'the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in Article 29(2) to refuse participation in, or to withdraw from, the clinical trial at any time, is respected by the investigator'.

Finally, Guidelines have been developed in the European Ethical considerations for clinical trials in paediatrics[37] and, more recently by the EMPREMA Working Group on Ethics that develops an overview tool[38] of the contents for assent/informed consent forms for all stakeholders (such as patients, sponsors and investigators) to support the conduct of high quality paediatric clinical trials in the EU across all paediatric age groups from birth to less than 18 years of age.

Principles governing children participation as a process

[29] See above note 12.

[30] Kuther TL (2003) Medical decision-making and minors: issues of consent and assent. Adolescence 38:343–358; Levy MDL, Larcher V, Kurz R (2003) Informed consent/assent in children. Statement of the ethics working group of the Confederation of European Specialists in Paediatrics (CESP). Eur J Pediatr 162: 629–633

[31] Lee KJ, Havens PL, Sato TT, Hoffman GM, Leuthner SR (2006) Assent for treatment: clinician knowledge, attitudes, and practice. Pediatrics 118:723–730

[32] Leikin SL (1983) Minors' assent or dissent to medical treatment. JPediatr 102:169–176

[33] World Medical Association (WMA), 'Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (as amended in 2013)' [1967], Paragraph 29.

[34] Council for International Organizations of Medical Sciences (CIOMS), 'International Ethical Guidelines for Biomedical Research Involving Human Subjects' [2002], Guideline 14.

[35] ICH E11 Clinical Investigation of Medicinal Products in the Pediatric Population [2000]. Paragraph 2.6.3, p. 11.

[36] EU Member States may foresee, in their national law, that the 'minor who is capable of forming an opinion and assessing the information given to him or her, should himself or herself assent in order to participate in a clinical trial'. Regulation (EU) N°536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use,and repealing Directive 2001/20/EC [2015] OJ L 158/1. Preamble Recital 32 and Article 29.8.

[37] European Commission, Ethical considerations for clinical trials on medicinal products with the paediatric population' Final 2017

[38] Enpr-EMA's Working Group on Ethics, Assent / Informed Consent Guidance for Paediatric Clinical Trials with Medicinal Products in Europe (2021) https://www.ema.europa.eu/en/documents/other/assent/informed-consent-guidance-paediatric-clinical-trials-medicinal-products-europe_en.pdf

Regarding the children's participation in matters that concern them, four levels of participation have been identified in the literature: (1) being informed, (2) expressing a view, (3) influencing a decision, and (4) being the main decision-maker. In turn, children's level of participation should be informed by both their abilities and preferences [39].

Conditions for an ethical and impactful participation

To ensure that children's participation is safe, ethical, inclusive and impactful, in line with the General Comment on Article 12 of the UNCRC, all processes in which children and young people are heard should be transparent and informative, voluntary, respectful, relevant to children's lives, in child-friendly environments, inclusive (non-discriminatory), supported by training, safe and sensitive to risk, and accountable.

The right to participate is important not only as a right and a general principle but also because taking children's views into account in decisions and actions that affect them brings significant immediate and long-term benefits for children. Children have unique knowledge about their lives, needs and concerns. Using this knowledge, their ideas and views can lead to more improved individual decisions for children, and enhanced fulfilment of children's rights. Participation is a right not an obligation. Children are entitled to choose whether or not to express their views or participate in decision making on issues that affect them.

Appropriate and accessible information as pre-requisite

Participation provides opportunities to acquire additional knowledge, skills, confidence, experiences, competencies and extend aspirations. Children must be given the opportunity to gain the confidence, the time and a "safe and inclusive space" to contribute their views. Appropriate and accessible information is an important pre-requisite for the ability to speak out and express views and negotiate decisions. Adults have a responsibility to find ways in which to enable children to communicate their views, concerns or ideas.

The Recommendation on Participation and UN General Comment 12 makes it clear, on one hand, that it is not enough simply to listen to children. It is also necessary to seriously consider their views and take what they say into account in any subsequent action. On the other, the right to participate does not automatically lead to children's views being followed, in all circumstances and in every respect. However, it requires that their views are given proper consideration and that any subsequent decision is reported back to children with an explanation of how their views had an influence, and why the decision was made.

