Children's Participation and Decision-Making in Medical Matters

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Helena von Troil

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Nordic Council of Ministers

Ved Stranden 18
DK-1061 Copenhagen K
Phone (+45) 3396 0200

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Foreword

The mission of the Nordic Committee on Bioethics is “to foster cooperation between the Nordic countries by bringing together representatives from different backgrounds to discuss and analyze issues in bioethics in order to achieve greater awareness, promote common understanding, improve policy making and present internationally a Nordic perspective on bioethical challenges.” To honor this mission the committee has, over the years, organized a number of conferences on topics related to medical, genetic and environmental ethics with the aim of encouraging dialogue between different disciplines and stakeholders.

Many of the conferences organized by the Committee, covering topics such as mental health, stem cell research, reproductive technology, biobanks and teaching bioethics, have addressed issues concerning children in one way or the other. Nevertheless, the committee decided in the year 2011 to put the interests of children in stronger focus. With this in mind the conference *Children's Participation and Decision-making in Medical Matters* was organized in Lund in October 2012. According to international and national agreements and conventions, children have a right to express their views in all matters affecting them. However it is one thing to state that children have a right to express their views, and another to stipulate to what extent they have a right to participate in decision-making regarding their medical treatment, their participation in medical research, or in clinical trials. At the conference various participants discussed how this right should be interpreted and applied in different contexts and situations.

When organizing its conferences, the Nordic Committee on Bioethics has made a point of bringing together a variety of stakeholders and people representing different disciplines. The conference on Children's Participation and Decision-making was no exception: physicians, policy-makers, parents, scientists, legal experts, ethicists, and representatives of the pharmaceutical industry were invited to share knowledge and experience. The outcome was an important dialogue between different stakeholders from all the Nordic countries.

This conference summary, compiled by Helena von Troil, highlights the main themes of the conference. The committee hopes that the report will be resourceful for everyone interested in these matters, and that the conference has served as an important contribution on this very important topic.

Salvör Nordal

Chair 2012

Nordic Committee on Bioethics

Förord

Nordisk kommitté för bioetik har till syfte att främja samarbete i bioetiska frågor mellan de nordiska länderna. Genom att sammanföra experter och företrädare för skilda perspektiv på dessa frågor vill man sprida kunskap, gynna samsyn, underlätta politiska beslut och i internationella sammanhang förmedla ett nordiskt perspektiv på bioetikens utmaningar. Kommittén har genom åren arrangerat ett stort antal konferenser med fokus på medicinsk etik, etisk genetik och miljöetik i syfte att stimulera till dialog mellan olika forskningsområden och intressenter.

Många av de konferenser som ägt rum på kommitténs initiativ, inom områden som psykisk hälsa, stamcells forskning, reproduktionsteknologi, biobanker och bioetisk pedagogik, har behandlat ämnen som på ett eller annat sätt berör barn. År 2011 beslutade kommittén dock att mer aktivt uppmärksamma barns intressen. Med detta i åtanke arrangerades konferensen *Barns delaktighet och beslutsfattande i medicinska frågor* i Lund i oktober 2012. Enligt nationella och internationella avtal och konventioner har barn rätt att uttrycka sin åsikt i alla frågor som berör dem. Det är emellertid en sak att fastslå att barn har rätt att göra sig hörda, och en annan att bestämma i vilken utsträckning de har rätt att delta i beslutsfattande i de fall där de blir föremål för medicinsk behandling, medicinsk forskning eller kliniska försök. Under konferensen diskuterade olika deltagare hur denna rätt bör tolkas och tillämpas i skilda sammanhang och situationer.

Nordisk kommitté för bioetik har vid sina konferenser varit mån om att sammanföra representanter för ett flertal forskningsområden samt andra intressenter. Konferensen om barns delaktighet och beslutsfattande i medicinska frågor utgjorde inget undantag: läkare, politiskt ansvariga, föräldrar, forskare, juridiska experter, etiker och representanter för läkemedelsindustrin inbjöds att dela med sig av sin kunskap och erfarenhet. Det resulterade i en viktig dialog mellan olika intressenter från alla Nordens länder.

Denna rapport, som är sammanställd av Helena von Troil, belyser konferensens huvudteman. Kommittén hoppas att den ska bli användbar för alla intresserade och att konferensen har fungerat som ett viktigt bidrag till denna angelägna diskussion.

Salvör Nordal

Ordförande 2012, Nordisk kommitté för bioetik

Introduction

According to international and national agreements and conventions, children have the right to express their views in all matters affecting them. This obligates parents, medical personnel and other responsible adults who make medical decisions that affect a child to consider the child's opinion. Yet, in some instances a child's right to be consulted may conflict with other interests or priorities. The result may be that the child's right to express its views is insufficiently considered in medical treatment or in research. For instance, concerns of risk, burden and safety raises many questions regarding the recruitment and participation of children in clinical trials, In medical treatment, questions may arise regarding who should make decisions on behalf of children, and in which ways children's opinions should be considered.

These, and other, issues were discussed at a conference in Lund in October 2012, organised by *The Nordic Committee on Bioethics*, during four sessions:

The speakers offered wide multidisciplinary perspectives on these topics:

1. Children's Participation in Treatment and Research,
2. Children's Right to Participation in Decisions on Medical Care,
3. Children's Participation in Research and Clinical Trials, and
4. Regulating Children's Rights in Research and Treatment.

Decision-making in medical treatment sometimes raises particularly difficult ethical and medical questions. These questions become even more challenging if the patient is a child. In some instances, the best available treatment offers a small chance of cure and continued life against a large risk of suffering and unsuccessful outcome. Deciding how to act in the best interest of the child demands assessing both medical and ethical aspects. The child's views should be considered, but there is no general consensus on how this may best be done.

Children may also participate in research and clinical trials, something that gives rise to special ethical concerns. Children have the right to best available treatments to meet their needs. Yet, they rarely benefit at all or benefit late from innovations due to their own participation in

research. When deciding whether to participate in clinical trials, parents and children may perceive risk and benefit differently.

