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COMMITTEE ON BIOETHICS

(DH-BIO)

CONCEPT NOTE & QUESTIONNAIRE

"Participation of children in the decision-making process on matters regarding their health"

Introduction

Over time, the importance of participation of children, particularly adolescents, in decision-making on matters regarding themselves has been recognized in international legislation, policy reports, youth health strategies (World Health Organization "The European child and adolescent health strategy 2015– 2020"), and position papers of prominent medical societies.

The Council of Europe Strategy for the Rights of the Child (2016-2021)[1] underlines that "Children have the right to be heard and participate in decisions affecting them, both as individuals and as a group. Indeed, everyone has the right to freedom of expression, as guaranteed under Article 10 of the European Convention on Human Rights. The UN Convention on the Rights of the Child (UNCRC) grants children the right to express their views freely in all matters affecting them and to have their views given due weight in accordance with their age and maturity".

According to human rights instruments, notably the UNCRC, children are rights-holders with a progressively evolving ability to make their own decisions. However, on matters concerning their health and general well-being, there is uncertainty as to how the increased recognition of their decision-making capacity should be addressed.

As underlined in the "Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025)"[2], finding the right balance between protection and autonomy (conceptualised as "the child's right to an open future") is a challenge when considering that children's rights are situated within a larger set of parental rights and responsibilities which also focus on their "best interests".

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

The legal context

The Oviedo Convention reaffirms that any intervention in the health field can be carried out only after the person concerned by that intervention has given free and informed consent to it. The word "intervention" shall include all medical acts (such as interventions performed for the purpose of preventive care, diagnosis, treatment, rehabilitation or research). Clear and suitably worded information shall be provided to the person concerned, and the consent can be freely withdrawn at any time.
Some persons may not be able to give full and valid consent to a given intervention due to either their age (minors) or to their mental incapacity. It is therefore necessary to specify the conditions under which the intervention may be carried out on such persons in order to ensure their protection. The Oviedo Convention leaves it to domestic law in each country to determine whether or not persons are capable of consenting to an intervention, taking into account the need to deprive persons of their legal capacity to consent only where it is necessary, in their best interests. Where, according to domestic law, a minor does not have the capacity to consent to an intervention, the authorisation of his or her representative or an authority or a person or body provided for by law is required. This person or body must always act in the best interests of the minor.

[1] Adopted in April 2016, para. 37, https://www.coe.int/en/web/children/children-s-strategy
[2] Adopted by the DH-BIO on 2 November 2019, para. 23 *et seq.*, https://www.coe.int/en/web/bioethics/strategic-action-plan.

Regarding the right of minors to participate in treatment decisions, from a legal perspective, considerable discrepancies exist across European countries. The statutory age to be considered able to consent varies from twelve to eighteen years. In legal systems in which the legal age for medical consent is the same as the age of legal majority, legal representatives of minors (such as a parent or guardian) are recognized as the only decision-makers until the age of maturity (e.g. Slovakia, Cyprus, Latvia, Luxembourg, Malta, Estonia, Italy, Poland, Greece). However, in some of these countries, laws recognize the need for informing minors and taking their will into account, with respect to their cognitive capacity. Other European countries (e.g. Denmark, Portugal, Hungary, Slovenia, Spain, Netherlands) set the age at which minors can consent to medical treatment without parents (age of medical majority) below the age of majority. Swiss legislation grants all patients with proven capacity, regardless of age, the right to independently decide and provide consent to medical care. In France and Belgium, the age of medical majority does not exist, but minors are entitled to information and decision-making taking into account their maturity and competence.

According to Article 6 sec.2 of the Convention on Human Rights and Biomedicine (Oviedo Convention), where, according to law, a minor does not have the capacity to consent to an intervention in the health field, the opinion of the minor shall be taken into consideration "as an increasingly determining factor in proportion to his or her age and degree of maturity". This means that in certain situations which take into account the nature and seriousness of the intervention as well as the minor's age and ability to understand, the minor's opinion should increasingly carry more weight in the final decision. In the context of research, it is specified that research may be undertaken only if, among other conditions, "the person concerned does not object" (Art. 17 section 1, 5th indent of the Oviedo Convention).

