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PRELIMINARY SUMMARY OF THE SURVEY RESULTS

ON CHILDREN PARTICIPATION IN DECISION MAKING PROCESS REGARDING THEIR HEALTH

**Summary commissioned by the Committee on Bioethics (DH-BIO) of the Council of Europe*

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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, children are rights-holders with a progressively evolving ability to make their own decisions. Notably, the UN Convention on the Rights of the Child (1989) 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" (art.12). 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).

Finding the right balance between protection and autonomy 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, a survey has been developed.

Methodology of the survey

The Survey is composed of 8 main questions and some sub-questions. Questions aim at identifying national provisions (including legal provisions and guidelines), especially regarding the implementation of the right of the child to be heard. They also aim at exploring initiative/practices aimed at increasing awareness of children and at including them in decision process in different therapeutic areas and research activities. Further, taking in mind that the child's autonomy has to be conceptualised as "the child's right to an open future" and that there is a need to safeguard children's rights in relation to medical practices which have future or long-term implications for them, it has been asked to detail eventual initiatives aimed at increasing awareness of children and at including them in decision process related to emerging technologies (such as gene editing, advanced therapies… information society technologies, nanotechnology…). Finally, we asked to detail eventual initiatives in COVID 19 pandemic situation in terms of prevention, healthcare and research.

This survey has been carried out on-line, by releasing a questionnaire to CDENF/DHBIO delegates and to the main stakeholders, including scientific societies, European networks, patients/children families' associations, research organizations, industries and European institutions representatives.

This survey was developed and released with the support of TEDDY, the European network of excellence for paediatric research, the first European multidisciplinary network devoted to promoting children-tailored medicine and guaranteeing children's rights and well-being, including 50 partners from 21 countries (EU and non-EU).

Results

We received **185 answers from 36 countries**. The most represented responder countries are France, Italy and Germany. Most of responders are healthcare professionals but some of them declared also to be members of scientific societies and research organisations. Members of children/family's associations actively participated in the survey. The high rate of negative answers on different topics suggests that there is a global lack of awareness of responders on provisions and initiatives related to children participation in decisions regarding their health. A summary of the legal frameworks, guidelines and practices/initiatives, outlined by the participants to the survey, is provided here below.

1. National legal provisions & guidelines

With reference to the existing national legislations, many responders refer to the art. 12 of the International Convention on the Rights of the Child, that introduced the right of the child to be heard. Reference is also done to the Oviedo Convention, and specifically to the art. 6.

National legal frameworks are very heterogeneous especially in the healthcare sector. Taking into account that to exercise his/her right to be heard a child has to be capable of understanding, the notion of discernment is an important notion to be considered.

According to national laws, the discernment can be evaluated by those who are supposed to interact with the child (notably the healthcare professionals) or can be determined either by the legislator who sets a minimum age for the exercise of the right to be heard, or the discernment.

The right to receive information and/or to express his/her will, on the basis of the evaluation of the degree of maturity or of the capacities or of the level of development of the child is recognized in **Italy, Belgium, France, Germany, Finland, Hungary, Monaco**. The situation is more complex in Spain, where different provisions exist according to the autonomous communities' laws.

In **France**, healthcare professionals do not have to obtain the parent's or guardian's consent when medical treatments are necessary to safeguard the health of a minor or when the minor expressly refuses the consultation of the holders of parental authority.

The exercise of the right to receive information or to express his/her will is recognized once the child reached the minimum age set by legislators in **Bulgaria, Italy, Norway, Ireland, Portugal, Netherlands and Denmark**. The age ranges vary from 7 to 16 years and are combined with different conditions.

For example, in **Norway**, the child who is able to form their own opinions has the right to receive information and give opinion from 7 years. From 12 child has the right to refuse to inform parents about his/her health and from 16 the child can give consent, unless special provisions, or where the nature of measures dictate otherwise.

In **Ukraine**, since children from 14 must consent to medical intervention but can receive information from the age of 18, a normative dissonance exist.