For the Nordic countries, regulating children's participation in medical treatment and research in the future poses several challenges. Children are involved in medical matters, both as present and potential patients. Making sure that therapies and medicines are developed for children as well as for adults should be given a high priority both as an ethical and a medical matter. In addition, European regulation requires pediatric development for new medicines. In order to reach this goal, it is necessary to involve children in research and clinical trials. At the same time, children are vulnerable and in need of protection. The European legal framework for recruiting children to medical trials establishes that the patient's interests are given precedence over possible scientific advancement if these two objectives are in conflict. However, there is a lack of knowledge and awareness of these European regulations and of ethical issues related to the participation of children in medical research. Also, there is need for further considerations on regulations on child involvement. We need more research into the views and needs of children, since we know little about how children experience certain difficult aspects of being patients and research subjects. In addition to further developing a Nordic framework for child participation in medical matters, it will be vital for the Nordic states to address these issues internationally.

Titti Mattsson

Nordic Committee on Bioethics

1. Children's rights and medical decisions

Ritva Halila, MD, PhD, specialist in pediatrics, Director of Hjelt Institute, University of Helsinki, Finland

Ritva Halila gave an overview of the issues involved in medical decision-making regarding children. She discussed the special status of minors, international conventions on children's rights and decision-making in difficult situations.

What is special with children?

"Childhood is a special part of human life," she said. "Children are a large and heterogeneous group of people. Children under fifteen years represent from thirteen to forty eight percent of the population of different

countries. The development and understanding of a newborn or toddler is very different from that of a child of school age or an adolescent. “

Small children are totally dependent on the care and help of their guardians and the societies. They grow slowly to independent and responsible citizens. There is also a huge difference in size between a newborn and child weighing seventy kilos. Growth and mental and physical development varies a lot between the different developmental stages and between individuals. The various organs develop in different stages and the water content of the body changes a lot during childhood. All these factors have to be taken into account when medication is given.

Children's rights

The United Nations' Convention on the Rights of the Child, the European Union Charter of Fundamental Rights and the Convention on Biomedicine all deal also with the rights of children. “Children have rights to grow and develop in a safe and supportive environment, surrounded by their families. They have the right to protection from violence, injury or abuse, neglect, maltreatment or exploitation,” said Halila.

According to the conventions children have the right to participate when decisions are made concerning them. Children must be treated equally and as individuals, and they should be allowed to influence decisions concerning them to a degree corresponding to their level of development. They also have the right to express their views freely in matters affecting themselves. The views and opinion of the child should be given due weight according to age and maturity.

Medicines for children

“Children have the right to enjoy the best possible health care without discrimination,” continued Ritva Halila. “But this is unfortunately not always the case. Millions of children still suffer from conditions that could be prevented and treated. It is also a fact that in health care children and adults are not equal. Medicines and care are not well studied in children, and a lot of medicines that are used have not been tested according to the standards we require for adults.”

“A lot of medicines on the market have not been studied in children of different age and size, and so optimal doses for children of different size

and developmental stage are not known,” said Halila. “This is why these medicines are usually not recommended for the use if children.”

Who decides?

Ethical principles have to be considered when the decision is made to involve children in medical research. “So, who should decide on participation – the child, the guardian or some other person or body?” asked Halila. “The ethics committee plays an important role in evaluating the research proposal and giving its consent. The parents are, of course, always involved when minors are concerned. But are they always best suited to make the decision? In the case of children in custody, the social workers have the task of seeing to the best interest of the child. Should they also have the responsibility to make this kind of decisions? Finally we have the child itself. At what age is the child mature enough to at least be heard and perhaps also be the one to decide?”

Finally, Halila pointed out that adolescents make up a special group. They are often mature enough to have their own opinion and make decisions regarding themselves. Many medical issues can be quite sensitive and a teenager might not necessarily want to involve her or his guardian in the decisions regarding e.g. human papilloma virus vaccine, contraception or abortion.

2. Children's rights and risks

Cecilia Sjölander, Director for the Program and Research Unit, The Ombudsman for Children's Bureau, Sweden

"Why did no-one see me? Why did no-one ask 'How are you?' And if I didn't answer, dare to keep on asking, again and again." Cecilia Sjölander began by quoting Lovisa, a girl with experience of violence in a close relationship. "Children experience that no one listens and no one cares, not even when there are clear signs that the children may have been subject to violence," she said.

"The children we meet in our work for the Children's Ombudsman often state that they would like personnel in the healthcare system to have more technical knowledge about different types of violence to children. They say that they wish that the personnel had informed them about their rights, and where they could have gone to get help and treatment," said Sjölander.

The work of the Children's Ombudsman

The mission of the Children's Ombudsman is to represent children and young people, and to monitor and promote the implementation of the UN Convention on the Rights of the Child in Sweden.

"In recent years, we have systematically listened to children and young people in situations in which they are vulnerable. We have organised expert group meetings with children who have been placed in foster care or institutions. These groups contain also children who have experienced violence and sexual abuse in close relationships," said Sjölander.

"A common theme arises in all of these meetings – children experience that no-one sees them and no-one listens. This is the case in many areas, including school, social services and the health and medical care system."

The UN Convention on the Rights of the Child

According to the UN Child Convention, from 1989, ensuring all rights of the child is based on the principle of best interest of the child, right to participate, right to survival and development, and the principle of non-discrimination. The child is to receive appropriate direction and guidance from parents or guardians in exercising his or her rights.

"It is the responsibility of every adult who meets children in the health and medical care system to enable the child to make his or her voice heard," said Sjölander. "The child must be given information and support in expressing her or his ideas and opinions. The child should experience that the adults are truly listening. The adults also have the responsibility to ensure that the child gets feedback and an understandable explanation in cases when a decision is taken that may be against the child's own wishes."

How can progress be made?

Sjölander mentioned four areas where progress can be made. The first is legislation and guidelines: "We all know that national legislation is important in securing the rights of the child. Legislation differs between the Nordic countries. A basis for dialogue with decision-makers can be created through comparing legislation and discussing challenges."