Involving minors in the decision-making process

There are several factors that may impact on the ability of the child to be involved in decisions regarding healthcare and or health research. Some of these factors relate to the child, including their capacity to be actively involved in these decisions. Others relate to the family situation, sociocultural context, or the underlying beliefs and practices of the healthcare provider involved.

According to scientific literature, to let young people to participate effectively in shared decision-making they need to develop the skills of engagement with healthcare professionals and confidence in interacting with them, and health professionals have to acquire the necessary skills to interact with them appropriately. Children and young people who participate in shared decision-making in healthcare are likely to be more informed, feel more prepared, also learning how to manage their condition and treatments on their own and experience less anxiety about the unknown.

The provision of appropriate information in simple jargon-free language can help children understand and feel more involved in decision-making. Checking a child's understanding of information provided, especially in relation to risks and benefits, and providing the child with the opportunity and time to express preferences and discuss issues may also help. Reassuring the child in terms of support from parents and professionals for the decision is vital as most children prefer to share the decision and do not want full responsibility. Giving the child time to consider options, providing the opportunity to discuss any change of preference and assessing decision satisfaction or regret is essential.

As such, inclusion in discussions about treatment decisions may help young persons to develop self-caring and participation skills that are necessary for long-term self-management. It is important that children get the opportunity to practice taking part in decisions so that they build and develop their skills of decision-making. Explore legal provisions, experiences and practices across Council of Europe Member States is essential to develop considerations and common positions.

Actions & Methodology to implement children rights and participation in decision making

To identify national provisions, guidelines and practices aimed at increasing children participation in decision making process in health care, research and more in general in biomedical field, a survey has been developed with the support of Dr Annagrazia ALTAVILLA[1], responsible of International Relations of Espace Ethique PACA Corse and Chair of TEDDY – the European Network of Excellence for paediatric research. The survey will be carried out on-line by the Committee on Bioethics of the COE and will be submitted to the main stakeholders (DH-BIO representatives, healthcare professionals, patients' associations, investigators, Ethics Committees, CROs, sponsors…)[2] also identified by TEDDY. Results of this survey will be used for developing a "Guide to good practice concerning the participation of children in the decision-making process on matters regarding their health". This Guide will be developed by the DH-BIO in co-operation with the Council of Europe's Steering Committee for the Rights of the Child (CDENF) and will be aimed at implementing children rights (their evolving capacities and autonomy, conceptualised as "the child's right to an open future"). It will primarily target healthcare professionals but will also be accessible to the children's parents and/or legal representatives.

Examples of regulations from the research context

In order to respect child developing autonomy and self-worth, the EU Regulation 536/2014 on Clinical trials, clearly specifies that 'the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in Article 29(2) [informed consent] to refuse participation in, or to withdraw from, the clinical trial at any time, is respected by the investigator'.[3] Nevertheless, Member States still have a large margin of manoeuvre in applying this principle, again possibly leading to some disparities, especially with multinational trials. The EU Regulation on clinical trials integrated also the concept of the assent of the child (introduced for the first time by the Declaration of Helsinki and further mentioned in the WHO-CIOMS and ICH-E11 guidelines), defined as the "child agreement to participate in research". It is recommended that assent be sought for participation in research at an age-appropriate level, and as suitable to the complexity of the project under consideration. If during a clinical trial the minor reaches the age of legal competence to give informed consent as defined in the law of the State concerned, his or her express informed consent shall be obtained before that subject can continue to participate in the clinical trial.
Specific requirements to obtain the child's assent, adapted to different age-ranges, have been provided in the "EU Ethical Recommendations" (2017). This document specifies that children have to be involved in the decision to take part in research decisions as their developmental capacity dictates, they should be provided with information in a way adapted to his or her age and mental maturity. In processing children data and information on their health national laws on data protection should be respected. The EU GDPR thus underlines the need to obtain "informed consent" from a child, after providing information in language that is clear and plain for children. Ethical norms and guidelines stress that consent is a continuing process that should be maintained throughout the course of research. Nevertheless, despite the existing legal frameworks for research involving children, many differences still exist across Europe. best-practice guidelines based on a well-sustained methodological approach and in compliance with national legislations need to be developed.

