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STEERING COMMITTEE FOR HUMAN RIGHTS IN THE FIELDS OF BIOMEDICINE AND HEALTH (CDBIO)

STEERING COMMITTEE FOR THE RIGHTS OF THE CHILD (CDENF)

GUIDE TO CHILDREN'S PARTICIPATION IN DECISIONS ABOUT THEIR HEALTH

Adopted:

- **by the CDBIO at its 4th meeting (14-17 November 2023, Riga)**
- **by the CDENF at its 8th meeting (14-16 November 2023, Strasbourg)**

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Abstract

International human rights instruments recognise that children are rights holders with evolving abilities to make decisions in all aspects of their lives, of which health care is a part.

Research also provides evidence of multiple benefits of meaningful participation relating to health and health care, and this has increasingly been considered an important contributor to high-quality care for children and to enable them to achieve the best possible state of health.

However, there is often uncertainty as to how to support the practical realisation of effective child participation in real-world health care situations that are often complex, and accounting for differing legislative frameworks and the roles of other actors such as parents and health professionals. As a result, children currently experience a wide spectrum of practice across member states of the Council of Europe and there is always room for improvement.

The Guide provides practical guidance, primarily for health care professionals, about how to involve all children in decision-making processes concerning their own health. It provides the reader with a concise understanding of the theoretical and legal context and progresses to describe important components of the decision-making process, helping health professionals to understand their role in supporting children, families, and other professionals to enact this in practice. Key concepts of consent, assent, and ‘best interests’ are discussed, as well as common health care situations where participation in decision-making may sometimes be perceived as more challenging. Examples and links to good practice are provided throughout.

I. Introduction

Human rights instruments, notably the UN Convention on the Rights of the Child (UNCRC), recognise that children are rights holders with a progressively evolving ability to make their own decisions. This reflects a change in the general perception of the autonomy and protection of children regarding their capacity to participate in decision-making. Since the adoption of the Convention in 1989, considerable progress has been achieved at the local, national, regional and global level in the development of legislation, policies and methodologies to promote the implementation of the right of all children to express their views.

Through its work, the Council of Europe strives to make this right a reality in its member states. The *Committee of Ministers Recommendation CM/ Rec(2012)2 on the participation of children and young people under the age of 18* provides guidelines on the implementation of active and meaningful child participation, which it defines as children 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", recognizing their evolving capabilities.
Further institutional guidance includes Listen – Act – Change - Council of Europe Handbook on children's participation - For professionals working for and with children (2020)

The UNCRC recognises that children have a right to express their views in all matters that affect them, and to have these views properly taken into account. Health is one such matter. Meaningful participation has increasingly been considered as a key standard for achieving high-quality care for children[1], as reflected in the Guidelines of the Committee of Ministers of the Council of Europe on child-friendly health care (2011). Through its current Strategy for the Rights of the Child (2022-2027)[2] and its Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025)[3], the Council of Europe seeks to further promote a child rights-based and participatory approach to health care and research.

Participation in health care in general, has been encouraged by the growing recognition that a patient is equipped with personal skills concerning their body and their state of health and that they are capable of actively contributing to the therapeutic relationship by collaborating and negotiating with the heath professional in order to achieve the best possible state of health.

Similarly, children have unique knowledge about their lives, needs and concerns and taking their views into account in decisions and actions that affect them brings significant immediate and long-term benefits for them, as well as for the community and enables to make better, more informed decisions. Children who actively participate in individual decision-making processes which concern them are likely to be more informed, to feel better prepared, and to experience less anxiety about the unknown. Participation instils children with a sense of control, which results in increased cooperation with procedures, better adjustment and adherence to treatment, which helps to reduce conflicts that may arise during these processes. Children develop competence and confidence,

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[1] WHO, Standards for improving the quality of care for children and young adolescents in health facilities, Report 2018, https://www.who.int/publications/i/item/9789241565554

[2] https://rm.coe.int/council-of-europe-strategy-for-the-rights-of-the-child-2022-2027-child/1680a5ef27

[3] https://rm.coe.int/strategic-action-plan-final-e/1680a2c5d2

leading to their empowerment and increasing ability. Participation also helps to improve care, as the child brings unique expertise from their own experience.

However, there is often uncertainty as to how the increased recognition of children's decision-making capacity in matters concerning their health and general well-being should be addressed in practice. Finding the right balance between autonomy (the right of children to be heard and their opinions considered) and protection (the responsibility of adults to protect children and to provide for them) is a challenge when considering that children's rights are situated within a larger set of parental duties and responsibilities which also focus on their best interests.

Scope and aim of the Guide

The Guide is intended to provide practical guidance about how to involve children in decision-making processes concerning their health. It aims, first and foremost, to help health care professionals, and other professionals involved:

1) to understand what their role is in supporting children, families and other professionals working to participate in the process,

2) to develop their practice in this area, informed by relevant principles, frameworks, legislation, and good practice.

It will also be helpful in sensitizing parents and/or legal representatives.

The Guide focuses on the participation of children in individual health-care decisions**.** However, children's involvement in the development of health policy and services also contributes to improving paediatric care generally, as well as individual decision-making processes (section IV).

For the purpose of this document, a "child" refers to any person under the age of 18 years. The term "parents" must be understood as "parents or other holders of parental authority".

Methodology

The Guide was prepared by a group of government[4] and independent experts and then submitted for consultation to key stakeholders (Council of Europe delegates, representatives of scientific societies, research organisations, health care institutions, etc) and its content was also discussed with a group of children.[5] The text was subsequently revised and enriched based on these contributions.

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[4] The drafting group comprised members of Council of Europe Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) and of the Steering Committee for the Rights of the Child (CDENF).

[5] Focus group discussions were held by TEDDY network and TEDDY Kids with 20 children aged 12-18 from six countries (Albania, France, Greece, Italy, Latvia, and Malta).

[This video was developed by TEDDY Network and TEDDY Kids, in coordination with the Council of Europe. A group of children took part in its design; they were aged between 12 and 18 years, coming from Italy, France, Greece and Albania, and included young patients and healthy children. It targets children of a similar age group.]

II. The legal and conceptual framework for children's participation in decisions about their health

A. The main provisions of international law

The United Nations Convention on the Rights of the Child (UNCRC)

In 1989, with the adoption of the *United Nations Convention on the Rights of the Child (UNCRC)*, a fundamental value underpinning children's rights was put forward: the vision that children, defined as any person under the age of 18 years[6], must be agents in their own lives, in particular, through **Article 12**, which sets out the right of all children to be heard and taken seriously, in a manner consistent with their evolving capacities:

> *Article 12: "1. States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.*

The right granted by this article later became known as "children's right to participation".

Through its *General Comment No.12 (2009) - The right of the child to be heard*[7], the Committee on the Rights of the Child provides guidance on how to interpret children's right to participate in different areas of life.

Regarding the provision of health care, it states the following:

- "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***".**

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[6] This definition is in line with the provisions of Article 1 of the UNCRC. Article 6 (2) of the Convention on Human Rights and Biomedicine, refers to the term "minor". For the purposes of this guide, the term "child" is used, unless direct reference is made to provisions using different terminology.

[7] UNCRC Committee (2009) General Comment No 12 The right of the child to be heard. Paragraphs 98-103 ; available at https://www2.ohchr.org/english/bodies/crc/docs/advanceversions/crc-c-gc-12.pdf.

- “States parties need to introduce legislation or regulations to 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. Children may need such access, for example, where they are experiencing violence or abuse at home, or in need of reproductive health education or services, or in case of conflicts between parents and the child over access to health services. The right to counselling and advice is distinct from the right to give medical consent and should not be subject to any age limit”.

- “Physicians and health-care facilities should 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 can be obtained in addition to other procedural safeguards.”

- Where fixed age at which the right to consent transfers to the child is established, *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 “

- *Where a younger child can demonstrate capacity to express an informed view on her or his treatment, this view is given due weight.*

Article 12 of the UNCRC, or the right of all children to be heard and taken seriously as a general principle, is linked to the other general principles of the Convention[8], and, in particular, is interdependent with primary consideration of the *best interests of the child* (article 3). It should therefore also be considered in the interpretation and implementation of all other rights.

The UN Convention makes no distinction based on age or other characteristics: all children have the right to receive appropriate information and to express their views, and therefore participate in the decision-making process, taking into account their best interests and what is necessary for their well-being and development.

The “Oviedo Convention”

At the European level, the *Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention, 1997)*[9], 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,** based on prior relevant information (article 5). An intervention on a child who cannot consent requires the **authorisation of his/her representative**, usually a parent, but his/her **opinion shall be taken into consideration as an increasingly determining factor in proportion to his or her**

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[8] such as the right to non-discrimination (article 2), the right to life, survival and development (article 6).

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

age and degree of maturity and, as a general rule, an intervention can only be carried out if it is for **the child's direct benefit** (article 6).

The *Explanatory Report to the Convention* specifies that:

- situations should take account of the nature and seriousness of the intervention as well as the child's age and ability to understand, and that the child's opinion should increasingly carry more weight in the final decision. It states that in some cases, this could even lead to the conclusion that the consent of a child should be necessary, or at least sufficient for some interventions (para. 45).
- In some very specific situations and under some very strict conditions in the context of medical research and the removal of regenerative tissue respectively, the rule of direct benefit of the person may be waived." (Articles 17 and 20 of the Convention (para.44)

Other legislation

Additional international legal instruments apply more specifically to specific health situations or to specific groups of children and re-affirm and/or complement the principles laid down by the two conventions cited above.

- **Children's participation in biomedical research**

Children's participation in biomedical research, including clinical trials, is subject to the general principles cited above but also to additional safeguards.

In particular, research cannot be carried out if a child explicitly objects to it**.** Even if the legal representatives provide their authorisation, a child's refusal or the revocation of their acceptance cannot be overruled.

This is reflected at European level, in the *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS No. 195)* that stipulates that research must not be carried out if a person who is not able to consent to research objects to it.

CHAPTER V – Protection of persons not able to consent to research
Article 15 – Protection of persons not able to consent to research

1 Research on a person without the capacity to consent to research may be undertaken only if all the following specific conditions are met:

i the results of the research have the potential to produce real and direct benefit to his or her health;

ii research of comparable effectiveness cannot be carried out on individuals capable of giving consent;

iii the person undergoing research has been informed of his or her rights and the safeguards prescribed by law for his or her protection, unless this person is not in a state to receive the information;

iv the necessary **authorisation has been given specifically and in writing by the legal representative or an authority**, person or body provided for by law, and after having received the information required by Article 16, taking into account the person's previously expressed wishes or objections. An adult not able to consent shall as far as possible take part in the

authorisation procedure. **The opinion of a minor shall be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity;**
v **the person concerned does not object**.

Within the European Union, *EU Regulation 536/2014 on clinical trials on medicinal products for human use* establishes that the explicit wish of a minor who is capable of forming an opinion and assessing the information, to refuse participation in, or to withdraw from, the clinical trial at any time, is to be respected by the investigator.

Article 32 **Clinical trials on minors**
1.A clinical trial on minors may be conducted only where, in addition to the conditions set out in Article 28, all of the following conditions are met:
(a) the informed consent of their legally designated representative has been obtained;
(b) the minors have received the information referred to in Article 29(2) in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;
(c) **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**;
(…)

2.The minor shall take part in the informed consent procedure in a way adapted to his or her age and developmental maturity.
3.If during a clinical trial the minor reaches the age of legal competence to give informed consent as defined in the law of the Member State concerned, his or her express informed consent shall be obtained before that subject can continue to participate in the clinical trial.