The second area is to develop expertise and change attitudes. "Knowledge and motivation are two preconditions for change," said Sjölander. "By discussing the child convention from the point of view of the rights of the child and how it can permeate work in the field, children's rights can be better granted."

The third area is direct information to children and young people. "The need for understandable information has become evident in our meetings with vulnerable children. Websites, information folders that target children and young people, and information placed in the arenas that they use, such as social media, can all be used," she said.

Finally, Sjölander emphasized the importance of following up of how children and young people experience care and treatment. The framework of follow up should include also a system to develop tools that measure how children and young people experience their care and treatment.

Several children whom the ombudsman has met have not been given any information at all by their parents. The desire to protect the child is often the explanation. But what is really in the best interest of the child? It is very important for young people to express themselves. Greater consideration has to be given to the opinions of the child. "Each child is an expert in his or her own life situation. By listening to the narratives of children and young people, and by nurturing their thoughts can adults who meet them come to better decisions ", concluded Sjölander.

3. Children's participation – a parent's perspective

Ragna Marinósdóttir, Director of Umhyggja, the organisation for chronically ill children, Iceland

“Chronically ill children with serious and long-term conditions,” have an in-credible perspective on everything that happens around them with respect to their disease, their prognosis, and their condition, said Ragna Marinósdóttir.

To have a chronically ill child

Ragna Marinósdóttir spoke mostly about her own personal experience. She is the mother of three children, all of whom have struggled with serious illnesses. As the director of Umhyggja, the organisation for

chronically ill children in Iceland, she also has a lot of experience of contacts with other families in difficult situations.

“Many children are capable of making very difficult decisions,” she said. “This is why they should be given the chance to participate in the decision-making when they are mature enough. But if the child feels terrible, I don’t believe he or she can think of anything but making the pain go away. When my younger son passed away at the age of thirteen, he had been feeling so awful that he asked to be allowed to die.”

Having a chronically ill child with a serious and incurable disease that grows steadily worse changes everything. “All of a sudden you find yourself in a world you have never seen, one you knew almost nothing about, a world nobody wants to live in,” Marinósdóttir said. “On receiving the diagnosis you don’t even know where to begin or what to ask. The future becomes impossible to plan for. The fact that there is no hope of cure is terrifying.”

Support from the professionals

Parents to children with serious illnesses are preoccupied with thinking about the health and well-being of the child. For this very reason, it is essential that they have ready access to professionals who can answer complicated and difficult questions. “In matters of medical opinion, parents are often at a loss when it comes to weighing the evidence and determining what to think. In such cases, the specialists should inform the parents about the pros and cons,” said Marinósdóttir. “If there is anything the parents can do to extend their child’s life, then they will try that using all possible means, even if some selfishness lurks beneath the surface.”

Ragna Marinósdóttir stressed that parents have to be able to trust the health care professionals to do everything with the child’s best interest at heart. The child should be shown respect and his or her needs and wishes should be honored. The parents are in desperate need of good professional support. The professionals have the knowledge, the experience, and the possibility to support the parents and help them with their decisions. “Many specialists do their best, but some cause a lot of damage with their comments and threats,” she said.

“The experts have a lot of power. They should be careful not to generalize regarding procedures and treatments and whether these actually benefit the patients. Twice has my family had to supply the specialist with the latest information on the uses and benefits of a procedure. It’s

terrible that doctors encourage patients to undergo unnecessary procedures that are of no benefit to them,” she said.

Many parents are strong and can support their children well. They can help their child through great difficulties and maintain the perspective on the broader circumstances. But there are also parents who lack resources and have little support from their families. They can find themselves in very difficult decision-making situations. These parents urgently need the help and respect of the professionals.

“The question about the right to decision-making can never be fully answered, nor should it be,” said Marinósdóttir. “These matters should be constantly under discussion, and experts should always try to improve the support they give the patients and their families. Even if it costs more time and work, it is invaluable if it prevents people from feeling miserable over their decisions for years to come.”

4. How can children participate in clinical trials?

Kjeld Schmiegelow, Professor in pediatrics and pediatric oncology, Rigshospitalet, Denmark

"I am strongly in favour of children's participation in clinical trials, but I admit that I have no easy solution for the ethical dilemmas it creates," declared Kjeld Schmiegelow when he began his presentation.

Concrete suggestions

Even if he didn't give any easy solutions he did present some personal viewpoints and concrete suggestions for clinical trials in children. "Treat the child as an adult," he said. "And be honest and admit that the primary benefit of the trial is not for that child, but for other children in a similar situation."

Accept that participation is emotional, rather than rational, was his second suggestion. Schmiegelow referred to a small scale survey among adolescents which showed that the most frequent reasons for enrolling in the trial were positive clinical benefit, needing an option, impact on quality of life, and few side effects or fewer than those of current or past treatments.

"Organise an informative meeting before the informed consent form is signed," he said. This increases the understanding of the issues and willingness to participate.

Schmiegelow's last suggestion was to invite peer ambassadors. That is a common procedure with adults, who are invited to bring a friend, but not used with teenagers. "There is nothing that says it could not work equally well with adolescents who could bring fellow patients or friends," he said.

Children and cancer

Today, one child out of five hundred gets a cancer. There are twelve thousand cases of child cancer in Europe each year. In adults there is a link between the behavior or the environment and the cancer. "Children's cancers are different and we don't know why children get cancer," Schmiegelow said. This is why research in the development and treatment of cancer in children is so important.

"We kill a certain percentage of our patients, not due to the disease, but due to the treatment," he continued. However, the cure rate in developed countries has increased during the last decades from less than fifty percent to more than eighty percent as a result of entering childhood cancer patients into clinical trials.

Regarding ethical and other dilemmas relating to clinical trial participation Schmiegelow said that these are especially complex for children with cancer. The diseases that the research concerns are often very rare, which means that patients and parents have no experience or other references. These diseases are life-threatening, without therapy all patients eventually die. In cancer, there is the need for extensive therapy when the disease is in clinical remission. That means that during most of the treatment there are no signs of the disease and the therapy can be extremely toxic.