[1] Lawyer, PHD Ethics, HDR - Chair of TEDDY -European Network of Excellence for paediatric research, and Responsible of international relations of Espace Ethique Paca-Corse (France).

[2] Non-Exhaustive list of stakeholders: Health care professionals, scientific societies, TEDDY Network/partners, EUREC, DH-BIO countries representatives, EUCROF, EMA EMPREMA, BBMRI, EPTRI, EJPRD, BENZI Foundation Partners/Network, EAHL, ECRIN, European Patients Forum, ERNs, C4C partners, ARISE EU project.

[3] EU Regulation 536/2014 on Clinical trials, Art. 32.1.(c).

SURVEY ON NATIONAL PROVISIONS, GUIDELINES AND PRACTICES AIMED AT INCREASING CHILDREN PARTICIPATION IN DECISION MAKING PROCESS IN THE BIOMEDICAL SECTOR

Background

Over time, the need to include children in making decisions about their health has been recognized in international legislation and public policies, policy reports, youth health strategies and position papers of prominent medical societies.

According to human rights instruments, notably the UN Convention on the Rights of the Child (1989), children are rights-holders with a progressively evolving ability to make their own decisions. The European Convention on Human Rights and Biomedicine of the Council of Europe (1997) presents a similar stance, such that the opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity" (Article 6, section 2). This means that in certain situations which take into account the nature and seriousness of the intervention as well as the minor's age and ability to understand, the minor's opinion should increasingly carry more weight in the final decision. (Art. 17 section 1) Thus, in the context of research, the respect of the wish of the minor concerned has been included in the legal framework. That means that the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to refuse participation in, or to withdraw from, the clinical trial at any time, is to be respected.

However, on matters concerning their health and general well-being, there is uncertainty as to how the increased recognition of their decision-making capacity should be addressed. Also, the level of parental involvement in decision-making may change as children grow older and become increasingly capable of participating in decision-making.

From a legal perspective, huge discrepancies exist in national laws regarding the recognition for minors of a right to participate in treatment and research decisions. The diversity in approaches across Europe to the inclusion of children in health-related decision-making also suggest widespread recognition of the need to encourage children to be involved in decision-making. Furthermore, despite the legal recognition of children's participation rights, and also the benefits that children experience by their involvement, there is evidence that legislation is not always translated into healthcare practice.

Finding the right balance between protection and autonomy (conceptualised as "the child's right to an open future") is particularly challenging. At different stages in their lives, children require different degrees of protection, provision, prevention and participation in accordance also to the "best interest" of the child. Many experiences have been developed at national and local level to foster children participation in the research sector as well as within healthcare. Explore provisions, experiences and practices across Council of Europe Member States is thus essential to develop considerations and common positions.

To identify national provisions, guidelines and practices aimed at increasing children participation in decision making process in health care, research and more in general in biomedical field, his survey has been developed with the support of TEDDY - the European Network of Excellence for paediatric research. It will be submitted to the main stakeholders and relevant paediatric initiatives across Europe.

Results of this survey will help in outlining best standards and practices and determining roadmap for developing a Guide that primarily target healthcare professionals but that can also be accessible to the children's parents and/or legal representatives.

Answer the online survey

- Replies to be submitted online before 31 March 2021 -

Transcript of questions contained in the online survey

Before starting, please specify which category you belong to:

- Healthcare professional
- Scientific society member
- Patients/parents/children
- DH-BIO delegate
- CDENF delegate
- European clinical research network member
- Research organisation member
- ***Other… Please specify***

Name

Surname

Position

Organisation

Email

Do you want to be contacted for providing more details (if relevant) or for further developments?

YES NO

Please note that data will be processed according to GDPR and used for the purpose of the survey, and that no personal data will be published.

QUESTIONNAIRE:

1. **Are you aware if specific provisions related to the children participation in decision making process in healthcare and research are included in your national legislation?**

   NO
   YES

   If YES please provide with more details, including the text of the relevant legal provisions also specifying if a right of minor to participate in treatment and research decisions is recognised.