- **Genetic testing**

The *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes (CETS No. 203)* provides that “Where, according to law, a minor does not have the capacity to consent, a genetic test on this person shall be deferred until attainment of such capacity unless that delay would be detrimental to his or her health or well-being” (article 10). And in any case, “(w)here, according to law, a minor does not have the capacity to consent to a genetic test, that test may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. 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” (article 12).

- **Emergency situations**

In emergency situations, health professionals may be faced with a conflict of duties between their obligations to provide care and to seek the patient's consent. The law provides for conditions under which medical decisions may be taken without the authorisation of the child’s legal representative.

🕮 Articles 8 and 9 of the Oviedo Convention allow the practitioner to act immediately in such situations without the consent of the patient, under certain conditions.

This possibility to act without the authorisation of the legal representative is restricted to :

- **emergencies which prevent the practitioner from obtaining the appropriate consent and is limited solely to medically necessary interventions which cannot be delayed.** Interventions for which a delay is acceptable are excluded;
- the intervention must be carried out **for the immediate benefit of the individual concerned;**
- in emergency situations health care professionals must make every reasonable effort to determine what the patient would want;
- when persons have previously expressed their wishes, these shall be taken into account. Nevertheless, taking previously expressed wishes into account does not mean that they should necessarily be followed;
- these provisions apply both to persons who are capable and to persons who are unable either *de jure* or *de facto* to give consent.

🕮 The EU Regulation 536/2014 on clinical trials also provides for specific rules concerning informed consent in emergency situations (art.35).

> Where, due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the clinical trial, and it is not possible to obtain informed consent prior to the intervention, patients may be enrolled in the clinical trial under the following conditions:
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> - the clinical trial relates directly to the medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative;
> - there are scientific grounds to expect that participation of the subject in the clinical trial will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement;
> - the clinical trial poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.
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> Any previously expressed objection by the patient should be respected, and informed consent from the subject or from his/her legally designated representative should be sought without undue delay and the information shall be given as soon as possible to the subject and to his/her legally designated representative.

- Children with disabilities

The *Convention on the Rights of Persons with Disabilities* (UNCRPD) reflects the right to child participation in Article 7.3 whereby "States Parties shall ensure that children with disabilities have the right to express their views freely on all matters affecting them, their views being given due weight in accordance with their age and maturity, on an equal basis with other children, and to be provided with disability and age-appropriate assistance to realize that right".

Through its *General comment No. 20 (2016) on the implementation of the rights of the child during adolescence*, the Committee on the Rights of the Child, reaffirms the right to child participation in general by stressing that "adolescents with disabilities should, in addition, be provided with opportunities for supported decision-making in order to facilitate their active participation in all matters concerning them." (paragraph 32).

In brief:

- Every child has the right to be informed and listened to before any health intervention.
- The weight given to the views of the child increases with age and maturity.
- Decisions should be taken in the best interests of the child.
- Medical research may not be carried out on a child if they explicitly object to it, even when the legal representatives have provided authorisation.
- Genetic testing on a child must in principle be deferred unless the deferral would be detrimental to their health.
- Children with disabilities enjoy this right on an equal basis with other children, and they must be supported to realize that right.

B. Relevant domestic law(s) in Council of Europe member states

There are substantial differences across Council of Europe member States in the way children's right to participate in decisions regarding their health is reflected in law and interpreted. [10][11]

The right to consent

To start with, the statutory age at which children can provide their consent varies from 12 to 18 years.

In a number of States, age of consent is the same as the age of legal majority. This is the case for instance in France, Italy and the Slovak Republic, where, as a general rule, all interventions on a younger child require the prior authorisation from their legal representatives. The law may provide for special circumstances where the obligation to obtain the authorisation from legal representatives may be lifted.[12]

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[10] European Commission. Evaluation of legislation, policy and practice in children participation in the European Union (EU). 2015, pages 56-61. https://op.europa.eu/en/publication-detail/-/publication/

[11] 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 Adolescent Health 2021 Feb 10. Doi: 10.1016/S2352-4642(21)00019-5

[12] For example, French law provides that healthcare professionals do not have to obtain the parents' or guardian's authorisation when the child expressly refuses their consultation, in circumstances where the concerned treatments are necessary to safeguard the health of the child. In Monaco**,** health professionals can be exempted from obtaining the authorization of legal representatives

In other countries, children who have not reached the age of legal majority may give their consent from a specific fixed age that is below that of legal majority. In Austria and Latvia, it is assumed that, as a general rule, a child of 14 years is capable of making decisions. Age of consent is 15 in Denmark and Slovenia, 16 in Bulgaria, Ireland, the Netherlands[13], Norway, and Portugal. However, national laws sometimes provide for exceptions to the general rule of consent. [14]

In Ukraine, children from 14 have the right to choose a doctor and treatments according to the doctor's recommendation. Medical treatment shall be provided upon their written consent as well as the authorisation of their legal representative. Similarly in Poland, a child's consent is necessary from age 16 but is not sufficient, and the authorization from the legal representative(s) is also required.[15]

Finally, in several States, children who have not reached the age at which they may give their (unconditional) consent can nevertheless provide valid consent if they are deemed mature and competent to do so in relation to the nature of the health issue(s) at hand. In other words, domestic law considers that consent is not - only - age dependent. In this respect, the notion of children's "competency" has grown in importance and is reflected in some national legislations – for instance in the UK - where children under the general age of consent (age at which the age to consent is unconditional) can be granted the right to consent if they are found to be "competent", i.e. mature enough to decide for themselves and not want their parents involved. This requires professionals to assess competency.

The right to receive information and/or to express a view

As stated already, according to the UN Convention, all children have the right to receive appropriate information and to express their views. The Convention makes no distinction based on age.

In some countries (such as Italy, Belgium, the Czech Republic, Denmark, France, Finland, Germany, Hungary, Monaco, and The Netherlands), this right is reflected in domestic law, and healthcare professionals must provide information to all children and seek their opinion, in a manner that is adapted to the capacities of the children. It is sometimes subject to the evaluation of the degree of maturity or of the capacities or of the level of development of the child, but not age.

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if the child refuses their consultation for the medical acts or treatments that can be carried out anonymously according to legal provisions in force.

[13] Dutch law recognizes that in some circumstances, it is however possible to carry out a procedure on a younger patient (aged 12 to 16) without the authorization of their legal representative, notably in cases where it is necessary to avoid serious harm to the patient.

[14] For example, Austrian law provides that, in case a child capable of making decisions gives their 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. Latvian law states that if a patient aged 14-18 refuses to give consent to medical treatment, but the physicians deem that the medical treatment is in the interests of this patient, the consent to the medical treatment shall be given by the lawful representative of the minor patient.

[15] In the cases of research or transplant, the age of consent is lowered to 13 years. In cases of conflicting opinions, there are various rules that require the authorization of a judge.

Other domestic legislations do not explicitly refer to the right of children to receive information, and/or to participate in decision-making, in the area of healthcare specifically.

Finally, in a number of countries (such as Austria, Bulgaria, Ireland, Norway, Poland, Portugal), these rights are recognized but as from a minimum age. This age varies from 7 to 16 years (and the age criteria is sometimes combined with different conditions and legal consequences). In Norway, a child has the right to receive information and give their opinion from 7 years of age, and from a younger age if the child is able to form their own opinion. From age 12, a child has the right to refuse to inform parents about his/her health under certain circumstances.

Biomedical research

National legislations of Member States generally reflect the fact that, in research settings, the refusal of a child to participate may not be overruled.

C. What is meaningful participation?

There are different principles that can help professionals to promote *meaningful participation* of children in decision-making processes. In this context, meaningful should be understood as involving children in a manner that is respectful, ethical and constructive.[16]

Participation in decision-making processes should be:

- **transparent and informative:** From the start, professionals should inform children about their right to be involved in decisions about their health. This means ensuring children understand their own role, their parents' and that of professionals; and how decisions will take place.

- **voluntary:** Children should have the possibility to choose the extent to which they want to be involved and the right to withdraw from any process, at any given time. Different children at different times might prefer to have varying degrees of involvement or responsibility. The level of involvement can differ from child to child and between circumstances. The child's wishes in this regard should be respected.

- **respectful:** Children should be treated with respect and provided with genuine opportunities to express their views and to be listened to. Professionals should also respect, and gain an understanding of, the family, school and cultural context of children's lives. Participation should be a way to help children build knowledge, skills, self-esteem and confidence.

- **relevant:** Children should be able to give their opinion and contribute to decisions and processes that build on their own knowledge and focus on issues,

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[16] This section is informed by the *General Comment 12 of the CRC, paragraph 134* - Basic requirements for the implementation of the right of the child to be heard

which are relevant to their lives. This also means that children should be involved in ways, at levels and at a pace appropriate to their capacities and interests.

- **child-friendly:** Child-friendly approaches should include allocating sufficient time to communicate effectively with children, developing professionals' attitude to children and to child participation itself, their capacity to adapt, as well as ensuring the availability of supportive resources, such as child-friendly information materials and an adequate physical environment.

- **inclusive:** Children's participation must provide opportunities for children in vulnerable situations to be involved and should challenge existing patterns of discrimination. This means that participation should be flexible enough to respond to the needs, expectations and situations of different groups of children, taking into account their age range, gender and abilities. Professionals must be sensitive to the cultures of all children participating.

- **participation is supported by training of adults:** Professionals working with children must have the knowledge and capacity to facilitate meaningful children's participation.

- **safe and sensitive to risk:** Adults working with children have a duty of care. Professionals must take every precaution to minimise the risks to children of abuse and exploitation and any other negative consequences of participation. Professionals should be aware of and adhere to their legal and ethical responsibilities in line with their agency's Code of Conduct and Child Safeguarding Policy.

- **accountable:** Following their participation, children must be provided with feedback and/or follow up regarding how their views have been interpreted and used, and how they have influenced any outcomes.

Children's participation is not a one-off event: Participation is a continuous process and does not stop with children's views being expressed, it also involves adults - notably health professionals and parents - and children co-producing decisions. Understanding participation in this way encourages children and adults to work together for meaningful participation. Participation contributes to improving practices by developing more effective **partnerships with health care professionals.**

Children's participation should be based on their evolving capacities: The concept of the evolving capacities of the child is fundamental and enshrined in the Convention on the Rights of the Child as it recognises children's developmental characteristics and needs, their competencies and emerging personal autonomy.[17] Children's age, maturity, but also their life experiences should be taken into account when enabling a child to participate. This is not to say that young children should not participate, but that as children grow and develop, they should be ever more involved in decisions. The practical implication of this is that even if a child does not yet have fully developed capacity for all types of decisions and participation, that does not mean that they lack any capacity for taking of decisions.

Participation should contribute to achieving the best interests of the child: The *principle of the best interests of the child* is enshrined in the Convention on the Rights of the Child and is crucial to any decision that concerns children. This principle, closely linked to the evolving capacities principle, places children at the centre of the decision-making process, looking at what is best for each *individual* child, taking into account their age, maturity, personal characteristics, but also the short, medium and long-term consequences of a given treatment and intervention to the life of that particular child. The child's best interests must not be seen as limiting his or her right to participate; on the contrary, the child's participation is a means of achieving his or her best interests.