Do parents and children have the same goals?

Parents and child patients perceive risk and benefit differently. "Some parents will pursue survival at any cost, nearly all will pursue hope," said Schmiegelow. Some children refuse life-saving therapy, not because they wish to die, but wish to *have a life*, and the proposed chemotherapy or surgery does not provide this life.

"One would expect that a rational individual can balance acceptability of toxicity in relation to risk of treatment failure," he said. "However, experience shows that in first line therapy parents will often emphasize cure whereas child patients tend to underestimate risk of failure. Because the failure is not immediate they emphasize the consequences of toxicity."

The parents consent to their child's participation in clinical trials is driven by motives that are strongly influenced by their expectations for the course of the disease. This becomes more pronounced in experimental therapy when the prognosis is poor. In such cases, parents may tend to underestimate the risks and overestimate the benefits of the therapy. "When parents recognize that their child will die, most will do anything to hold on to hope," concluded Schmiegelow.

5. What counts as participation? Some cautionary remarks

*Linus Broström, PhD and researcher, the Department of Medical Ethics,
Lund University, Sweden*

Linus Broström suggested ways in which children's participation in medical decision-making could be facilitated. But he also cautioned against letting the importance of promoting children's participation come at the price of diluted notions of participation, or of not acknowledging children's vulnerabilities as decision-makers.

The ideal of participation

Participation, autonomy, self-determination, empowerment, shared decision-making, these are all catch words frequently used today. "Everybody agrees that participation is a good thing and great emphasis is put on shared decision-making," said Broström. Still, there is reason to ask ourselves what we really mean by those catch words.

Sometimes the word participation is used to mean making the "right choices" or vetoing somebody else's "wrong choices." "Getting to express our desires, perspectives and experiences is also a kind of participation," he said. Having one's wishes, perspectives and experiences not only respected but also actually taken into account is a variety of participation.

Still, the deeper questions remain. "When has a child been given the chance to make a genuine choice and what counts as an expression of choice?" he asked. "Is a verbal expression of one's will enough or has it to be in writing? What about non-verbal physical expression of will e.g. turning away or crying? What is meant by "considering" a child's view? For how long should you listen to the child, should you also act on it, when and how should you act etc."

Dilution and coercion

"The greater the pressure to say that children should be able to participate the more you dilute the participation" stressed Broström. "Everyone wants to say that they promote children's participation. Dilute the notion enough, and they will be right."

He also cautioned against surrogate participation decisions and coercion. There are examples of substituted judgment in cases when decisions have been made claiming that this would be as the patient would have wanted if he had been able to make the decision himself. Broström also made comparisons to cases of informal coercion that occurs in psychiatry and elderly care. "Are we at risk of doing the same to children?" he asked.

Power imbalance

Broström referred to the power imbalance between children and adults and asked how much real choice do the children have? Often they get to participate only to fulfill the participation requirements formally or make trivial choices. The child may, for example, be allowed to pick the music she wants to listen to during MRI scanning. Often the children are asked of their views or opinions, but when they answer they are not really listened to. Children may be given a choice with little regard for the child's cognitive or emotional vulnerabilities or with little attention given to the information the child needs.

“Much more attention should be given to the power relationships between children and adults and the possibilities a child has to make genuine choices,” said Broström. “We have to consider the differences in child and adult psychology when it comes to decision-making and we should try to learn how information and communication works with children. We are often too lazy to do that, we just ask and let their voice be heard. But we don't make an effort to think about the prerequisites for real participation in the decision-making. All this is important,” he said. “Because diluted notions of participation can disguise violations of children's rights and interests, can disguise their vulnerabilities and does not make us seek better protection of the children. We have to genuinely respect the children and their opinions.”

6. Who decides on initiating, continuing and discontinuing treatment in extremely ill children?

Anders Castor, Child oncologist and Head Physician, Child and Youth Hospital, Lund, Sweden

Decision-making regarding very sick children often poses a mix of difficult medical and ethical questions. Physicians and other health care personnel can approach these questions in different ways. Sometimes the solution is sought only in the medical facts and circumstances, but there might be ethical considerations pointing in another direction. Anders Castor discussed the difficulties of decision-making in extreme cases.

Doing the right thing

“Whatever we do will very likely be the last thing we do for the child before he or she dies. These very high stakes makes it even more important that the decision is the right one,” said Anders Castor. In medical treatment and procedures in cases with extremely ill children, for example young children with leukemia, the balance between benefit and burden can sometimes be extreme. There may be a very small chance of a very great benefit (e.g. cure and continued life). On the other hand there may be a very large risk of significant burden (pain and suffering) and unsuccessful outcome.

A medical decision is about what can be done. It should be based on research results and experience. “What we ought to do is an ethical decision,” emphasized Castor.

“How do we know what is in the best interest of the child? How do we weigh life without burden on the one hand and burden and death on another,” asked Castor. “We cannot use the same scales.” He said that it’s impossible to get numbers, with which to calculate the maximum expected benefit in a certain case. This is not a question that can be answered by experimental research. The answer depends entirely on how life, death and burden are valued. “In child oncology we tend to value life very high,” he said. “But can it trump every other consideration? If it does, it would make all ethical deliberations and end-of-life treatments redundant. Modern medicine would become inhumane, and very expensive.”

Castor stressed that the weight of the burden never should be underestimated. He gave examples of adults today who were severely ill as children. They now think that the doctors made the wrong decisions when giving aggressive treatment that probably saved their lives. The suffering was so hard.

Who should decide?

Someone has to make decisions also in very difficult cases. The view that it should be the health care personnel is based on the idea that the decision is connected to a complicated medical issue. Also, doctors and nurses might have a lot of experience with severely ill and dying children.

The other alternative is that the parents should decide. They have the right and duty because it is their child and they know their own child best. "Children are the most precious that we have. It can be claimed that our whole being is directed towards protecting our children, particularly in the face of a real and significant threat of death," said Castor.