Participation as a rolling process

The Recommendation also makes it clear that children's participation is not a one-off event. Participation is a rolling process and does not stop with children's views being expressed, it involves adults and children co-producing decisions. Understanding participation in this way encourages children and adults to work together for a meaningful participation.

Finally, it has to be stressed that right to participation does not contradict the right to protection. Protection benefits from participation[40].

Aspects to be considered and further elucidated for the implementation of the right of the child to participation and to be heard

[39] McCabe MA (1996) Involving children and adolescents in medical decision making: developmental and clinical considerations. J Pediatr Psychol 21:505–516.

[40] UNICEF (2018) Conceptual framework for measuring outcomes for adolescents' participation https://www.unicef.org/media/59006/file. See also "Listen – Act- Change, Council of Europe Handbook on children participation for professionals working for and with children" (2021) https://rm.coe.int/publication-handbook-on-children-s-participation-eng/1680a14539.

Evidence from scientific literature indicates that children are generally excluded and not sufficiently involved in health decisions[41]. This exclusion includes their rights to information (CRC article 17) and the opportunity to express their views and concerns (CRC article 12) in the context of processes concerning informed consent on treatment and interventions as well as of research, service improvement, and policymaking impacting the health sector. Despite the legal context and the evidence that children benefit from participating in the decision-making process regarding their health, some challenges have to be faced for the engagement and the involvement of children in decision making process.

Challenges in implementing children participation

Children participation requires appropriate means and language to be adapted to key factors influencing children comprehension such as age, physical condition, previous knowledge and mental state, and socio and cultural contexts.

Factors such as parents' values, socio cultural background, physician's attitudes, the capacity of a child and the seriousness of a decision required all impact on the potential for a child to be actively involved in decisions regarding their health.

Ensuring participation of youth, especially young children, requires knowledge, self-confidence, imagination, and trust on the part of both providers and their paediatric patients. Paediatricians have expert knowledge about disease pathophysiology and treatment options that may be difficult to communicate to parents and children. Also, parents and legal representatives, within their responsibilities, may have their own perspectives that they may impose consciously or unconsciously on their children. Children, to the contrary, are often open and receptive to new information and knowledge—regardless of their age. Participation of children in paediatric care means that the child's voice must be heard, and his/her opinion respected. It is the responsibility of duty-bearers (e.g., physicians, nurses, parents) to ensure the rights and interests of rights-holders (children) are fulfilled.

Difficulties in assessing decision-making capacity of children

Physicians are mainly responsible for assessing decision-making capacity (DMC) but may encounter difficulties arising from the limited basis of evidence with regard to this concept in paediatrics. Three issues contributing to this paucity of knowledge on DMC of children can be identified: (1) conceptual blurriness and absence of clear terminology, (2) lack of validated tools to reliably assess DMC in the paediatric population, and (3) a need to include a developmental framework to understand DMC in children and adolescents[42].

In the medical, legal, and ethical literature children's DMC and their ability to satisfy these criteria for consent has been widely debated with regard to cognitive and behavioural characteristics of children[43], principles of child development[44], ethical considerations (e.g.,

[41] Moore M, Kirk S. A literature review of children's and young people's participation in decisions relating to health care, Journal of Clinical Nursing, 19, 2215–2225

[42] Ruhe K M, Wangmo T, Badarau D O, Elger B S, Niggli F, Decision-making capacity of children and adolescents—suggestions for advancing the concept's implementation in pediatric healthcare Eur J Pediatr. 2015 Jun;174 (6): 775-82.

[43] Grisso T, Vierling L (1978) Minors' consent to treatment: a developmental perspective. Prof Psychol 9:412–427

[44] Koocher GP, DeMaso DR (1990) Children's competence to consent to medical procedures. Pediatrician 17:68–73

autonomy vs. best interest approach)[45], parenting practices [46], professional attitudes [47], and legal issues [48].

Nevertheless, there is a need to promote research aiming at providing conceptual clarity, assessment tools, and profound knowledge of DMC within a developmental framework. By doing so, DMC may become informative and fruitful in providing paediatric patients with adequate and achievable possibilities to participate in or make healthcare decisions.