III. Supporting the realisation of children's participation in decisions regarding their health

A. The key stakeholders in the decision-making process: the roles of children, parents, professionals

The therapeutic relationship in child health care is typically triadic, involving the health professionals, the young patient and his/her parents or legal representative.

Meaningful child participation in health care decision-making involves doing away with practices based on the assumptions that a parent or doctor automatically "knows best" (based on age, life experience and professional expertise). It requires for a shift towards a shared decision-making model which respects 1) the views and the emerging capacity of the child patient, 2) the parental authority and 3) the knowledge and the expertise of the health care professionals. Under this new paradigm, adults and children work together to reach decisions.

As emphasised throughout the Guide, a good decision must take account of, consider and balance what the child wants, what is needed to secure the child's health and wellbeing (including their survival, healthy life and development), what the other stakeholders (parents and health professionals) want and what is genuinely in the best interests of each child.

Children

The views of children must be sought, obtained, and given due weight. A child's age or degree of maturity does not determine the existence of his/her right to participate, but rather the weight that

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[17] Lansdown, Gerison (2005) The evolving capacities of the child. UNICEF Innocenti Research Centre

ought to be given to the child’s view. Children must be considered as individuals, with specific characteristics and needs that need to be taken into account.

The level of participation of a child will differ according to their capacity, life experience and individuality but it is also very much dependent on the attitude of adults, who need to promote and encourage participation and create an environment and conditions in which it can happen. While some children will easily take part in the process, others may not feel authorised or comfortable to do so, and will need to be invited, sometimes repeatedly, and encouraged, using appropriate methods. Some children, especially those who are not used to being consulted, may be inclined to "self-censorship".

Many children will want their parents to be involved in decisions. Some will want to be heard and considered but may find it overwhelming to decide and will want to leave it to their parents. Such wishes must be equally respected and are an equally valid form of child participation. While participation in decision making processes is extremely important, and all efforts be made to ensure the conditions for children to participate - particularly children who have not been previously encouraged to do so -, children should not be put in a position where they are asked to carry the burden for decision making processes if they are not comfortable with this.

In all cases, children should be guided by adults, based on their experience and expertise, but provided from a place of respect and consideration in relation to children and ensuring that there is the necessary space for children to interact.

Parents

Parents, and other holders of parental responsibility, are key players in this shared decision-making model. As in other areas of life, parents are legally required to provide their children with the “appropriate direction and guidance”[18] and have a key role in their protection and in the achievement of their best interests. In many legislations, parents will be the *de facto* decision-makers (or substitute decision-makers) as they are required to authorize medical acts on behalf of their children, until these reach either a certain age or stage of maturity.

But parents’ duties and responsibilities are to be considered as limited in time, as determined by the evolving capacities of the child, limited in scope as determined by his/her best interests, and functional in nature as they are to provide for the care, protection and well-being of the child.[19] Parental duties and responsibilities change (and usually diminish) over time: whereas parents and legal guardians are the de facto decision-makers in early infancy, thereafter, their role evolves, ie “(T)he more a child knows and understands, the more his or her parents will have to transform direction and guidance into reminders and gradually to an exchange on an equal footing”.[20]

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[18] UNCRC Article 5: **“**States Parties shall respect the responsibilities, rights and duties of parents or, where applicable, the members of the extended family or community as provided for by local custom, legal guardians or other persons legally responsible for the child, to provide, in a manner consistent with the evolving capacities of the child, appropriate direction and guidance in the exercise by the child of the rights recognized in the present Convention”.

[19] Roberta R, Volnakis D, Hanson K, The inclusion of ‘third parties’: The status of parenthood in the Convention on the Rights of the Child, Children's Rights Law in the Global Human Rights Landscape, Isolation, inspiration, integration ?, Edited by Brems E, Desmet E, Vandenhole W, Routledge Research in Human Rights Law, 2017, pp.71-89, pp. 82-83. See also: Jonathan Law, Elizabeth A. Martin, A Dictionary of Law, 7th edition, Oxford University Press, 2014.

[20] General comment No. 20 (2016) on the implementation of the rights of the child during adolescence, paragraph 18.

In order for parents to take an active part in the decision-making process and to support and guide their child, it is essential that parents are sufficiently empowered / supported. Supporting parents in supporting their children is therefore of great importance. To start with, parents need to be adequately informed about their child's health condition and about the different options for treatment, in a way that they understand.[21,22] A lot of the guidance on the kind of information a child must receive (see section III.b.1 below) applies to parents. What differs is how the information will be given.

In that respect at least, parents are partly dependent on *if*, *how* and *when* health care professionals involve them in decision-making about their child's health. Their degree of involvement will also vary depending on their life experiences, cultural background, parenting culture (the way parents involve their children in matters of daily life) and degree of health literacy. Health literacy is linked to literacy and entails people's knowledge, motivation, and competencies to access, understand, appraise, and apply health information in order to make judgments and make decisions in everyday life concerning healthcare, disease prevention and health promotion for themselves and those around them.[23] For example, some parents are not involved or listened to and may feel powerless and uncertain about their child's health care - which in turn limits their ability to support their child[24,25]. Their participation will also vary according to the type of medical act that is being considered and in certain circumstances, families may feel that standardised protocols leave them little room for choice[26].

Generally, the better parents are informed, the better they will be in a position to guide the child. However, this does not remove the obligation to inform the child directly or to include the child in discussions; and the idea that information given to a parent will be adequately shared and discussed with the child should not be assumed. While involving parents is crucial, it is important that the process remains child centred. In that respect, interestingly, research on interactions during paediatric consultations has suggested that children's contribution to the interaction with the doctor tends to be inversely proportionate to the contribution of the parent(s).[27]

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[21] Jackson C., Cheater F. M., Reid I. (2008). A systematic review of decision support needs of parents making child health decisions. Health Expectations, 11, 232–251. 10.1111/j.1369-7625.2008.00496.x

[22] Uhl T., Fisher K., Docherty S. L., Brandon, D. H. (2013). Insights into patient and family-centered care through the hospital experiences of parents. Journal of Obstetric, Gynecologic & Neonatal Nursing, 42, 121–131. 10.1111/1552-6909.12001

[23] Guide to health literacy – Contributing to trust building and equitable access to healthcare, Steering Committee for Human Rights in the fields of biomedicine and health (CDBIO), Council of Europe, page 8. Available here: https://rm.coe.int/inf-2022-17-guide-health-literacy/1680a9cb75

[24] Tallon M.M., Kendall G. E., Snider P. D. (2015). Development of a measure for maternal confidence in knowledge and understanding and examination of psychosocial influences at the time of a child's heart surgery. Journal for Specialist in Pediatric Nursing, 20, 36–48. 10.1111/jspn.12096

[25] Edwards, M. , Davies, M. , & Edwards, A. (2009). What are the external influences on information exchange and shared decision-making in health care consultations: A meta-synthesis of the literature. Patient Education and Counseling, 75, 37–52. 10.1016/j.pec.2008.09.025

[26] Coyne I, Amory A, Kiernan G, Gibson F (2014) Children's participation in shared decision-making: children, adolescents, parents and health care professionals' perspectives and experiences. Eur J Oncol Nurs 18:273–280

[27] Wassmer E., Minnaar G., Abdel Aal N., Atkinson M., Gupta E., Yuen S., Rylance G. (2004), « How Do Paediatricians Communicate with Children And Parents? », *Acta Paediatrica*, 93, p. 1501-1506 (2004) cited in Stefania Fucci, "L'écoute des enfants dans les contextes de soins", *Revue des sciences sociales*, 63 | 2020, 88-95.

Health care professionals

Health care providers, while not decision-makers *per se*, have a significant role in medical decision-making throughout childhood. They have a legal responsibility and professional duty to ensure that the rights, dignity and safety of children are upheld, and therefore have a central role in advocating for and facilitating child participation in practice.

This includes a duty to provide patients and other persons involved with the necessary and adequate information. It also requires investing time and building trust so that the child feels comfortable and safe throughout the process[28] and can effectively co-construct the decision concerning him/her. A child's participation will very much depend on the manner in which the professional(s) or team of professional(s) prompts and supports her/him to do so.

Most of the time, health workers partner with parents/legal representatives, for example, to simplify complex treatment regimens whenever possible and educate the family to avoid behaviours that will put the child at risk. However, sometimes they may need to advocate and challenge the views of parents when these do not seem to reflect the child's best interests[29]. Given the great responsibility on them, health care professionals (just like parents or legal representatives) must be aware of how to act in the best interests of the child and act on their behalf in terms of the decision-making process. The Guide considers some avenues for how to address conflicts that may arise during the decision-making process, among the different stakeholders.

From theory to practice

While it is increasingly recognized that child participation is desirable, that children can understand and act competently and that direct communication between health professional and child yields benefits, in practice, adults still often tend not to involve (or to disregard) children in decisions regarding their health.

It has been observed, for example, that in paediatric consultations, the health care professional will often involve children by asking them questions, in view of obtaining information, but will then turn to the parent(s) when providing explanations about a diagnosis and children are unlikely to participate in other parts of the discussion, such as treatment planning and discussion, and this regardless of the child's age.[30] Moreover, if a health professional is talking with a child and a parent interrupts, the consultation is likely to revert to an adult–adult conversation. As a result, adults often dominate and control these consultations.[31]

Professionals sometimes justify this by invoking factors such as a lack of time or bad organization or other. It may however also point to other reasons, such as a difficulty to share decision-making

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[28] Sjöberg C, Amhliden H, Nygren J M, Arvidsson S, Svedberg P, (2015) The perspective of children on factors influencing their participation in perioperative care, Journal of Clinical Nursing, 24, 2945–2953, doi: 10.1111/jocn.12911

[29] Beauchamp, T. L., & Childress, J. F. (2013). Principles of biomedical ethics. New York, NY: OUP.

[30] Favretto A.R., Zaltron F. (2013), *Mamma non mi sento tanto bene. La salute e la malattia nei saperi e nelle pratiche infantili*, Roma, Donzelli Editore.

[31] Cahill P, Papageorgiou A. Triadic communication in the primary care paediatric consultation: a review of the literature. Br J Gen Pract. 2007 Nov;57(544):904-11. doi: 10.3399/096016407782317892. PMID: 17976292; PMCID: PMC2169315.

power, not knowing the patient well enough, wanting to protect the child or a lack of adapted communication skills.[32]

A lot can still be done, from the part of health care professionals, to ensure that children are enabled to participate meaningfully and actively in decisions regarding their health. Health professionals of all levels need to receive regular training and supervision, about how to support children's (and their families') individual participation needs, capacities, preferences, and expectations, and to help them better respond to those needs and develop their communication skills for children of all ages and all developmental stages. The next section looks at how health professionals can support child participation throughout the decision-making process.

B. Creating the conditions for meaningful child participation

The participation of children in decision-making processes concerning their care should be seen as a progressive and rolling process. Each visit or hospitalisation is an opportunity to build children's competencies and ability to learn about their health, understand related processes and be more effectively involved in decision-making processes affecting their own lives. Children who are in regular contact with healthcare services, including children with chronic conditions, often have more power to negotiate, more space for participation and more autonomy with their parents and health professionals, as compared to other children.[33]

To ensure that participation happens in a meaningful way, professionals must pay attention to providing appropriate information to children, listening to them and taking their views seriously into account. Professionals must also understand how to manage conflict, while respecting children's rights.