"With the decisions comes a responsibility for the consequences," said Anders Castor. "They are never certain, just more or less probable. The doctor is responsible for the medical decision to give chemo therapy or perform bone marrow transplantation. A parent cannot take responsibility for that. On the other hand, the parents have to carry the consequences, whatever they are, of the decision way beyond the chemo or the transplantation. "

Castor argued for children's right to decide and said that he does not believe in age limits. Children's capacity to decide depends on maturity and prior experience. "Children are competent in many ways," he said. They are capable to receive and understand information. They know and understand consequences, but may not give the right weight to the various consequences. Children also usually know what they want.

Finally Castor cautioned against coercion. He said that a competent decision maker should be able to express his or her wishes and be free to make an independent decision. With children these requirements are not always fulfilled. Children often look to their parents to see what the right thing to do is in a certain situation.

7. Children's participation in the decision-making from a legal perspective

Titti Mattsson, Professor of public law, Lund University, Sweden

Titti Mattsson is an expert in child law and has worked with child issues in the Swedish social welfare system. She looked at what the participation principle means in a legal perspective and how it is implemented in Nordic health care law.

Participation as a principle

“I think most people agree that participation is about fundamental values in our society, like democracy, legal security and protection of the individual’s integrity,” began Mattsson. “For example, the right to expression is a fundamental right in the western world. Excluding certain groups in society from these kinds of rights would mean that the individual’s equal rights are ignored.”

She said that participation also is seen as a tool for development. Respecting and listening to children and young persons is supposed to favour their development and also favour the society, giving knowledge about their lives and living conditions.

The UN Child Convention is the basis for the participation principle for children and young persons in law. It says that the child should be able to participate in all decision-making that affects her or him, and be able to influence decisions according to age and maturity. The right to participation is based on respect for, and recognition of, the child as an individual with human rights, and the potential of an autonomous individual.

“But in practice participation is not obvious,” said Mattsson. In the yearly report of the Swedish Ombudsman for Children in 2006, only fifty percent of the children answered that they had been listened to at the health care clinics. Only one third said that they had participated in some way. Children say that they find it difficult to trust adults to understand and take their stories seriously. Often children themselves feel that they signal to the environment that they are not feeling well, but the adults in their lives either do not perceive their signals, or choose to ignore them.

Levels of participation

Several models describing participation of children and young people can be found in the literature. Common to all of them is that they include different levels of participation: Firstly, the child has been informed. Secondly, adults have listened to the child. Thirdly, the child, if possible, has had a possibility to express itself (feelings, emotions, wishes etc). The fourth level is that the child has had a meaningful role in the decision-making process. And finally, the participation has been voluntary. “So, merely to be informed and to be heard is not seen as participation in full according to these models. There is also a demand for an active listener,” said Mattsson. “This is in line with research that shows that children themselves often feel that to be heard is most important.”

Participation in health law

Titti Mattsson also discussed the participation principle in Nordic health law and gave some examples of how the law sets standards for child participation in the Nordic countries.

In some statutes the right to participation exists as a mandatory obligation to involve the child in all decision-making after a certain age of the child. The right to participation can also be regulated as a mandatory obligation irrespective of age but based on the maturity of the child. A third variant is to give the child the right to veto a decision.

Mattsson mentioned the Danish health law as an example of the first category. It covers the general regulation of health care for children. It is age-based and gives children right to information, dialogue and consent as a general rule with possibility to limit this autonomy. A patient who is fifteen years old can give informed consent to treatment. The guardian shall receive information and be involved in the minor's decision.

Mattsson's example of the second category came from Finland. An individual assessment of the child's age and maturity, but no specific age limit, is included in the Finnish legislation on children as patients in care. A minor patient's opinions on a care or treatment measure should be investigated, if it is possible taking into account the patient's age and development. The care of a minor patient should be agreed with the patient, if he with regard to the age and development can make these decisions.

And, finally, sometimes the child has a right to participate irrespective of age. This is the case in the Swedish Act on Circumcision of Boys of 2001. According to the act, such bodily intervention shall be preceded by the child's opinion. The child has the right to receive information if he is old enough to understand it. His attitude towards the intervention should be investigated, and he has the possibility to stop the intervention, irrespective of his age.

8. Children and medicines – ethical concerns in testing medicines on children

Kalle Hoppu, MD and PhD, Director of the Poison Information Centre, Helsinki University Central Hospital, Finland

Kalle Hoppu, a pediatrician with many years of experience, looked at the special ethical concerns that are connected to clinical trials on children.

Lack of approved medicines

“Today children do not benefit at all or benefit late from innovative drug development,” said Hoppu. “It is a big problem that pediatric drug formulations often are unavailable. There is also a lack of pediatric data. This may

lead to unlicensed and off-label use in children. There is also an increased risk for adverse effects of the drugs and a risk for suboptimal efficacy.”

“Children have the right to the best available treatments, including medicines, to meet their therapeutic needs. These needs cannot be met, if children are excluded from the potential benefits of medical research,” Hoppu said. He pointed out that the general obligation to protect minors is an important consideration by the parents or legal guardian. Often this is seen only from the point of protecting minors from research. “But minors should also be protected from suffering and ill effects caused by diseases,” he said.

What is special about children?

Hoppu listed some characteristics specific to clinical trial research in children. One of the main differences, compared to trials with adults, is the fact that children generally have good health. As a result, populations with problems relevant to a study are comparatively small. Another difference has to do with the growth and development of children. Children are small in size and this leads to special challenges and limitations. Also, children have a limited ability to understand facts and explanations and to express their own views and will. Among children there are considerable developmental variations which makes age grouping difficult. And finally, there is a need for age appropriate formulations and methods to assess efficacy.

“What is the acceptable ratio between benefit and risk in pediatric clinical trials,” asked Hoppu. The answer is that an acceptable risk is not enough to merit a trial, but there should also be a requirement of minimal harm and some concrete benefit. There has, among specialists in the field, been some discussion of what this means. A suggestion has been put forward that the benefit should be either directly for the children involved in the trial or indirect for a group of children with the same problem.