Assent of children: a complex notion

The concept of assent has received criticisms. On one hand, it has been stressed that, although assent is widely acknowledged to be desirable, its understanding remains blurry. If wrongly applied, it could represent a threat to the decision-making rights of those children who have DMC because physicians may content themselves with seeking assent while parents give consent. Furthermore, it could fail to provide guidance in situations where children and parents disagree[49].

On the other hand, it has been emphasized that an understanding of assent does not necessarily have to be linked to the questions of who makes the final decision. Assent represents a means of ensuring that children who are capable of grasping some aspects of the decision at hand are not overlooked and included in the decision process to an appropriate extent. Not soliciting assent even in situations where treatment is considered imperative could overlook the importance of taking into account the child's view. Furthermore, in case the child disagrees, such conflict should be addressed, and attempts should be made to resolve it together with the patient[50].

Hence, conceptualizing assent as inferior to consent does not appear to be useful for a developmental conceptualization of decision-making capacities. Instead, the capacity to assent needs to be perceived as a steppingstone in capacity development carrying value in informing appropriate participation.

As there are several levels for possible participation, it becomes evident that an accurate assessment of patients' abilities is important not only with regard to a threshold (i.e., who makes the final decision) but also to adequately determine the extent of children's involvement.

In this context, it has to be stressed that chronological age alone is identified as the main criterion for allowing children to participate in decision-making, ignoring the principle of "evolving capacities" promoted in a number of CRC articles. In few European countries the developmental stage of competence is regarded as the key factor for involving children in decision-making. [51] The age limit for seeking children's consent before invasive diagnostic or therapeutic measures ranges between 12 and 18 years. Health education is generally included

[45] Miller VA, Drotar D, Kodish E (2004) Children's competence for assent and consent: a review of empirical indings. Ethic Behav 14: 255–295

[46] Scherer DG, Reppucci ND (1988) Adolescents' capacities to provide voluntary informed consent: the effects of parental influence and
medical dilemmas. Law Hum Behav 12:123–140

[47] Mårtenson EK, Fägerskiöld AM (2007) A review of children's decision-making competence in health care. J Clin Nurs 17: 3131–3141

[48] Schlam L, Wood JP (2000) Informed consent to the medical treatment of minors: law and practice. Health Matrix 10:141–174

[49] Baines P, Assent for children's participation in research is incoherent and wrong. Arch Dis Child (2011) 96:960–962

[50] Bartholome WG, Informed consent, parental permission, and assent in pediatric practice. Pediatrics (1995) 96:981–982

[51] Ehrich J, Damm L, Leiss U, Guerreiro AJ, Lenton S. Partizipation europäischer Kinder in der Medizin. Paediatr Paedolog 2014; 49 (Suppl 1):19-24.

in school curricula; however, it is unclear if the child's rights to health, participation, equity, and social justice are also included[52].

Training and play to learn

Training regarding access to information, communication, and participation with children was reported to be rare in most European countries. The spectrum of European countries' translation of the principles and standards of the CRC and children's rights into practice is also to be highlighted. National guidance with respect to youth participation in health venues is based less on science and more on culture and history. [53]

A lack of ongoing training of healthcare professionals in communicating with children is an important factor that negatively influences the participation of children. This is despite the associated finding that promoting children's competence in complex decision-making is an essential factor in improving their health.[54]

Furthermore, a core principle of the right to participation is that information must be provided in a language and/or form of communication that is congruent with the child's evolving capacity to understand and respond. Issues may occasionally arise in which parents' perspectives of what is in their child's best interest (CRC article 3) differs from that of the child and/or provider. It is important in these situations to ensure the child has access to information that s/he can understand and process in order for him/her to have an informed voice in decisions that are being made on his/her behalf.

To this aim, in line with self-determination theory, age appropriate and child friendly training, as well as game design elements can be used to enhance children (learners') autonomy and competence, to foster their knowledge and awareness of relevant issues as well as their intrinsic motivation and feelings of relatedness. Nevertheless, a thoughtful approach and consideration of children peculiarities and overarching learning objectives should be taken when developing training and integrating game design[55] elements especially in health sector.