1. Providing appropriate information

Any decision-making process should be based on clear information about what is known and what can be expected both in terms of the process itself and the roles of different stakeholders involved. In health care, informing children can help them understand their situation, overcome possible fears and anxiety surrounding treatments and generally empower them. Information is also a pre-requisite for meaningful participation and is applicable to all children, independently of their age, background or health status.

Some children face additional challenges or barriers to being included in decision-making processes, for example, children with a disability, children experiencing mental health problems or a specific health condition, young children, as well as children from vulnerable groups. Therefore, targeted and appropriate support should be provided on a case-by-case basis, to enable the equal exercise of children's right to participate.

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[32] Coyne I. (2008), « Children's Participation in Consultations and Decision-Making at Health Service Level: A Review of the Literature », *International Journal of Nursing Studies*, 45, 11, p. 1682-1689. DOI : 10.1016/j.ijnurstu.2008.05.002, cited in: Stefania Fucci, "L'écoute des enfants dans les contextes de soins", *Revue des sciences sociales*, 63 | 2020, 88-95.

[33] Stefania Fucci, "L'écoute des enfants dans les contextes de soins", *Revue des sciences sociales*, 63 | 2020, 88-95.

Children should be provided with appropriate and necessary information to enable them to acquire competence for making decisions, to weigh the aim, methods involved, necessity and usefulness of a proposed treatment or intervention against its risks and the discomfort or pain it will cause.[34] Information, communication and education should also enable children and families to play active roles in achieving, protecting and sustaining their own health.

A sensitive issue sometimes is whether and how to talk to children about serious consequences. One may be tempted to avoid mentioning possible fatal outcomes, pain, risks of disability, etc. This requires an assessment of children's maturity in receiving this type of information and their capacity to express their opinion on the subject, as well as a thorough evaluation on the timing and best way to communicate, but it should not be assumed that such serious subjects should be avoided with children. The giving of information actively helps many children to cope with even the most difficult of circumstances, and the absence of information may exacerbate fear and distress. Information to children about serious consequences should always be given carefully and psychological support should be offered to children and their families throughout the information process.

Information should be given about the following aspects:

- ✓ The specific situation the child is going through, such as information about a new illness, developments of a chronic or other long-term illness or planned hospitalisation experience;
- ✓ Type of treatments and duration, benefits to the child and related risks or possible effects (i.e. what could go wrong, cause problems or make the child worse);
- ✓ Any alternatives to treatment that are suitable to the child;
- ✓ Any additional needs that may influence the choice of treatment;
- ✓ What might happen if the child does not receive the proposed treatment;
- ✓ Which health care professionals they will meet, who they are, and what their role is;
- ✓ Children’s right to be informed throughout the process, to ask questions, express their views and how they will be involved in the decision-making process.
- ✓ Children’s rights concerning their participation in paediatric research and clinical trials, where applicable.

The information provided by health care professionals must be sufficiently clear and suitably worded, for example, professionals should avoid the use of medical jargon and include terms that the child can understand. Conversely, if the language used is too childish, the child may feel patronised, so the right balance is important. Sometimes it may be necessary to give information in stages that can be understood and absorbed, and it may be useful to repeat the same information at different times and stages or to complement verbal information with written information where possible and appropriate.

Child-friendly information materials can be used to support the communication and mutual understanding of children, parents and health care professionals. It also helps children to reflect on

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

the information they received orally and to identify questions for a follow-up conversation with the health care professionals. Child-friendly materials may cover any of the topics listed above and can be developed with a participatory methodology to be better adapted to children's needs and understanding. Possible formats of child-friendly information material include brochures and leaflets, videos, information accessible through social media, specific websites or applications, games and other. Professionals may also use dolls or toys for "pretending" or simulating.

In any case, it is important that health care professionals who interact with the child make sure they coordinate among themselves to avoid giving potentially contradictory information or repeating the same information too many times.

🕮 **Useful resources**: Examples of child friendly charters and information on children's right to be informed and heard (suggestions):

☞ Illustrated EACH charter (active link), see articles 4 and 5 with annotations

☞ National Healthcare Charter for Children, Ireland, especially the section on Communications and information (page 15).

☞ Charter on Children's Rights in Primary Healthcare, Instituto de Apoio à Criança (Child Support Institute) and Directorate General for Health, Portugal

☞ Charter of the Rights of the Child - Patient drawn up by the Children's Rights Defender and the Patients' Rights Defender in Poland

☞ Kuba and Buba in hospital - almost everything about children's rights: a guide to patient children's rights in book form (in Polish)

☞ Video: Kinderrechte | Kinderklinik und Kinderpoliklinik im Dr. von Haunerschen Kinderspital (lmu-klinikum.de) and brochure.

☞ ISupport Rights-based standards for children having tests, treatments, examinations and interventions (2022)

✋ **Good practices: Examples** of child friendly information about consent:

☞ Consent to medical research – Taking part in research – How might your medical data and samples be useful for researchers (in different languages – active link) - University Hospital of Vaud canton in Lausanne, Switzerland) –- Also a video (in French only - active link)

☞ What is consent and why am I being asked for it? - Great Ormond Street Children's Hospital – NHS – UK

✋ **Good practice** – Using digital communications:

☞ "My Clinical Trial Center" – a serious game / app (see Annex - Item 1)

☞ Facilitating direct online communication between children and health professionals (see Annex 3 - Item 2)

✋ **Good practice**- Removing barriers to child participation:

☞ Linguistic cultural mediation services in Azienda Ospedaliero-Universitaria Meyer (AOU Meyer) University Hospital in Florence, Italy (see Annex - Item 3)

☞ Transcultural mediation at Hôpital Necker (Paris, France): ACCUEIL - CENTRE BABEL (centre-babel.fr) + pdf (https://centre-babel.fr/wp-content/uploads/2021/11/La-mediation-transculturelle.pdf)

✋ **Good practice**-

☞ Providing comprehensive education to children with diabetes and their carers – Division of Paediatrics of the University Medical Centre Ljubljana, Slovenia (see Annex Item 4)

2. Helping children express their views

Enabling children to express their views is a very important part of a decision-making process. The ability of children to express their views and opinions can be influenced by many factors, including their age, capacities and maturity; whether they have or have not had any experience of participation either in health care or other relevant decision-making processes (at home, school or other); the extent to which they understand their situation; and how comfortable and engaged they feel within the decision-making process.

To support children in expressing their views, health care professionals should:

- ✓ Build a trusting relationship to ensure mutual respect, both in the short- and long-term perspectives; and
- ✓ Consider children's needs, including privacy and confidentiality issues that are important (but often neglected) for children and particularly relevant for older children.

Children are more likely to express their views when they trust the person they are talking to. To the extent possible, health care professionals should get to know the child and their personal needs and characteristics; and always be honest. Children may need to be reassured that their opinions and thoughts are important, even "small" concerns that may not seem important to the health professional.

Privacy is an important issue when working with children, especially when sharing or discussing information concerning their own health. Even with younger children, it may be important, or even necessary, to allocate time alone with the child to provide space for him or her to discuss whatever matters to them. It is critical to discuss confidentiality issues with children, at the outset and allow them time to ask questions. Access to confidential medical counselling and advice without parental authorisation should be ensured, irrespective of the child's age, where this is needed for the child's safety or well-being (for instance, in cases of suspected child abuse and maltreatment).

Strategies to support children in expressing their views include:

- ✓ Making sure health care professionals introduce themselves by name and talk to the child using their name.
- ✓ Supporting and inviting children to talk about to what extent they wish to participate, in what way and when.
- ✓ Asking and clarifying the children's preference about talking with a health worker in the presence of parents or alone.
- ✓ Playing with the children while talking to help reduce the stress of discussing difficult topics and to be able to express themselves more freely.
- ✓ Carrying out both active questioning and active listening.
- ✓ Checking that the children understand the information that has been given.
- ✓ Asking the children what they think, as this gives the children permission to express – professionals should not assume children will share their thoughts voluntarily.
- ✓ Encouraging them to ask questions and reply.
- ✓ Avoiding making judgements in all interactions.
- ✓ Allowing more time for children to think, if they want and need it.
- ✓ Respecting a child's silence while ensuring that the child has opportunities at later stages to express their views if they wish to do so.
- ✓ Taking into account the child's biological rhythm, tiredness and length of appointments.

These strategies should be done across the health care teams and a continuum should be ensured, for example, with good communication between nurses, doctors or other professionals involved. All healthcare professionals working with children must be trained, including on communication skills. In some national contexts, health workers with a specific training, such as health play specialists or Child Life specialists, positively reinforce teams, supporting children and families by using age and developmentally appropriate methods to help them better understand and cope with health care situations and treatments, and by being a learning resource for other health professionals to develop similar skills.

(Example: ☞ Children's Hospital in Munich establishes ChildLife Specialist programme.)

✋ **Good practice**: Training / capacity-building of professionals

☞ 0-18 Guidance for doctors, UK General Medical Council - A section on communication can be found at the following webpage: Communication - ethical guidance - GMC (gmc-uk.org)

🕮 **Useful tools**:

☞ The following Council of Europe guidance on how to connect with children may also prove useful when supporting children in health care related decision-making:

CONNECTING WITH CHILDREN[35]

- Participation depends on both adults and children believing in each other and in the process. Children need to know that professionals are interested in their opinion and want to find a solution which takes their views into account. Where professionals involved in decision making are doctors, nurses, teachers, social workers, early years workers or managers who already know the child or children involved, children will use past experiences of those individuals as the basis for decisions about whether to trust them. For example, children who feel their teachers listen to and take seriously their idea during day-to-day classroom activities are more likely to talk to that teacher about serious concerns when they arise, such as bullying or sexual violence. Known professionals can build trusting connections with children through respecting their views.

- Professionals should provide information about themselves, their role, the limits of confidentiality that will apply and the length of time they are likely to be involved in a child's life. This can be done with the support of accessible information (e.g. leaflets or videos) prepared as described in the subsection above. But it is also important that this is provided to children in a personalised way. Sometimes known professionals will need to provide this kind of information because the decision-making process is new to the child. When the meeting is with a new person, and is not an emergency, children should be given information beforehand about what will happen. Where possible, professionals meeting children for the first time should be introduced by someone a child knows. For example, a parent or foster carer might introduce a new social worker to their child and stay with them until the child feels confident to meet with the social worker alone. Information is often best provided through a personalised conversation, so that children are encouraged to speak and feel listened to at the very start.

- Even in the shortest encounter and in difficult circumstances, research evidence shows that effective communication can be established when professionals, such as immigration workers, share a little of themselves. With one question, about for example hobbies, doctors can create an atmosphere in which it is easier for a child to speak. One of the goals of this interaction is to ensure that children feel comfortable in stating or showing their preferences, and that they feel their wishes will be taken into account. Professionals should consider how they can build at least one moment of human connection into their first encounters with children.

- The extent of time taken to build effective connections will depend on each child's circumstances and on the skills of the professional. Investing the necessary time in this phase will help improve the quality of the process for everyone concerned. There may also be times throughout the participation processes where returning to this phase of building a connection and rapport becomes necessary. This is particularly likely in circumstances where a child has lost trust in adults who are meant to be responsible for them or their care. Professionals can promote sustained meaningful connections with children by being honest and available.

☞ ISupport Case studies

The team behind ISupport Rights-based standards for children has developed four case studies or scenarios that aim to demonstrate how the standards for child-centred healthcare can be applied in a range of clinical contexts and procedures. In each case, a clinical situation is given and explored, first without applying the standards and then, applying the rights-based standards. Whilst the first example within each case study results in a procedure being completed, this is often at the detriment of a child's short and long-term well-being as their interests are not prioritised over those of the parent/carer, professional or institution.