Hoppu also stressed the importance of pediatric expertise in the ethics committee approval process. “Only the pediatric experts have the expertise to evaluate the scientific validity of the proposal,” he said.

Informed consent

Involving children in clinical trials requires informed consent from the parents or legal guardian. “It is not always clear whether consent is needed from both parents,” said Hoppu. The consent must reflect the minor’s presumed will. The views of the child have to be given due weight in accordance with age and maturity of the child. Trial participants with appropriate intellectual maturity should personally sign and date either a separately designed written assent form or the written informed consent form. Prior to giving assent or consent, the minor should be given information according to its capacity of understanding, from staff with experience of minors.

FINPEDMED – initiatives

Hoppu ended by briefly presenting the FINPEDMED-network. The Finnish investigators’ network for pediatric medicine is a joint collaboration between Finland’s five university hospitals and their pediatric clinics. It strives to improve both academic and sponsored pediatric clinical trials for the benefit of children’s health. One of the network’s activities has been to develop tools for informed consent in child clinical trials that are adapted for children of different ages. Trial information and informed consent document templates for clinical trials have been produced. Picture cards intended for use as an aid when study information is given to young children are also available. More information on the activities of the network can be found at www.finpedmed.fi.

9. Do we need pediatric ethics committees?

Göran Elinder, Professor in pediatrics, Karolinska Institutet, Sweden.

Göran Elinder discussed the pros and cons of special pediatric ethics committees. He came to the conclusion, that the gain in quality of such committees would probably not outweigh the additional costs. Instead he recommended more pediatric training for ethics committee members and authorities.

The need for special committees

Using the actor model, Göran Elinder analysed the potential benefits and impacts of special pediatric ethics committees from the perspectives of the various stakeholder groups. He came to the conclusion that pediatric

ethics committees would benefit the interests of children and families. For the researcher, the society and the pharmaceutical industry, however, there would be both positive and negative effects.

A pediatric ethics committee could better defend the values and interests of the child and its parents. It would also have better child knowledge and more respect for the integrity of the child. The striving to minimize the pain and extra burdens caused by the research would probably gain more weight. The child would, of course, also benefit from increased knowledge about the health problem being investigated and the children as a group would benefit from better knowledge of children's health issues and greater respect for the child's perspective.

From the researcher's perspective, a special pediatric ethics committee could potentially make better informed choices regarding the scientific issues without affecting the general scientific rules and values. Nor would there be any effects on the researcher's career. But, there could be negative effects on the optimal use of the given resources, increased costs and a prolonged time before the possible benefits of the research would reach the patient.

The society would benefit from a special pediatric ethics committee because new knowledge for better health for all age groups would be generated. However, the life for citizens would probably not become any simpler, nor would this lead to less bureaucracy.

"New scientific knowledge about children's health problems and drugs for children would, of course, be valuable for the pharmaceutical industry," said Elinder. "On the other hand, the bureaucracy would probably increase and the launching of new drugs would be postponed."

"In summary, the ethical analysis to evaluate if a special pediatric research ethical committee could increase the quality of research ethical decisions indicates, that the increase in research quality probably does not weigh out the costs of increased bureaucracy and delayed time from research to patient benefit," concluded Elinder.

The need for more training

Göran Elinder has made a survey and comparison of the research ethics committees in the Nordic countries. It shows many similarities, but also differences between the countries. The organisation and decision-making levels are very similar in all Nordic countries. But the pediatric influence in the committees is more prominent in Finland and Sweden than in the other countries. In these two countries the committees have

members with special pediatric competence. Elinder had also looked at projects rejected by the central ethics committees. In four of the six cases he analysed, pediatric knowledge was essential for the evaluation. "This fact supports the view that there is a need for increased pediatric expertise in the committees," he said.

Göran Elinder recommended that the Nordic central ethics committees should be encouraged to stimulate pediatric training among their members. The members of the existing research ethics committees should be given pediatric training on a regular basis. Such training would also be beneficial for the responsible authorities in all Nordic countries.

10. Regulations, guidelines and structure for scientific studies on children in Europe

Agnes Saint-Raymond, MD, European Medicines Agency, Great Britain

“Children have been neglected in the development of pharmaceuticals,” stated Agnes Saint-Raymond, as she began her presentation. “Medicines have been developed for adults, and children are not small adults. Children have not been provided with medicines that were fully studied and assessed for them. As a consequence, children have been the victims of the harmful effects of dangerous substances, such as thalidomide, ethylene glycol, phenol barbitol, and benzyl alcohol.”

Challenges and incentives

“We need clinical trials with children and, at the same time, we have to protect the children,” said Saint-Raymond. She said that there are a number of challenges in the development of pediatric medicines. As examples she mentioned the need for multiple subgroups, different endpoints and therefore trials. There is also a need for formulations and dosage forms that are adjusted to the age and size of the patient. The measures of outcome have to be validated for use in children. Today, the tests are usually standardised for adults and may be impossible to perform on children. And finally, there is a need for facilities that are adapted to children and for trained personnel. Trials with children are complex and the most complex have to be conducted with neonates.

“But there are also incentives,” she said. Incentives for the proper development of medicines for children have been set up both in the United States and in the European Union. A mandatory development of drugs has been implemented in areas where there are both unmet pediatric needs and potential use of the medicines. The European Paediatric Regulation (EC) No 1901/2006 requires pediatric development for all new medicines, and for new indications, routes of administration or pharmaceutical forms of authorized patented medicines. As a reward, the product can get an extension of its patent, or for orphan medicines, market exclusivity.

Clinical trials with children

“Clinical trials with children are necessary for a number of reasons,” said Saint-Raymond. “The aim must be to be able to prescribe drugs to children only based on evidence of the effect. Prescription of untested medicines is unethical. Children differ from adults in physiology and metabolism. The doses have to be adapted to the child and this has to be done scientifically. Safety aspects have to be taken into account and these are different from safety aspects concerning adults.”