In **Italy**, the minor or the person must receive information concerning their choices with regards to their health in a way that is appropriate to their capacities, so as to being in proper conditions to express their willing. Furthermore, not specifically for the healthcare sector, it is specified that the minor from the age of 12, or even younger where capable of understanding, has the right to be heard in all the matters and procedures that concern him or herself.

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

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

Age	Country
7	Norway *
12	Netherlands (child can be associated to decisions) Italy (right to be heard not only in the healthcare sector)
14	Austria*, Ukraine *
15	Denmark (right to consent/refuse)
16	Bulgaria, Ireland*, Norway* Netherlands* Portugal

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

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

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

With reference to the existing guidelines, most of the responders refer to the legal frameworks and, in some cases (e.g. France and Finland), identified as guidelines the national charters for Children in Hospital that comes from the European Charter for Children in Hospital adopted in 1986, that establishes the right for the children to be informed and the right of participation in all decisions involving their health care. In **Albania** and in **Germany,** guidelines on children rights including recommendations for children participation but not specifically applicable in the healthcare sector exist. In **Albania**, the guideline for "General criteria for participation in activities, consulting and decision-making processes related to children and for children", has been approved by the Minister of Health and Social Protection in 2020. During the process of drafting this guideline many consultations and meetings were organised with the children. In **Germany**, a Child Protection Guideline has been developed under the auspices of the German Medical Society for Child Protection (DGKiM) in collaboration with 82 expert associations from the fields of healthcare, youth welfare services and education and with financial support of the German Federal Ministry of Health. The guideline, focused on children abuses, contains also some recommendations for participation of children and adolescents in the field of medical child protection.

In **Sweden,** patient-reported outcome measures (PROMS) and patient-reported experience measures (PREMS), including also digital feedbacks, are used to support the clinical-patient communication and the children's participation in decision making process, especially within research activities. To be defined as compliant with University Hospital Standards, by the National Board of Health and Welfare, health care providers shall comply with specific minimum criteria related to the involvement patients and their families in both research and health care improvement and development projects.

In the context of research, the respect of the wish of the minor concerned has been included in many legal frameworks. National legislations on research are essentially compliant with EU Directive 2011/20 and/or Oviedo Convention provisions (with some national specificities, especially in terms of age ranges). This means that, within research, the explicit wish of a minor who is capable of forming an opinion and assessing the information referred, to refuse participation in, or to withdraw from the clinical trial, at any time, is to be respected.

Finally, in terms of self-determination in sexual and **Reproductive Health**, the following legislative examples have been reported. In **Mexico**, Official Mexican Standard on Reproductive Health considers that children aged 10-18 are entitled to make decisions regarding pregnancy prevention and points out that parental consent is not necessary for adolescents to receive information concerning sexuality and pregnancy. In addition, the System for the Comprehensive Protection of the Rights of Girls, Boys and Adolescents (SIPINNA, for its acronym in spanish) mandates the direct participation of girls, boys and adolescents in decision-making in any area. In **Malta**, the Gender Identity Gender Expression and Sex Characteristics Act specifically bans normalising treatments on intersex children without their informed consent.

2. Initiatives & experiences relevant for healthcare and research

With the reference to the experiences and procedures aimed at fostering participation in decision making process within healthcare, the most relevant activities identified are education of young persons, education for parents/family members, training of healthcare professionals and exchanging of information.

These activities are essentially carried out at national and/or local level. The most relevant field in which these initiatives are developed are rare diseases, oncology, chronic disease and general medical practice. Responders underlined that the activities are developed essentially to implement children rights. As other aims, they identified the empowerment of children, the need to increase the involvement of children in research, as well as the need to improve the efficacy of the treatment and the patients' adherence to the treatment.

The age of the child has been identified as the most important driving aspect for developing initiatives and, in the free answers, responders underlined that, fostering children empowerment with the aim to increase the participation and the adherence in treatment, self-management of diseases forward adulthood are important aspects to be taken into account in developing activities.