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[35] Listen – Act – Change - Council of Europe Handbook on children's participation - For professionals working for and with children, p.37

The physical environment can also play an important role. For example, ensuring that children can express their views in a private office or room or that there are no interruptions, such as a support or other professionals often coming into the office or room. For younger children, a more friendly environment can also help them to feel at ease (i.e. a room with toys, sitting down on the floor or other strategies).

✋ **Good practice –** Child-friendly and family-friendly hospital environments

☞ Sant Joan de Déu Children's Hospital in Barcelona, Spain (see Annex- Item 5).

3. Considering children's opinions

As emphasised in this Guide, participation is a rolling process that encompasses different considerations. Importantly, even where, according to national legislation, children may not be able to give their consent to a treatment or intervention, **their views and opinions should nevertheless *genuinely* influence decisions**. This means that children's views and opinions should be taken seriously and given due weight in any final decision. This should be done by taking children's evolving capacities into account. **Childhood is not a single, fixed, universal experience.** At different stages in their lives, children require different degrees of protection, provision, prevention, information and participation. Children's wishes should be considered seriously, most of all in relation to health care and biomedical research.

The issue of *seriously* considering children's views is a fundamental one. At times, children may be listened to only when the issue at stake is trivial. The more serious the situation, the less likely it may be that the child's views are considered, particularly where they may be different from the views of adults.

Also, when children's views differ from those of adults, whether parents or professionals, they might be simply disregarded and children do not receive explanations as to why another option was finally decided upon, other than the one they preferred. However, professionals *do* have a duty to ensure that children's rights to participate in their own care is respected and the severity of a situation does not alter this right, which is equally important in all situations.

Conversely, matters that may appear trivial to adults can have great importance for a child. Neglecting to recognise children's participation in those decisions can erode the child's trust in larger ones and in the people around them. In more severe circumstances, failure to recognise and facilitate a child's right to participate in significant decisions and ensure that these are demonstrably given consideration, may not only erode a child's trust, but also create further divisions and difficulties later, at a time when the supportive relationships that are often so important for a child, may already be strained or damaged. This may be particularly so in situations where a child may be considered as competent and their viewpoint well-informed.

The level of children's participation should be informed by their abilities and preferences.[36] Children must be guided throughout the process and adults must ensure the conditions in which these can be met, by providing appropriate information, listening to the children and taking their opinions seriously into account. All efforts should be done to maximise the opportunity for any

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

child to choose to participate in decisions regarding their health if they choose, at the highest level of his/her ability. The confidence and competence to be involved will be gradually acquired through practice, but this does not mean that young children should not be involved as well as older children. For example, enabling children to take part in decisions of "lesser importance", such as whether they would prefer an injection on the right or left arm or to be seated or lying down during a treatment, can instil a culture of child participation in daily clinical practice.

A starting point for identifying a reasonable treatment decision for a child involves weighing the benefits against the burdens of a proposed treatment or research in the context of what is known of the patient's values, beliefs, family relationships and cultural norms. Children can form and express views already from an early age but the nature of their participation, and the range of decisions in which they are involved, will necessarily increase in accordance with their age and evolving capacities. This requires professionals to recognise the diverse capacities of each individual child and tailor their interactions with them in a way that neither overestimates nor underestimates their capacity. For some professionals or other adults, this may be a fundamental shift from the way they view children, by not seeing age as a barrier. Clearly, very young children or for instance, some children with disabilities, cannot do certain things just as some adults have limited capabilities. This should not bring into question or negate the capacities that they do have, nor the need to support them in expressing these or having them recognised. Children can make or contribute to complex decisions.[37]

4. Reaching a decision

▪ Determining children's best interests

Reaching any decision concerning a child's care must be based on what is in the **best interests of the child**. Assessment and determination of the child's best interests must be centred on the individual child and include consideration of the child's health needs, their own views, safety, protection, care and overall well-being.[38]

Many aspects should be given due weight to assess and determine a child's best interests. However, there is no fixed recipe for every situation. Respect for the best interests of the child and, indeed, respect for children's participation requires a balance between what professionals (ideally all professionals working in a multidisciplinary team with an integrated approach to care) and parents consider to be the best for the child, given the illness or health problem, available treatments, effects and so on; and the child's views on what is 'best' for them. Exploring children's preferences, family culture (including participation culture), past experiences and other factors will help professionals support and facilitate the best possible decision for the child. Consideration must also be given to the children's right to an open future, meaning that preference should be given, when possible, to options which least restrict their future choices.

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[37] **LISTEN – ACT – CHANGE"** - Council of Europe handbook on children's participation (page 38)

[38] UNCRC General comment No. 14 (2013) on the right of the child to have his or her best interests taken as a primary consideration (art. 3, para. 1)

✋ Example of guidance for Assessing a child’s best interests during health care decision-making processes

☞ Example from the UK (see Annex – Item 6)

▪ The notions of consent, assent and dissent

For certain treatments or interventions, through protocols specified by law, professionals will need to obtain the formal agreement of parents or of the child him/herself.

According to the Oviedo Convention, the term “*consent*” is used when the formal agreement is given by the person concerned by treatment or act, whereas the term “*authorisation*” refers to the formal agreement given by the parents/legal representatives or body provided by law.

According to the World Health Organization (WHO), informed consent “relates to the formally expressed (usually written) agreement or permission for any health intervention, such as vaccination, effective surgery, choosing or terminating a treatment. [39]”

As mentioned in section II.b., in national legislations, children’s right to informed consent to treatment can be based on age criteria. Additionally, another concept has emerged, that of ***children’s competencies***. The notion of children’s competency was discussed in a case brought to court in the UK in 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.” [40] The so-called *Gillick competency* grew in importance and is increasingly recognised as a determining factor for giving children the right to consent to treatment. Assessing competency is left to the health care professionals and there is no universally agreed-upon method to do so. However, guidance will usually include assessing children’s ability to understand their situation, to weigh the different options available to them and to understand the consequences of each.

The emergence of methods and practices to assess competency have been intended to increase child inclusion, participation and rights in decision-making. This places a duty on health professionals to ensure that children are given appropriate information in a way that is understandable to them in order to facilitate their competence. It also requires that health professionals recognise that some children may require information in different ways in order to achieve the same level of understanding and competence.

✋ Examples of guidance on assessing a child’s competency:

☞ Guidance Notes, Cheshire West & Chester Council (see Annex – Item 7)

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[39] Pocket book of primary health care for children and adolescents: guidelines for health promotion, disease prevention and management from the newborn period to adolescence. Copenhagen: WHO Regional Office for Europe; 2022. Licence: CC BY-NCSA 3.0 IGO. Page 666

[40] The so-called Gillick competency derives from the *Gillick v West Norfolk and Wisbech AHA* Case (1986), *In* Hastings AM & Redsell S *Listening to Children and Young People in Health care Consultations* (2010))

☞ WHO guidance (see Annex – Item 8)

Children can also, according to national legislation, provide their assent or express their dissent. The terms assent and dissent generally describe when children give their agreement or disagreement to a treatment, in situations where they do not yet have a legal right to give their consent.

If children are considered capable of assent, their assent should be sought in addition to parental authorisation.

In many European countries, written authorisation of parents in addition to the child's own assent is required.

In order to ensure that children can exercise their right to consent or assent, hospitals and other health services should put in place different measures, including:

- Adopting a hospital or health service consent policy, reflecting national legislation
- Ensuring that health professionals are aware of this policy;
- Promoting capacity building of professionals to ensure they have the knowledge and competencies to engage and involve children in the decision-making process in a meaningful way and that they ask for their consent to treatment whenever it is required;
- Engaging with children regularly to assess existing policies and practices, as a way to improve these and also children's experiences of care.

Cultural differences may lead to misunderstandings. Where appropriate a translator and/or a cultural mediator should be available during the process of information and consent/assent and in the planning of the research. This person should be familiar with medical terminology, experienced in the language, social habits, culture, traditions, religion, and particular ethnic differences. This person may need to be available throughout the medical intervention and/or clinical trial, e.g. to facilitate exchanges, adverse events reporting.

Taking into account the national legal framework, seeking agreement should put in balance the emerging capacity of an adolescent for independent decision-making with the need for continued special protection as provided by the parents/legally designated representative in compliance with national laws. The specific aspects of disclosure to parents of information concerning adolescents should be made clear to the adolescent concerned.

For younger or non-verbal children who are not able to raise or express verbal objections, any signs of resistance or protest should be identified and discussed with the parents to assess and recognise whether the behaviour is merely an expression of an acceptable burden or can be considered a concern on intervention continuation. It should also be recognised that for many children, the people best placed to understand or interpret non-verbal indications will be the parents.

In all circumstances, and regardless of the outcome or direction of a decision, the conclusions of any decisions made should be carefully and kindly explained to the child.

▪ Managing disagreements and conflicts

Inevitably, situations will arise when there is a difference of opinion or disagreement. This may typically be between children and their parents, or children and health professionals, or both. It is important to support and manage disagreements with care and according to rights-based principles, so as to enable the best decisions to be made, to protect the ongoing relationships that are often vital to children's continuing health care, and to enable all parties to move forward beyond the current situation.

The role of health professionals to protect, facilitate and advocate for each child's right to participate remains unchanged in any circumstance. However, that does not imply that health professionals should agree with or take sides in any disagreement, it is about ensuring that the child is supported to express their opinion, and to ensure that this opinion is considered properly and with due weight in accordance with their rights. Each situation brings its own challenges for health professionals to try to navigate in order to support each child to achieve this right to the greatest extent; whilst enabling the important supportive relationships between the child, parents, and health professionals to remain intact.

Situations of disagreement may test the willingness and skills of health professionals to promote children's right to participate, who may also worry about damaging relationships with those in disagreement. But the protection of this right is a central duty of health professionals and the principles for meaningful participation referred to in section IIc can help.

Similarly, whilst health professionals have a duty to support and enable children's rights to participation, they should not be expected to go beyond the laws of their own country. Therefore, it is important for health professionals to know the legal parameters in their country.

Episodes where there may be different views, or where children may express disagreement with a proposed action, range across a wide spectrum of focus and severity. Scenarios where there may be different views and disagreement occur in all areas of health care.

1) Disagreements may arise in situations where no procedure as such is involved, such as in areas of information-giving. For example, a child may wish to take part in a health survey or needs assessment, and the parents may disagree. In such circumstances, any reasons for parental reluctance should be explored and where possible, any unfounded fears met with reassurance where possible (for example about how information is used or how data is stored). However, when assessing 'best interests', health professionals also need to remain objective and open to the possibility that in some circumstances (for example, violence in the home), parents may seek to block their child from disclosing concerns and needs; in which case the child's 'best interests' may lie in advocating internally for a way to enable this child to participate, assuming this is possible within the legal framework of the country.

2) In primary health care, immunisation can also be a controversial issue within some families, and it is not uncommon for children or adolescents to want a vaccination and the parent be reluctant, for example for COVID-19 or for HPV. This can be a reflection of parent's own concerns and sometimes be the result of misunderstanding or misinformation.

Providing accurate and clear information about the purpose of the intervention is important and can be reassuring and helpful, ensuring that this is objective and not directive. Similarly, explaining to parents about the rights that their child has and why these are important can be helpful, as parents are sometimes not aware of these or may be sceptical.