“But, at the same time, the children are vulnerable and have to be protected,” Saint-Raymond pointed out. She emphasized that it is important that the evaluation of benefits and risk is done thoroughly and with expertise. Special precautions have to be taken because of the vulnerability of the child. An active ethical oversight has to be implemented and children cannot be used as a commodity, which means that healthy volunteer children are not acceptable.

Ethical and legal framework for European trials

Agnes Saint-Raymond briefly described the ethical and legal framework for clinical trials involving children in the European Union. The most important regulation is the EU Clinical Trials Directive, the so called GCP Directive from 2001, and its implementing texts. There are also practical ethical recommendations for the implementing of the GCP Directive.

An ad hoc group has produced a document called Ethical considerations for clinical trials on medicinal products conducted with the paediatric population, 2008. (ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethical-considerations-paediatrics_en.pdf)

The recommendations follow the principle that the patient's interest prevails over that of science and society. According to the recommendations, a number of conditions to protect minors have to be met. Saint-Raymond gave some examples. Regarding consent to participate in a clinical trial it is recommended that consent should be given preferably by both parents. There is unfortunately no requirement for assent of the child in the Directive, but assent should be sought. The given information should be adjusted to the level of understanding of the child. An explicit wish by the child to refuse participation or to withdraw must be respected.

There should be a direct benefit for the group. "This is problematic because we need to discern between individual benefit and group benefit," she said.

A regulation on medicinal products for pediatric use was passed in the European Union in 2006 (Regulation (EC) No 1901/2006 of the European Parliament and of the Council). The objective of the regulation is to improve children's health. This should be done by increased high quality, ethical research in medicines for children leading to evidence-based information. Also, the availability of authorised medicines for children should be improved. All this should be achieved without unnecessary studies in children and without delaying authorisation for adults.

11. Challenges for European ethical committees in overseeing research on children – data from the Teddy study

Anna Grazia Altavilla, lawyer and associate senior lecturer, EEM-Bioethics Research Centre, University of Aix-Marseille, France

“In ethics committees, there is a lack of knowledge and awareness of the current European pediatric regulatory framework, of awareness of ethical issues related to pediatric research and of involvement in pediatric research”, began Anna Grazia Altavilla.

She said that a number of ethical concerns are connected to research on children. They are linked to ethical values such as dignity, bodily integrity, autonomy and privacy. “These ethical concerns have been addressed in a complex regulatory framework containing specific ethical and legal provisions concerning matters like participant safety, informed consent, compensation and confidentiality,” she said. “The correct implementation of these provisions is the responsibility of the national and local ethics committees.”

TEDDY study results

“Training, educational programmes and networking are essential tools to enhance the role of ethics committees in supporting pediatric research. This is the main result of the TEDDY study,” said Altavilla.

The Task-force in Europe for Drug Development for the Young (TEDDY) set up an inventory of ethics committees in Europe and carried out a survey among them in 2009. The aim was to evaluate the impact of the new European pediatric regulatory framework on ethics committees’ activities and to assess their involvement and interest in research on children.

The inventory shows, that the number, competence and composition of ethics committees vary a great deal across Europe. Italy has the largest number of ethics committees, 270. In eight countries there is only one ethics committee. In the Nordic countries, the number of committees range from three in Iceland to twenty five in Finland. “These differences could reflect the diverse legal and social backgrounds and the different organisation and funding of the healthcare systems across Europe,” said Altavilla.

TEDDY also points to a gap between the regulation and the awareness, knowledge and understanding of the major issues in pediatric clinical research among the ethics committees. This is shown by the fact that very few ethics committees said that they have discussed and analysed the most important legislation pertaining to pediatric research in Europe. The survey data also suggest, that the ethics committees in the newer member states are more active in trying to integrate and harmonise with European Union research and health norms than are the committees in the older member states.

The committees were also asked how they see the effects of the new pediatric regulation. In their answers, the ethics committees mentioned an increase in the number of medicines tailored for children and a larger

number of well designed clinical trials involving children. On the other hand, it was pointed out, that there still is a lack of knowledge about the risks and burdens that are acceptable for children of different age groups.

Practical suggestions

As several other conference speakers, also Altavilla called for increased competence in pediatrics and the ethics of pediatric research among ethics committee members. She also said that the implementation of the ethical recommendations at the national and local level could be improved.

“Increased capacity building is important,” said Altavilla. “And networking is the best tool to enhance the collaboration between the European ethics committees and the exchange of information and experiences. This is particularly important in the newer member states where the number of clinical trials on children is increasing.”

12. Ethical assessment of pediatric trials: examples of issues with risk assessment moral obligations for participation?

Inez de Beaufort, Professor of Medical Ethics, Rotterdam University, the Netherlands

Inez de Beaufort discussed four ethical issues related to medical research on children.

Non-therapeutic research

“Under what conditions is it acceptable to do pediatric research that is not in the interest of the child, so called non-therapeutic research?”

asked de Beaufort. This is a debate that has been going on for a long time. Some philosophers argue that such research is totally unacceptable. Others hold the view that it is a morally good thing to participate in such research, because the children will benefit from it indirectly.

“Recently a third argument has been put forward,” said de Beaufort. According to that, the classical distinction between non-therapeutic and therapeutic trials does not do justice to the complex reality of research with children. The problem is that some therapeutic research includes clearly non-therapeutic elements or procedures. Often it is a question of extra diagnostic procedures that would otherwise not be carried out.

“We have to look very carefully at each individual therapeutical research protocol in order to detect the non-therapeutic parts and thus avoid justifying too much, or vice versa,” said de Beaufort. “This will not solve all the moral problems, but it does justice to the real life situations.”