What about the initiatives developed more specifically in the field of biomedical research? The most relevant activities identified are always education of young persons, education for parents/family members, exchanging of information and training of healthcare professionals. Enhancing children participation in minor decisions (choices about care delivery) is also considered important to gain their cooperation, make treatment more palatable, give back a sense of control and building trusting relationships. These activities are essentially carried out at national and/or local level.

The most relevant field in which these initiatives are developed are again rare diseases, oncology, chronic disease, and general medical practice.

Responders underlined that, also in biomedical research field, the activities are developed essentially to implement children rights. They pointed out that the empowerment of children, the need to increase the involvement of children in research, as well as the need to improve research practices and the self-management, while fostering the empowerment of children and the respect of the children's opinions and preferences, as other aims for developing initiatives.

The age of the child has again been identified as the most important driving aspect for developing initiatives. In the free answers, it has been underlined that medical conditions and the diversity of the group are important aspects to be taken into account in developing activities.

A convergence between activities developed in the biomedical research context and those developed in the context of healthcare appears. It is demonstrated by the fact that activities developed in the context of research projects focus also on aspects relevant also for healthcare. These activities are educational programmes, booklets, serious games, videos and working groups focused on children participation and empowerment.

Responders make reference in both cases (research and healthcare) to activities carried out by **Young Persons Advisory Groups (YPAGs)**, set up to underpin clinical trials but de facto operating in a larger context. 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, healthcare, and children's rights. 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 these 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 in clinical trials, such as relevant endpoints, protocol design, formulations, age-appropriate information, and patient tools. Kids Groups developed under the coordination of TEDDY Network, focus not only on biomedical aspects but also on innovation and information, humanization of healthcare, ethical issues and fundamental/children rights.

YPAGs have been created in **Spain, France, Austria, Monaco, Italy and Albania** (Kids Bari and Albania, are developed under the coordination of TEDDY Network). They have been formalised in many cases by legal status, or by the integration within European and international projects, sometimes with specific funding and support, especially if they are hospital based. Existing and new YGPAs can also adhere to the European (EYPAGnet) and international (International Children's Advisory Network - ICAN) networks.

To have a more comprehensive approach, within TEDDY, a specific “Working Group on children active engagement”, composed of experts from TEDDY Network, has been set up with the aim, among others, to promote the dialogue among main stakeholders to increase the active engagement of children and adolescents in biomedical field, to promote children involvement fostering self-determination according to children rights and encouraging the sharing of information and best practices among the different YPAGs at European and international level.

To foster children participation in decision making regarding their health, other initiatives have been identified as relevant by the responders to the survey. In particular, it has been pointed out the **Child Life Specialists** (existing in **Germany, Spain, UK** and **United States**) that are experts in child development who advocates for children rights in healthcare, providing interventions to ensure that children's voices are heard and needs responded to in a developmentally appropriate way. Certified Child Life Specialists are educated and clinically trained in the developmental impact of illness and injury. Their role helps in improving patient and family care, satisfaction, and overall experience.

A reference is also done to the **Ombusdam and/or Ombudsperson for Children**, established for example in **Ireland, Croatia** and **Austria**. Children’s Ombusdam is a representative for children’s interests and defender of their rights, aimed at promoting the rights of the child in the public and private spheres by providing advice and information. In many cases, it investigates complaints about services provided to children by public organisations.

Finally, taking in mind that having an advisory role means to seek to inform a decision process, while having an advocacy role means ensuring a particular outcome (that here is the respect of children rights guarantying their best interests), consultation, education, forum and information campaigns are identified as more common and relevant activities, often combined with feedback systems, to foster advisory/advocacy roles for children.

3. Initiatives and Experiences relevant for emerging technologies & COVID 19

Regarding the initiatives developed to foster the inclusion of children in decision processes related to the application of **new emerging technologies**, (such as genome editing, advanced therapies, genetics…), responders identified some education and awareness activities (debates, training, research groups focused on ethical, legal and social aspects).