Sometimes, moral, religious or cultural beliefs contribute to conflict around medical decisions. Such concerns should be identified and addressed in a respectful manner as early as possible and discussions should be truthful and transparent, always assuming that the primary focus of decision-making remains the child patient's best interests. Getting the support and mediation of a trusted religious or community leader where available, can be helpful.[41]

3) In situations requiring urgent decisions or actions, such as procedures to insert an intravenous cannula to give medicines to treat a serious infection or take blood for an important test, it is not uncommon for children to initially refuse or not to want this, particularly being young.

   In such circumstances, the conclusion may be non-negotiable and that it is in the child's best interests to have the treatment. However, this should be explained kindly and carefully to the child concerned, and the child concerned should still be given choices that enable some sense of control and influence on other elements of the care provided, such as sitting position, which arm/hand is used, etc. It is also important to choose the least intrusive treatments possible and to seek alternatives that would be acceptable to the child.

4) There are some situations where the physical holding of a child who resists a procedure may be required to provide health care or to prevent greater harm to the child. These typically occur with young children requiring urgent care, as described in the paragraphs above, and sometimes in complex mental health care settings. Situations like these often create ethical conflicts for health professionals and challenge the application of children's rights. Physical holding should only occur when there is serious risk to the child's health if the intervention is not performed, if proactive and preventive strategies have been exhausted. The legal guardians would as a main rule need to approve of the action. The action must be justified and proportionate to the health risk one is seeking to mitigate, and there are legal requirements for this that will vary between member states. All efforts should in any case be made to reduce the level and intensity of this situation and the degree of force should be confined to only what is necessary to hold the child for the shortest amount of time whilst minimising injury to all involved.[42] Decisions to use any form of restrictive physical intervention must be based on the assessment that no other method is available and that its use will cause less harm than not intervening. Even if the necessity has been explained before the intervention, it should always be followed by a discussion where the professional explains why this has been necessary and the child should be given an opportunity to debrief, including emotionally.

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[41] Kevin W. Coughlin, Medical decision-making in paediatrics: Infancy to adolescence, Canadian Paediatric Society, Bioethics Committee, Ottawa, Ontario

[42] Royal College of Nursing (2019) Restrictive physical interventions and the clinical holding of children and young people - Guidance for nursing staff; Royal College of Nursing, London

5) Differing views may also arise in situations relating to sexual and reproductive issues, for example if an adolescent seeks advice or health care in relation to concerns about a sexually transmitted disease and does not wish to tell their parents. The child's right to confidentiality and access to counselling is important and should be respected. In such circumstances, health professionals may encourage children to open up to their parent(s) and offer support and mediation between the child and the parent(s) if necessary.

   In parallel, health professionals also have a duty to assess the circumstances to consider if the child is in an abusive situation and needs protection, or if the child's mental and physical wellbeing is at risk. These and other factors need to be balanced by health professionals in determining the 'best interests' of the child and whether parents should be informed.

6) There are some situations where the focus of disagreements has particularly serious implications, for example, disagreements between children and parents or health professionals about whether to continue active treatment or interventions when there is little hope of recovery (maybe in the case of continuing treatment for cancer, after previous treatments have failed).

   In such cases proposed intervention should be delayed while an attempt at resolution is made. Such situations are always very emotive and health professionals should be compassionate but objective in supporting every effort to understand and respect differences of opinion between the children and their parents/legally designated representative. Objections from children, capable of forming an opinion, should be advocated for and respected; and the opinion of legal representatives should be taken into account in interpreting the wishes of children.

Enabling open communication is often key to resolving issues. However, sometimes serious disagreements over what are the children’s best interests remain among parents, children and health care professionals, even after a collaborative decision-making process. It is part of the health professional’s role to mediate and help to restore positive relationships following this.[43]

- Children, parents/legal representatives and health care professionals should be helped to clearly identify the values contributing to conflict and discuss the goals of the proposed treatment/research ;
- Early discussion around the expectations, limitations and uncertainties of treatment options and outcomes may help establish mutually agreeable treatment/research plans;
- Cases should be discussed within multidisciplinary teams ;
- Further discussions and/or referral for a second, independent medical opinion, should be promoted;

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[43] Kevin W. Coughlin, Medical decision-making in paediatrics: Infancy to adolescence, Canadian Paediatric Society, Bioethics Committee, Ottawa, Ontario

- Consulting with and mediation support from a spiritual care leader, social worker, relevant peers, patient relations expert, bioethicist or a bioethics committee, or with institutional or personal legal counsel ;
- In very serious or complicated situations (when the child’s life is at risk or where a severe permanent injury can occur) a court can be asked to decide whether it is right to proceed with a particular treatment.

✋ **Examples of guidance / national guidelines on how to manage conflicting views between children, parents and healthcare professionals:**

☞ France: Refusal of care expressed by the minor (section 2-4) – Guidance by the Ministry of Health (see translation in Annex – Item 9).

✋ Good practice

☞Italy: Bioethics committee for paediatrics (see Annex – Item 10)

IV. Improving health care provision of all children through child participation

This Guide mostly focuses on how a child can be involved and supported in individual decisions regarding his/her health.

However, greater routine integration and inclusion of child participation and perspectives at other levels of policy, planning, service design, delivery and evaluation can result in better informed decisions that also bring great benefit to children in general and individually. General Comment 12 of the CRC[44] states that children should also “contribute their views and experiences to the planning and programming of services for their health and development”, including on “how to promote children’s capacities to take increasing levels of responsibility for their own health and development”.

In relation to health care delivery, children should be given the opportunity to provide confidential or anonymous feedback on their health care experience after they have used services by means of “experience of care” feedback, satisfaction questions or other methods.

Tools such as Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs) [45] are increasingly being adopted in paediatric population.

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[44] paragraph 104

[45] PREMS are validated questionnaires, that gather patients' and families' views of their experience receiving care and are commonly used to measure the quality of care, with the goal to make care more patient and family centered. PROMs are questionnaires measuring patients’ views of their health status. PREMs and PROMs have been fast developing in over the last 15 years. The OECD monitors PREMS in outpatient care in 19 countries, the results of which are published every two years in 'Health at a glance'. The OECD has also launched the PaRIS (Patient-reported Indicators Survey) initiative on PROMS and PREMS that can be compared internationally (https://www.oecd.org/health/paris/).

Similarly, engaging children in the design of training curricula for health professionals, of information material or of new health facilities brings important insights and benefits for children that use services in future.

Enabling and facilitating children to discuss and share their views collectively, by participating in regular children's councils, advisory groups (for example of 'expert-patient' children with specific chronic conditions) or other forums and networks, not only provides channels for informed feedback to influence change in care delivery or design, but can also increase mechanisms of peer-support between children.

☞ **Young Persons Advisory Groups' (YPAGs) role and activities having an impact on individual decision-making process -** see Annex Item 11

This type of structured participation is increasingly institutionalised in hospitals or other health organisations and rely on participatory approaches where the child is not only a respondent but also engaged in meaningful dialogue. When integrated and facilitated on a regular basis within health services, these approaches also provide platforms to increase the accountability of decision-makers and health professionals to children.

☞ **Ireland: National Healthcare Charter for Young People – in association with the Youth Advisory Council** – see Annex Item 12

✋ **Good practices**:

☞ **A network of Swedish paediatric hospitals in involve children and young patients to improve quality of care - Sweden (**see Annex Item 13).

☞ "**Imagine Your Hospital**" – French hospital selects three projects presented by children during its first-ever Children's Users' Commission (see Annex item 14).

V. Conclusion

Children are rights holders with a progressively evolving ability to make their own decisions. They have the right to express their views on all matters that affect them, namely in the field of health care, and to have their view taken into account.

This requires paying particular attention to children's participation in decision making processes on matters related to their health.

Benefits of child participation are many. They are not only beneficial to individual children but serve the community as a whole and improve the general quality of health care delivery (or provision).

In this context, healthcare professionals and other professionals involved need to understand the importance of their role in supporting children and their families in this process.

The Guidelines for child friendly healthcare adopted by the Committee of Ministers of the Council of Europe in September 2011, requested member states to support programs and policies aimed at raising the awareness of children and their parents of their rights to active participation in decision making and the promotion and protection of their health, by creating legal structures and policies that support the promotion of children's rights in health care.

How to enable and facilitate the participation of children in decision-making processes on matters relevant to their health, and how to give information to children and their families, should be subject of training and education of health professionals that work with children.
Good practices and tools relevant to children's participation, including in the research context, need to be developed and promoted.

Special attention and additional support must be given to children who may face additional challenges or barriers to participate in decision making processes (including but not limited to, children with disabilities, with mental health problems, migrants, linguistic, cultural and other minorities).

VI. Annex: useful resources and good practices

Item 1 - Serious game

“**My Clinical Trial Center**” is a digital game with an educational purpose. It aims to explain to children in a fun way what clinical trials are, how they work and why they are so important to developing medicines suitable for children.

The game is extremely informative: game-players will learn about clinical trials, study protocols, informed consent and assent in children, phases and procedures of clinical trials, data collection, and pharmacovigilance. It can be downloaded in Play Store and Apple Store. The game is currently in English. The game was developed with a participatory methodology by the TEDDY KIDS (KIDS Bari and Albania young) members and received approval of the International Children's Advisory Network (iCAN).

https://www.teddynetwork.net/2021/06/29/4676/

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Item 2 – Facilitating direct online communication between children and professionals

eHealth as an aid for facilitating and supporting self-management in families with long-term childhood illness – development, evaluation and implementation in clinical practice

Since 2018, research has been conducted within the eChildHealth research program, funded by Forte until 2025, with the aim to develop safe and satisfactory child-centered care with the support of e-health. The research follows the Medical Research Council's framework for developing, evaluating, and implementing complex interventions in healthcare.

The overall goals are:

1) to push the boundaries of current knowledge about clinical efficacy and cost-effectiveness for e-health as a tool for promoting and assisting self-care for children with long-term illness and their families.
2) to build a sustainable multidisciplinary environment for the development, evaluation, and implementation of e-health in support of self-care for children and their families.

The research program includes several clinical studies in paediatric care with the aim of strengthening and developing safe and satisfactory child-centered care with the support of e-health. But also, studies of implementation, technical development, health economics, and cultural actors. Subprojects are conducted in Sweden, Denmark, and Ethiopia. The focus is on complex, long-term, and costly challenges in paediatric care.

In Sweden, this applies, for example, to surgery for children born with malformations of the gastrointestinal tract and/or with heart defects, children born prematurely, and children with cancer. The technology being studied is an application in an e-tablet where parents and staff communicate via chat, photo, text message, film, and repeated reports about the child's condition. The goal is to give the child and the family security and support at home and reduce the family's need for travel and return visits to the hospital. In Denmark, it is being investigated how a mobile application can be used as an aid for the early identification of cerebral palsy in children and how e-health can be used as a tool for intravenous treatment at home for children and young people with acute or long-term illness. Ethiopia is investigating whether text message reminders are an effective strategy to increase adherence to treatment for young people living with HIV.

The end-users, (the parents, or the children/adolescents, as well as the professional caregivers) participate throughout the research process. The project includes three phases: development, evaluation, and implementation. Both validated and reliable questionnaires, as well as qualitative interviews, are used for data collection. The research is conducted by a multidisciplinary research team in health sciences, medicine, economics, technology, and social sciences, which work together on common research issues. Computer technology expertise analyses the conditions for using IT in healthcare; health economic evaluations are made in parallel with the clinical studies; and the challenges that arise as a result of e-health changing the relationships between children, families, and professional actors, are studied in the basis of cultural perspectives and implementation research.