Contexts raising specific ethical and legal issues

Finally, technological developments in the field of biomedicine create new possibilities for intervention in individual behaviour. Certain technologies allow for the permanent health monitoring of individuals. Moreover, the evolution of existing practices, such as the collection and sharing of genomic and health data, as well as the use of advanced therapies and genetic techniques (having also future or long-term implications for children) raise novel questions relating e.g., to autonomy, privacy, and even freedom of thought. Furthermore, the current pandemic crisis has a severe impact on individuals and societies. It raises major ethical challenges that professionals and competent authorities have to address in the health care of patients, taking also into account the needs of children. There should also be consideration of other important social trends (e.g., pressure of social media on young people) and changing societal perceptions in how to balance the protection and respect for autonomy of children, with increased recognition of their decision-making capacities and their rights.

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[52] The International Network of Health Promoting Hospitals and Health Services (HPH). http://www.hphnet.org/index.php?option=com_content&view=article&id=1551:hp-for-children-a-adolescents-in-a-byhospitals-&catid=20&Itemid=95 .

[53] Ehrich J, Damm L, Leiss U, Guerreiro AJ, Lenton S. Partizipation europäischer Kinder in der Medizin. Paediatr Paedolog 2014; 49 (Suppl 1):19-24.

[54] Damm L, Leiss U, Habeler U, Ehrich J. Improving care through better communication: understanding the benefits. J Pediatr 2015;166:1327-8.

[55] Rutledge C, Walsh CM, Swinger N, Auerbach M, Castro D, Dewan M, Khattab M, Rake A, Harwayne-Gidansky I, Raymond TT, Maa T, Chang TP; Quality Cardiopulmonary Resuscitation (QCPR) leader board investigators of the International Network for Simulation-based Pediatric Innovation, Research, and Education (INSPIRE). Gamification in Action: Theoretical and Practical Considerations for Medical Educators. Acad Med. 2018 Jul;93(7):1014-1020. doi: 10.1097/ACM.0000000000002183. PMID: 29465450.

In this context, a guide on children participation in decisions regarding their health is developed to assist health care professional, but also parents, guardians and other persons having responsibilities for children, to better understand, support and implement the children's rights to participation and to be heard.

After having introduced the main internationally recognised principles governing the right of the child to participate in decision making process, especially regarding his/her health, this guide will present principles and considerations that can help main stakeholders in developing a participatory organisation and environment in healthcare/research settings. Moreover, supporting participation of individual children in decision making by promoting adequate activities (training, pay and learn, evaluation…) are explored.

Keeping in mind that the child's autonomy has to be conceptualised as "the child's right to an open future" and that there is a need to safeguard children's rights in relation to practices which have future or long-term implications for them or imply a risk of infringement of fundamental rights, areas that deserve special attention (reinforced actions at national, hospital and individual level) have been identified and more adequate provisions will be developed to be implemented in these contexts.

The Guide also regularly refers to the results of a survey specifically carried out for its preparation. 185 replies were collected from 36 countries, including those of healthcare professionals, members of scientific societies and research organisations as well as members of children/family's associations.

Definitions:
For the purpose of the present guide:
- "children" refers to any person under the age of 18 years;
- "participation" is about individuals and groups of individuals having the right, the means, the space, the opportunity and, where necessary, the support to freely express their views, to be heard and to contribute to decision making on matters affecting them, their views being given due weight in accordance with their age and maturity. Participation is also **an ongoing process of children's expression and active involvement in decision-making at different levels in matters that concern them. It requires information-sharing and dialogue between children and adults based on mutual respect**[56].

[56] UNICEF, Every Childs Right to be Heard, Report 2011, https://resourcecentre.savethechildren.net/node/5259/pdf/5259.pdf

OUTLINE

Introduction
1.Children participation in decision making process related to their health: legal/ethical framework

- **Legal context (consent, assent, information, DMC)**
- **Principles governing children participation**
- **The role of parents**
- **The role of healthcare professionals**
- **…and children**

2. Developing participatory organisation and environment in healthcare/research settings

- Organisational Policy and procedures
- Building staff capacity / Training health professionals/family
- Child friendly complaints/evaluation mechanisms

3.Supporting the participation of children in decision making

- Improving information
- Exploring children's views
- Training for children
- Play and learn
- Following up actions
- Actions within challenging biomedical contexts (examples from pandemic situations, advanced therapies, genetics, sensitive paediatric data use and sharing…)