In **France**, the Espace Ethique Ile de France develop the initiative **“Transmissions”** aimed at giving the means to the young generations to develop a disposition to reason, considering other’s point of view and acting on questions of bioethics, medical ethics and society by organising debates and analysing case studies. This initiative is carried out within partnerships established with high schools.

In **Germany**, the **Ethical, Legal, and Social Aspects (ELSA)** funding initiative have been promoted by the Federal ministry of Education and research, to establish findings regarding the opportunities and risks presented by the modern life science. The results will serve as a basis for societal discourse, research and development, medial practice and decisions taken by politicians and legislators. One of the objective of ELSA is to enable young participants in young discourse to build their own informed opinion on ELSA topics (joint research groups and seminars are the main activities).

Within the project **RESTORE** a videogame has been developed with the aim to raise awareness of young persons on advanced therapies. Restore is a EU initiative aimed at transforming Advanced Therapies into a reality through the development of new Advanced Therapies and their implementation in clinical practice to enhance the value-base outcome of patients.

Concerning the current **COVID-19 pandemic** situation and relative issues, responders identified some interactive and age-tailored initiatives, developed with the aim to increase children’s awareness on COVID19 pandemic and support them during the health emergency.

Interesting initiatives such as recommendations or platforms focused on the rights and well-being of children aimed at providing tailored information and support to children according to their age, health and emotional status have been promoted.

In **Belgium**, a Scientific paediatric platform **(Joy Platform)** providing children and young people with scientifically based useful information about COVID-19 has been set up, including specific pages dedicated focused on the rights, well-being and development of all children and young people in Belgium during and after COVID-19.

In **Norway**, it is available an **interactive platform** aims at giving information and support to children in a friendly and tailored manner according to the user’s age, health and emotional status.

Thus, the website gives advice, tips and details describing a situation or example with some precious written support for the user, according to the most representative situation chosen by the user. There is a specific page on COVID-19 pandemic (“When it feels like the corona situation steals your life”) which describes the impact of COVID-19 pandemic on society and school life, also providing some useful advice from an emotional perspective. A chat box is available on the webpage to give the possibility to start a conversation and better interact with the user.

Italy, Lebanon, Singapore and the **UK** are involved in **ECORYS - Growing up under COVID-19**, a transnational action research project, which aims to provide insights to the impact of the COVID-19 public health crisis on young people's lives, and to inform the development of appropriate tools and measures to safeguard children's well-being and rights during and beyond the pandemic. Young people joining this project are invited to use participatory action research (PAR) to document their lives and to share their thoughts, feelings and experiences about how the authorities and the public are responding to the pandemic at different scales.

Finally, **Conect4Children**, an IMI-EU founded project, has worked at international level to bring together a range of **trusted resources on COVID-19**, in a variety of European languages and formats, to empower citizens, especially children and young people.

4. Conclusion

In conclusion, the high rate of negative answers on different topics points out a lack of awareness of issues related to participation of children in decision making regarding their health. National legal frameworks implementing the UN Convention on the Rights of the Child (art.12) are heterogeneous. To develop a clear analysis of national legal frameworks implementing this article could be extremely useful.

Initiatives aimed at fostering children participation have been initially set up within the framework of clinical research activities and include issues related also to healthcare, essentially because of the overlapping existing between healthcare and biomedical research activities. According to the comments of responders, there is the need to work more on the topic “children participation in decision making” with a pluridisciplinary approach, to avoid the risk of “Tokenism” (meaning making only symbolic efforts without real impact on practices). To this aim, a stronger engagement and collaboration among all the stakeholders (healthcare professionals, patients/children, European institutions, national/local authorities, civil society, academia…) should be promoted.

The analysis of the results of the survey carried out will help in outlining best standards and practices and determining roadmap for developing a Guide for healthcare professionals, patients/parents’ association, expected in 2022.