See also: eHealth in Paediatric Oncology — Lund University – Sweden

Item 3 - **Linguistic cultural mediation services**

Progetto Intercultura: Re-organising services at hospital level to respond to the needs and rights of migrant children - Meyer University Children's Hospital, Florence, Italy

Already nearly two decades ago, in a national and regional context of increasing immigration, the Meyer University Children's Hospital took steps to respond to the health needs of migrant children and their families, particularly by ensuring appropriate information.

The hospital introduced cultural and language mediation in different languages (including Albanian, Arabic, Chinese, Romanian, Somali, French, English, Spanish, Polish, Czech, Slovak, Macedonian, Serbo- Croatian, German and Filipino). An interpretation service was also made available via telephone, used especially in cases of emergency.

Upon suggestion from the hospital staff, a SOS Intercultural Team was set up. This group was composed of professionals working in the hospital with language competence in 10 different languages (Albanian, Arabic, Bulgarian, French, English, Iranian, Romanian, Spanish, German and Hungarian). This team did not substitute the formal cultural and language mediation services, but provided an emergency substitute, face-to-face or by telephone.

- To ensure the respect for the spiritual and cultural dimensions of health, the hospital undertook the dissemination of the contacts of the religious entities present in the region in all departments and services. It also established a protocol between the hospital and religious communities to ensure the necessary religious assistance to the patients of migrant background and it prepared of 'Intercultural' Calendars, which were disseminated in every department and service to increase awareness of the main religious events. The hospital also provided 'free and flexible' menus, which were translated into different languages, in order to guarantee, as much as possible, the respect of the different cultural and social eating habits.

Read more: Ensuring the Right of Migrant Children to health Care: The Response of Hospitals and Health Services, Background Paper, International Organization for Migration (IOM), 2009, pp.32-33 (https://www.researchgate.net/publication/301682535_Ensuring_the_right_of_migrant_children_to_healthcare_the_response_of_hospitals_and_health_services)

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Item 4 - **Division of Paediatrics of the University Medical Centre Ljubljana provides comprehensive education to children with diabetes - Slovenia**

In Slovenia, the Division of Paediatrics of the University Medical Centre Ljubljana provides comprehensive education to children with diabetes and their parents in order to improve diabetes decision-making. Firstly, initial health education course for children and parents is given and later on further education when technological devices are introduced. The centre also organises a yearly rehabilitation retreat.

In addition, every year training for educators, teachers and sports trainers who care for children with diabetes is organised. To further improve the diabetes care and involvement of patients and their parents they have also produced a number of publications covering different aspects of diabetes management (at school, in sports, regarding nutrition...). There is also a web site with emphasis on the issues regarding patient's rights in diabetes care.

Learn more here: https://www.sladkorcki.si/o-sladkorni-bolezni/pravice-otrok-s-sb/

https://vestnik.szd.si/index.php/ZdravVest/article/view/3104

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Item 5 -**Child-friendly and family-friendly hospital environments**
Sant Joan de Déu Children's Hospital in Barcelona, Spain

The Sant Joan de Déu Children’s Hospital has a range of initiatives aiming to provide children and families with a comprehensive child- and family-friendly environment. Some measures include information for patients on how the visit to the hospital will take place, a comprehensive welcome guide, information for international patients, cultural mediation and other information of relevance.
There is a dedicated webpage for children and families, where all this information is gathered (Para pacientes y familias | Hospital Sant Joan de Déu (sjdhospitalbarcelona.org).

SJD Barcelona Children's Hospital has also started using a **new magnetic resonance device** that help in reducing the duration of anaesthesia, which some patients need for these procedures, as well as an improved and safe experience for the patient and the family members who accompany them. The magnetic resonance facility has also **been made more child-friendly**, with themed decoration based on the planets, outer space and magnetic fields. This means that children will find a spaceship with an astronaut and information about gravity, the planets and the distance between objects and planet Earth, as well as the friendly dog Laika. This **theme-based decoration has been used around the entire Diagnostic Imaging Area,** creating a much brighter and more orderly ambiance.

https://www.sjdhospitalbarcelona.org/en/diagnostic-imaging-department-ground-breaking-initiative-europe-implementation-new-15t-resonance

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Item 6 - **Guidance on Assessing a child's best interests during health care decision-making processes - UK**

"An assessment of best interests will include what is clinically indicated in a particular case. You should also consider:

a. the views of the child or young person, so far as they can express them, including any previously expressed preferences
b. the views of parents
c. the views of others close to the child or young person
d. the cultural, religious or other beliefs and values of the child or parents[4]
e. the views of other healthcare professionals involved in providing care to the child or young person, and of any other professionals who have an interest in their welfare
f. which choice, if there is more than one, will least restrict the child or young person's future options.

This list is not exhaustive. The weight you attach to each point will depend on the circumstances, and you should consider any other relevant information. You should not make unjustified assumptions about a child or young person's best interests based on irrelevant or discriminatory factors, such as their behaviour, appearance or disability."

In UK General Medical Council. Guidance for practitioners, available at: Assessing best interests - GMC (gmc-uk.org)

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Item 7 – **Example of guidance on assessing a child's competency (UK)**

From Cheshire West & Chester Council, Young People and Consent Guidance Notes :

To be considered competent, a child should have:
- The ability to understand that there is a choice and that choices have consequences
- The ability to weigh the information and arrive at a decision
- To communicate that decision
- A willingness to make a choice (including the choice that someone else should make the decision)
- An understanding of the nature and purpose of the proposed intervention
- An understanding of the proposed intervention's risks and side effects
- An understanding of the alternatives to the proposed intervention and the risks attached to them

- Freedom from undue pressure
- The ability to retain the information

Read more: https://www.cheshirewestandchester.gov.uk/documents/social-care-and-health/children/team-around-the-family/young-people-and-consent-guidance-notes-130219.pdf

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Item 8 – **WHO guidance on assessing the competence of children**[46]

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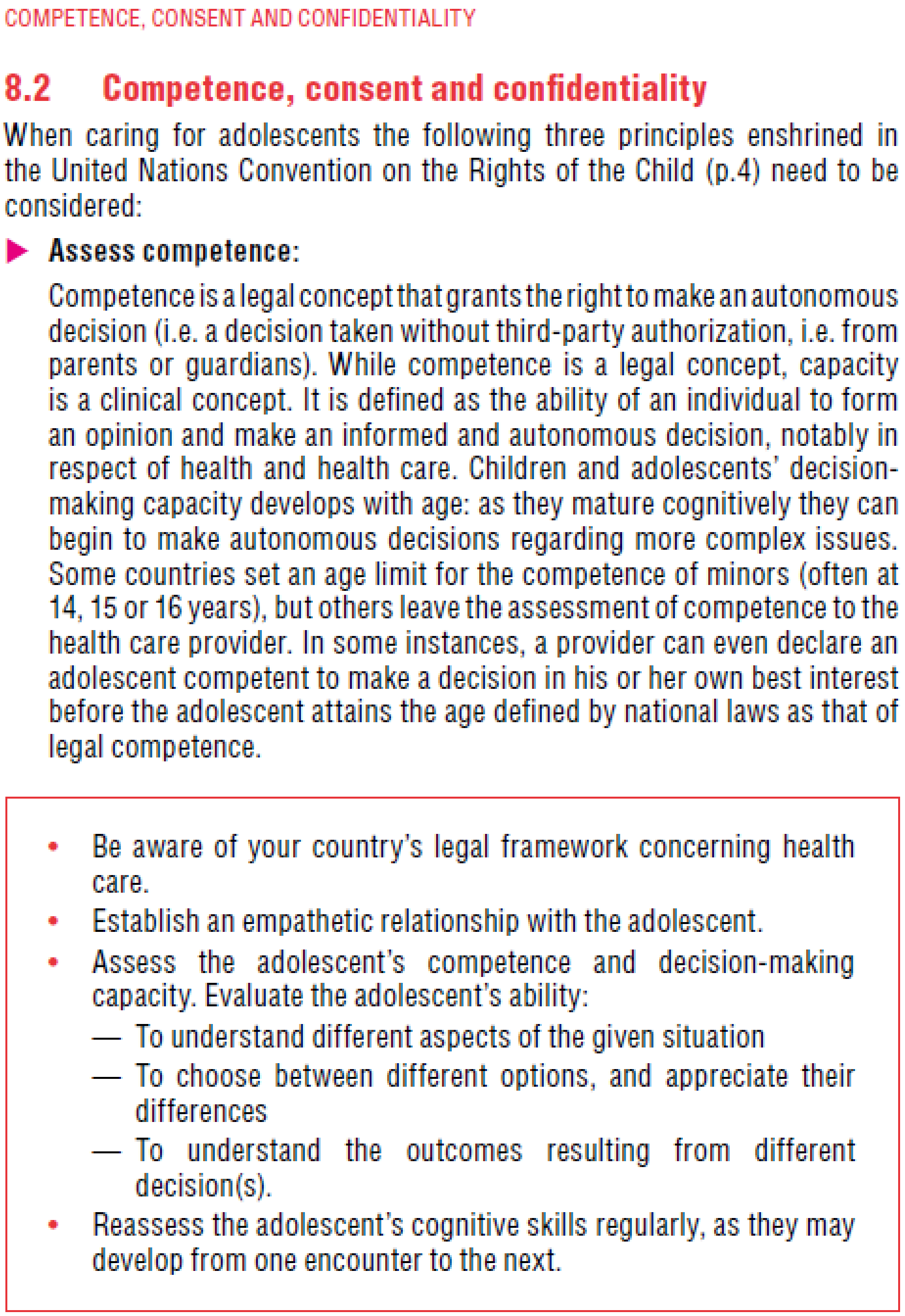
[46] Pocket book of primary health care for children and adolescents: guidelines for health promotion, disease prevention and management from the newborn period to adolescence. Copenhagen: WHO Regional Office for Europe; 2022. Licence: CC BY-NCSA 3.0 IGO. Page 666



COMPETENCE, CONSENT AND CONFIDENTIALITY

8.2 Competence, consent and confidentiality

When caring for adolescents the following three principles enshrined in the United Nations Convention on the Rights of the Child (p.4) need to be considered:

▶ **Assess competence:**

Competence is a legal concept that grants the right to make an autonomous decision (i.e. a decision taken without third-party authorization, i.e. from parents or guardians). While competence is a legal concept, capacity is a clinical concept. It is defined as the ability of an individual to form an opinion and make an informed and autonomous decision, notably in respect of health and health care. Children and adolescents' decision-making capacity develops with age: as they mature cognitively they can begin to make autonomous decisions regarding more complex issues. Some countries set an age limit for the competence of minors (often at 14, 15 or 16 years), but others leave the assessment of competence to the health care provider. In some instances, a provider can even declare an adolescent competent to make a decision in his or her own best interest before the adolescent attains the age defined by national laws as that of legal competence.

- Be aware of your country's legal framework concerning health care.
- Establish an empathetic relationship with the adolescent.
- Assess the adolescent's competence and decision-making capacity. Evaluate the adolescent's ability:
  - To understand different aspects of the given situation
  - To choose between different options, and appreciate their differences
  - To understand the outcomes resulting from different decision(s).
- Reassess the adolescent's cognitive skills regularly, as they may develop from one encounter to the next.