Minimal risk and burden

“Should there be exceptions to the condition of minimal risk and burden in cases of non-therapeutic trials?” was de Beaufort’s second question. Also this issue has been much debated. A proposed solution is that two exceptions could be allowed: the value of the study and the assent of the research subject. For a study to be exceptionally valuable, the desired data must be truly indispensable for improving medical care for children. “When discussing the assent of the child it is important to remember that even those children who can assent to the research may be vulnerable,” said de Beaufort. She pointed out that we actually know very little about how children experience certain burdens. “We need more research into the views and needs of children,” she said.

Ethical review

There are many complaints about ethical review, said de Beaufort. “But I would be quite upset if procedures are adapted under the threat of taking the review to other places where it is easier, faster and less critical,” she continued. “It has happened before that research has been switched to countries where people are rather naïve when it comes to the rights of research subjects,” she said. “And this is a problem that really worries me. There is a possibility that parents and children are exploited because they are poor. Some people in these countries may very much

want to have the money that comes from the research. Or families may be exploited because they are desperate and want to do anything for a chance, however small. “

High cost of new treatments

The final issue that de Beaufort talked about was the issue of the extremely high costs of the new biological treatments. The costs are so high because the diseases that are treated are extremely rare and the companies have to find a way to earn a return on their research and development investment.

Different arguments have been used in the debate. It has been suggested that regarding these rare diseases the usual demands on cost-efficiency should not be applied. Research is also more complicated because a very small number of children suffer from such a disease. In addition, the research population is heterogeneous, which means that some patients benefit from the research whereas others do not.

“If we know beforehand that the treatments will be very expensive, should the research not be done?” asked de Beaufort. “That doesn’t seem practically feasible nor does it do justice to the way scientific developments go. But to proceed almost automatically without paying attention to possible future problems is also ethically wrong.”

Leaving the very rare diseases out of the research agenda would be to discriminate people who suffer from these illnesses. But is it not unfair towards people who suffer from very common diseases to spend very big sums in the treatment of very few? “These are societal problems that none of us can disregard completely,” said de Beaufort.

13. Sammanfattning

Enligt internationella och nationella avtal och konventioner har barn rätt att uttrycka sin mening i alla frågor som rör dem. Föräldrar, sjukvårdspersonal och andra vuxna som fattar medicinska beslut gällande ett barn är därmed skyldiga att ta hänsyn till barnets åsikt, men i vissa fall kan barnets rätt att rådfrågas strida mot andra intressen eller prioriteringar. Följden kan bli att man inte tillräckligt beaktar barnets uppfattning i samband med läkarvård eller i medicinsk forskning. Rekryteringen av barn till kliniska prövningar och barns medverkan i dessa kräver noggrant övervägande av risker, ansvar och säkerhet. Vid läkarvård av barn kan det vara oklart vem som ska fatta beslut på deras vägnar och på vilka sätt barns åsikter bör tas i beaktande.

Dessa frågor, bland andra, diskuterades vid en konferens i Lund i oktober 2012, arrangerad av Nordisk kommitté för bioetik, under fyra temarubriker: 1) Barns delaktighet i behandling och forskning, 2) Barns rätt till delaktighet i beslut om läkarvård, 3) Barns deltagande i forskning och kliniska prövningar, samt 4) Att reglera barns rättigheter under forskning och behandling. Konferensens talare belyste dessa teman ur ett brett tvärvetenskapligt perspektiv.

Vid beslut om läkarvård väcks ibland särskilt svåra etiska och medicinska frågor, som blir än mer utmanande om patienten är ett barn. I vissa fall ger den bästa tillgängliga behandlingen små utsikter till bot och fortsatt liv, att väga mot en hög risk för lidande och misslyckat utfall. För att kunna avgöra hur man bör agera till barnets bästa måste man ta hänsyn till både medicinska och etiska aspekter. Barnets åsikter ska beaktas, men det finns ingen allmänt vedertagen uppfattning om hur detta bör ske.

Barn kan även bli föremål för forskning och kliniska prövningar, vilket ger upphov till särskilda etiska svårigheter. Trots att barn har rätt till bästa tillgängliga behandling drar de sällan nytta, eller gynnas först i ett sent skede, av de medicinska framsteg som sker tack vare deras egen medverkan i forskning. Vid beslut om deltagande i kliniska prövningar kan föräldrar och barn göra olika bedömningar av risk och nytta.

För de nordiska länderna innebär reglerandet av barns villkor under läkarvård och medicinsk forskning i framtiden ett flertal utmaningar. Att utveckla behandlingar och läkemedel för barn såväl som för vuxna bör ges hög prioritet. Enligt europeiska riktlinjer måste alla nya läkemedel

även anpassas för barn, vilket förutsätter att barn medverkar i forskning och kliniska prövningar. Samtidigt är barn sårbara och i behov av skydd. Den europeiska lagstiftningen gällande hur barn rekryteras till kliniska prövningar slår fast att patientens intressen ska prioriteras framför vetenskapliga framsteg om dessa båda mål står i strid med varandra. Det råder dock brist på kunskap och medvetenhet om dessa bestämmelser, samt om etiska problem som rör barns medverkan i forskning. Vi vet inte mycket om hur barn upplever de svårigheter de kan möta i egenskap av patienter eller som deltagare i medicinska studier. Därför krävs mer forskning om barns egna synsätt och behov.

Utvecklingen av ett nordiskt ramverk för barns delaktighet i medicinska frågor bör fortsätta, men det är också nödvändigt att de nordiska länderna lyfter fram dessa frågor internationellt.

Titti Mattsson

Nordisk kommitté för bioetik

norden

Nordic Council of Ministers

Ved Stranden 18
DK-1061 Copenhagen K
www.norden.org

Children's Participation and Decision-Making in Medical Matters

According to international and national agreements and conventions children have a right to express their views in all matters affecting them. However it is one thing to state that children have a right to express their views and another to stipulate to what extent they have a right to participate in decision-making about their medical treatment, participation in medical research or in clinical trials. At the conference Children's Participation and Decision-making in Medical Matters, organized 2012 by the Nordic Committee on Bioethics, various participants discussed how this right should be interpreted and applied in different contexts and situations. This conference summary highlights the main themes of the conference.

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