2. **Are you aware of specific provisions related to the children participation in decision making process in healthcare and research are included in your national/local guidelines?**

   NO
   YES

   If YES please provide with more details …

3. **Are you aware of experiences/procedures aimed at increasing children participation in decision making process within healthcare?**

NO
YES

If YES:

3.1 Which kind of initiatives have been developed:

- Education for young persons
- Training of healthcare professionals to better involve children
- Education for parents /family members
- Exchanging of Information (verbally?, on paper? On-line?)
- Encouraging the expression of preferences (verbally?, on paper booklet?, on-line?)
- Eliciting post-decision reactions from the child (either satisfaction with care or regret)
- Enhancing children involvement in major decisions (treatment decisions) including the respect of their refusal
- Enhancing children involvement in minor decisions (choices about care delivery) with the aim to e.g. gain their cooperation, make treatment more palatable, give back a sense of control and build trusting relationships
- Peer group initiatives
- Other: …Please specify

At what level?

- At European level
- At national level
- At local level

3.2 These initiatives have been developed taking into account:

- The age of the child
- Cultural backgrounds
- Previous experiences of the child in the biomedical field
- Other… Please specify

3.3 These initiatives have been developed in the following fields:

- General medical practice
- Rare diseases
- Oncology
- Genetics
- Transplantation
- Chronic diseases
- Other…Please specify
    - **These initiatives have been developed with the aim to increase awareness and knowledge on:**
- Children rights
- Data protection
- Other: Please specify
- **Please provide with more details…**

4. **Are you aware of initiatives/procedures aimed at increasing children participation in decision making process within biomedical research?**

NO
YES

If YES please provide with more details …

4.1 Which kind of initiatives have been developed:

- Education for young persons
- Education for parents/family member
- Training of healthcare professionals to better involve children
- Exchanging of Information (verbally? on paper? On-line?)
- Encouraging the expression of preferences (verbally? on paper (booklet?) On-line?)
- Eliciting post-decision reactions from the child (either satisfaction with care or regret)
- Enhancing children involvement in major decisions (treatment decisions) including the respect of their refusal
- Enhancing children involvement in minor decisions (choices about care delivery) with the aim to gain their cooperation, make treatment more palatable, give back a sense of control and building trusting relationships
- Peer group initiatives
- Other…Please Specify

4.2 These initiatives are developed taking into account:

- The age of the child
- Cultural backgrounds
- Previous experiences of the child in the biomedical field
- Other… Please specify
    - **These initiatives have been developed in the following fields:**
- Rare diseases
- Oncology
- Genetics
- Transplantation
- Chronic diseases
- Other…Please specify

Please provide with more details…

- **These initiatives have been developed with the aim to increase awareness and knowledge on:**
- Children rights
- Data protection
- Other: Please specify

5. **Are you aware of initiatives aimed at engaging children in an advisory/advocacy role in the biomedical field (healthcare and research)?**

NO
YES

IF YES

5.1 Which kind of initiatives have been developed?

- Debates
- Consultation
- Forum
- Education
- Information campaigns
- Other…Please specify

Please provide with more details …

6. **Do Young Persons Advisory Groups exist in your country/institution?**

NO
YES

If YES

6.1 How have they been formalised?

- By legal status (association? Foundation? Consortium? …)
- By devoted funding/grants support
- By integration in international/European/national projects
- Other…. please specify

Please provide with details (link, websites, documents…)

7. **Are you aware of initiatives aimed at increasing awareness of children and at including young persons in decision process related to the application of new/emerging technologies (e.g. in genetics, advanced therapies, gene editing, information society technologies …)?**

NO
YES

If YES

7.1 Which kind of initiatives have been developed?

- Debates
- Consultation
- Education
- Forum
- Information campaigns
- Other…please specify

8. **Are you aware of initiatives aimed at increasing awareness of children about COVID-19 /pandemic situation (prevention, healthcare and research)?**

NO
YES

If YES

8.1 Which kind of initiatives devoted to children have been developed:

- Education for young persons by health authorities
- Education for young persons by school/teachers
- Education for parents and family members
- Information on prevention measures (verbally? on paper? On-line?)
- Information on available therapies (verbally? on paper? On-line?)
- Information on research (verbally? on paper? On-line?)
- Focus Groups
- Forum
- Specific websites
- Other…Please specify

If YES please provide with details (link, websites, documents…)

Many thanks for your contribution