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Item 9 – **Guidance on how to manage refusal of care (France - MoH)**

(Translation)

2-4-Refusal of care expressed by the minor

The minor's participation in the decision and the collection of his or her point of view cannot take precedence over the decision of the holders of parental authority.

Minors may not refuse hospitalisation.

When a minor expresses a refusal out of weariness, fear of pain or even in the event of irreversible consequences, appropriate dialogue will be required. The medical team, in conjunction with the family, should try to convince the minor.

When the medical acts performed on the minor are not necessary for his or her health, the child has a right of veto prohibiting the holders of parental authority from imposing the act in question. This applies to bone marrow collection for the benefit of a family member or participation in biomedical research.

2-5-Refusal of care expressed by one or more holders of parental authority

It may happen that the parents or legal representatives of minors object to treatment or surgery being carried out or that they decide to take the child out of the health establishment against the advice of the doctors.

The question is to what extent hospital staff can intervene to protect the child against the parents' wishes.

The law states that the doctor must respect the parents' wishes after having informed them of the consequences of their choice.

When the health or physical integrity of the minor is in danger of being compromised by the refusal of the minor's legal representative or the impossibility of obtaining the latter's consent, the doctor must inform the doctor in charge of the service who may refer the matter to the public prosecutor in order to initiate educational assistance measures enabling him or her to provide the necessary care.

In the event of extreme urgency, the law requires the doctor to provide essential care, i.e. that which will protect the young patient from serious consequences for his health. In this case, the doctor will decide to intervene after consulting another doctor and will then draw up a certificate of the urgency of the situation, without waiting for an educational assistance measure from the public prosecutor.

In the absence of an emergency, if the parents or legal representative refuse to sign the authorisation for care or if their consent cannot be obtained, no act of care can be carried out, they must sign a certificate of refusal of care. The parents may avail themselves of the provisions of the Public Health Code when the care does not significantly affect the minor's state of health or if the abstention from care is in keeping with the family's cultural background and its own health beliefs.

If there is no emergency but the medical or surgical procedure is essential, the doctor must inform the director who will alert the public prosecutor so that an educational assistance measure can be taken. The duty public prosecutor should be contacted.

→ The doctor should mention in the medical file the need for the treatment, the proportionality of the procedure, the impossibility of obtaining the agreement of the holders of parental authority and the means used to change their minds.

→ The decision to operate must be signed by the doctor and co-signed by a representative of the hospital administration or by a doctor with no hierarchical link (check feasibility)

2-6-The case of refusal of blood transfusion

In case of emergency, the parents must be informed of the risk to the child if he/she is not transfused.

If the opposition persists, an educational assistance procedure must be initiated by the public prosecutor's office to lift parental authority.

The doctor then takes the decision to transfuse the child because of the urgency of the situation. If the blood transfusion is not essential for the child's survival and the parents or legal representative refuse it, they must sign a certificate of refusal of care.

Source: Fiche n°3: Information et consentement aux soins d'un mineur - Direction générale de l'offre de soins (DGOS) -ONVS Observatoire nationale des violences en milieu de santé

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Item 10 – **Italy – Italian Children's Hospital sets up Clinical Ethics Committee to advise and resolve conflicts**

In 2016, the Ospedale Pediatrico Bambino Gesu'(Rome) set up a Bioethics Function, a Clinical Ethics Service and in 2021 it established a Clinical Ethics Committee with the aim of providing advice and specialist training in Clinical Ethics for children.

The purpose of Clinical Ethics consultancy is to identify, analyse and propose solutions to ethical problems and conflicts that arise in patient care.

https://www.ospedalebambinogesu.it/etica-clinica-in-pediatria-89876/

There were 12 cases involving children brought to the attention of the Committee in 202, 15 cases in 2022, and 11 cases between January and July 2023. The numbers include all the ethical consultancy of Bioethics Resource some of which were discussed and evaluated together with the Committee.

Clinical cases are analyzed using four criteria: 1. Indications for medical intervention: what is the medical problem and how can it be solved; 2. Patient preferences: what the parents want and, *when the child can express himself, what the patient prefers;* 3. Quality of life: compared to the present conditions, how can the future life of the patient be improved; 4. Contextual aspects: for example the needs of siblings, closeness or distance from the hospital, economic or social problems.

The main and frequent ethical questions raised to the Bioethics Resource and to the Committee of Ethics concerns *therapeutic obstinacy*. Above all in paediatrics, clinical persistence and experimental obstinacy are often practiced because almost instinctively, even at the request of parents (due to understandable emotional feelings), the physician is inclined to do as the parents wish and do everything possible (both pharmacologically and technologically) to preserve the child's life, without considering the negative effects in terms of outcomes and further pain and suffering. Sometimes, clinical persistence is consciously practiced as a defence against any possible accusations of failure to provide medical assistance or active interruption of care or life-sustaining treatments (the so called ‘defensive medicine’). In the majority of cases, clinical persistence is accompanied by the use of often sophisticated technologies. For this reason, the term "clinical persistence" is also associated with "technological obstinacy". Issues involving clinical persistence in paediatrics need to be addressed on a case by case analysis which takes into account the specific circumstances prevailing in the different concrete realities: An increase of these situations is foreseeable in paediatrics environment given the rapid developments in science and technology.

The main ‘lessons learnt’ in the Committee in this context are the following:

In the first place, *the need for the identification of clinical obstinacy through scientific and medical elements* that describe the patient's clinical condition, as in paediatrics the subjective elements that refer to the patient's experience are often lacking. In the case of children, there is a lack of a sufficiently conscious participation in the choice, as they may not be able to express themselves because of their age or immaturity, or in any case be in a condition incompatible with autonomy or full awareness. The description of the clinical condition is necessary in order to justify a possible gradual suspension of an ongoing medical treatment in children with a negative prognosis and in conditions of limited life expectancy, excluding any reasonable possibility of recovery and improvement of the clinical conditions, but only increasing the pain and suffering of the child. The reality is often even more complex: some children do not have a diagnosis (as, for example, is the case with rare diseases); others have a diagnosis but not a prognosis. It should always be considered that in children the unpredictability of the evolution of the clinical framework calls for special attention in careful consideration of each term used ; even the reference to "incurability" is dynamic, revisable in relation to the evaluation moment by moment of the evolution of the pathology, of the rapid progress of medical science; even more so with the expressions 'terminality' or 'imminence of death' which are temporally and clinically vague given the prognostic difficulty. And even pain and suffering are not easily detectable and still difficult to measure above all in children. The *best interest of the child* should be the inspiring criterion in the situation and should be defined starting from the contingent clinical condition. Doctors should avoid implementing ineffective and disproportionate clinical pathways only in order to comply with parental requests and/or to meet defensive medicine criteria. The Committee helps doctors and parents (often through hearings and direct dialogue during meetings) to base their reflection on the best interest of the child.

A second important element is *communication*. The decision of the medical team should necessarily be made by involving the parents in the cure and care of the children, devoting particular attention to the empathic understanding of the dramatic situation that the parents are facing and guaranteeing them time and space in communication. Information to parents should be provided by a multi-specialist medical team, of variable composition in relation to the typology of the child's illness, the examination of the possible clinical implications associated with it, the risks and benefits of treatments and their burden. It should be kept in mind that the information cannot always have clear and definitive contents, given the complexity, uncertainty and unpredictability of the condition. However, the information should be continuous for the duration of the entire therapeutic process, also through the elaboration of shared treatment plans or decisions, according to the evolution of the child's conditions in the context of a care relationship, which contributes to the construction of a climate of trust between doctors and family. Often in the process psychologists need to be involved to support both the parents and the children. The quality of life of both the children and parents should be considered, as well as the context (cultural, socio-demographic conditions).

A third element is the need to implement *the training of doctor and healthcare personnel, to create a core group of professionals* (together with social workers, psychologists, bioethics experts, family associations) able to support parents on an emotional and practical level and accompany them in the difficult path given by the conditions of illness and vulnerability of the child in extremely precarious clinical conditions. There should also be recognition of the important role of the Associations of the parents of sick children in order to consolidate the networks for joint support from parents and from society itself.

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Item 11 - **Young Persons Advisory Groups' (YPAGs) role and activities having an impact on individual decision-making process**

YPAGs have already been set up across Europe and at international level to underpin clinical trials. The YPAGs include young people aged between 8-19 years (although some groups have older young adults up to the age of 21) who are patients, regular attenders at hospital, and/or healthy youths having an interest in science and healthcare. YPAGs are predominantly facilitated by a professional involved in a clinical research facility, children's hospital, or academic institution. They are recruited by means of schools, associations, hospitals and the patients' and families associations, and were selected according to their motivation and interest in being involved in this kind of empowerment activities. YPAGs provide a platform for children and young people to have a voice, share their opinions, and apply their experience to a variety of issues relevant for biomedical research.

Item 12 – National Healthcare Charter for Young People - Ireland

NATIONAL HEALTHCARE TEENAGE (12-18) CHARTER

A1 wallchart

We acknowledge the hard work and dedication of the Youth Advisory Council (YAK) for helping to develop the poster of the charter aimed at young people.

YAC YOUTH ADVISORY COUNCIL

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Item 13 – A network of Swedish paediatric hospitals involve children and young patients in view of improving quality of care

The network aims at improving the quality of paediatric care, with the involvement of young patients, parents and staff. It has its foundation in a set of quality criteria derived from law, professional standards, knowledge of care environment, and the expressed opinions of children (primary and high schools) from Patient Reported Experience Measure (PREM) surveys and young adviser groups (YPAGs).

The health facility self-evaluates its practices and includes children and families in the process. The evaluation reports are developed by receiving feedback from children and families, and they are exchanged with a clinic of a similar type to do a thorough mutual collegial examination. When the final reports have been exchanged the clinics have a clear idea of what to improve, including improvements to be done with children. In terms of methodology, routines for how staff involve child patients in planning their care, communicating their opinions and preparing for medical measures or interventions are required. The clinic carrying out the evaluation on its practice has to demonstrate how the staff has these skills.

The network offers advice and sample questions to be used, for example in PREM surveys, and methods for involving children in care environment surveys.

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Item 14 - **Children Users' Commission - France**

In France, each hospital has a users' commission (*commission des usagers*) that examines complaints addressed to the establishment and makes proposals to improve the stay and care of patients and their relatives. Typically, the committee is composed of adults. In 2022, the University Hospital (CHU) in Reims set up its first users' commission exclusively dedicated to children, with the aim of collecting their voices, regardless of their age and experience of hospitalization. It was composed of ten children aged 4 to 17, their parents, the hospital director, other representatives of the hospital and external associations. This was a first-time experience in France.

For an entire month, hospitalized children were asked to fill in questionnaire similar to the user satisfaction surveys that are usually released to adults at the end of their hospital stay. Topics included the way in which patients had been welcomed, the quality of meals, accommodation or the management of pain. Children and parents were also invited to submit ideas and projects. Four proposals were selected and projects will see the day within the following year: 1) allowing children to meet with their pets during hospitalization, 2) creating an app for parents to be informed of how their child's stay at the hospital is going, 3) providing all children with access to Disney+ platform, 4) introducing à la carte meals (rather than a set menu for all).

The hospital wishes to conduct such consultations on a yearly basis.

Learn more here: https://www.reseau-chu.org/article/lhopital-imagine-par-les-enfants-pour-les-enfants/

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