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The Storage and Use of Biological Tissue Samples from Minors for Research: A Focus Group Study

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Key Words
Biobank · Ethics · Focus group · Minors · Stored tissue samples

Abstract
Genetic research on pediatric stored tissue samples raises specific ethical questions that differ from those raised when adults are the donors. To investigate opinions on this matter, we conducted 10 focus group discussions. Five focus groups were conducted with adult participants and 5 had teenage participants between 15 and 19 years old. The discussions were analyzed with NVIVO 8 (qualitative research software). We found the following recurrent categories: the requirement that research should not pose any burden on children and that it should benefit other children, the trust people had in the role of parents, the need for information and the growth towards autonomy. Both the adults and teenagers we interviewed thought that the inclusion of tissue samples from minors in research had ethical implications. A major concern was that nontherapeutic research would pose no extra burden on children, which would assume the use of nonintrusive methods of gathering samples and the use of samples that were gathered in a diagnostic context. Participants, however, also understood the necessity of such research. The overall impression was that parents would be the best persons to make decisions on behalf of a small child and that the same parents would engage their children in the decision-making when they grew older. People thought that there was a duty to recontact minors when they reached the age of competence but on a best-effort basis.

Introduction

Biomedical research on biological material from minors and the associated medical records can yield valuable information on the development and genesis of early-onset disorders and the early interaction of environmental and genetic factors [1, 2]. However, research on biological samples from children raises specific ethical questions that are different from those associated with biological samples from adults or from those associated with clinical trials with children [3]. Literature has already been published on this topic: we found theoretical articles [4–19], empirical studies [20–24] and reviews of existing guidelines [3, 25]. Themes discussed were consent, risks, benefit, and return of results. First, with regard to consent, the questions discussed primarily were whether parents are allowed to consent to the storage and use of materials from their children. Most authors agreed that parents or legal guardians are the most appropriate persons to consent if a child cannot do so [14–17]. Only Baumann thinks parents do not have the moral authority to decide for their children. She believes the risk for dis-

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crimination of children based on genetic results is too high [8]. Some authors think that, given the fact that some of the information that can be acquired from stored tissue samples is familial in nature, families should be involved in the information process [9]. Many authors also think that the opinions of children should be sought in the form of assent (the child's willingness to participate) or dissent (the child's objection) [9, 10, 15, 16, 18]. The literature does not agree on a specific age from when on children would be able to make such decisions. For example, Wendler and Shah suggest that the scope of children's research decision-making should be based on the principles of respect for autonomy and nonmaleficence and set the threshold for assent at 14 years [26]. The study by Goodenough et al. mentions an age of 9–11 years [20], and Meaux and Bell suggest that children as young as 5 years can understand research [27]. Another question is whether minors should be recontacted to give consent on research on their tissue samples. Most literature agrees that this is good practice, but it is unclear whether this should be done at a certain age or based on a level of maturity [16, 17]. Also, it is not definite what should happen to samples if a researcher is unable to recontact a participant for consent, which can happen if samples are completely anonymized or if the current address of a participant is unknown. In this respect authors also did not question the right of minors to withdraw from a study [15, 16, 20, 21].

A second theme in literature deals with the concept of risk. Guidelines refer to the idea that nontherapeutic research on tissue from minors can be done if there is no more than minimal risk [3, 28–35]. Two types of risk associated with the storage and use of stored tissue samples are discussed in the literature. The first is the risk of physical and emotional harm. Children might experience fear, for example of venipunctures, or would be overburdened by participation. In the case of longitudinal cohort studies, children might feel uncomfortable about certain questions and knowledge [20, 21, 24]. The second type of risk is confidentiality-related; third parties could access the information which would lead to discrimination of participants or to personal stigma [5, 8, 15, 17].

A third theme discusses the question who should benefit from research on stored tissue samples of minors. General principles of research on children mention that research on such tissue can only be done if it is not possible to obtain the same results with participants that can consent and that participants should either benefit directly or children of the same age or with the same condition should benefit [3, 29–31, 33–35]. It is unclear how children might benefit directly from biobank research, although in the case of longitudinal cohort studies, where there is more contact between the researchers and their subjects, regular health checkups may prove to be beneficial [24].

A fourth theme is the question whether incidental findings should be returned to participants and/or their parents. Some authors state that the return of results of especially genetic analysis to parents can trigger anxiety and change the way in which parents treat their children [6, 9, 17]. They would hence restrict this to results that could be used to improve health outcome.

Next to theoretical ethical literature, we found 5 empirical studies dealing with the topic of stored tissue samples from minors. A first study was part of the EPEG project (Ethical Protection in Epidemiological Genetics), which is associated with the ALSPAC ('children of the nineties') longitudinal study. This study describes 40 interviews with children aged 9–11 and describes how child participants perceive and understand their involvement in a major longitudinal epidemiological and genetic study [20]. A second study is also associated with the same project. It contains an analysis of the viewpoints of both the parents and the children, a discussion of the ethical and legal rights of the parents to consent for their children and a description of how child participants perceive notions of risk with regard to different type of information [21]. A study by Neidich et al. describes a survey of 299 women, who delivered at the University of Chicago, about their willingness to enroll their children in a hypothetical biobank [23]. Kaufman et al. describe focus group research to check whether and under which conditions children could be included in a cohort study planned by the US National Institutes of Health [24]. A Canadian study describes interviews with 8 clinical researchers in the field of pharmacogenetics on the inclusion of children in such research and also contains a reflection on the inclusion of children in biobanks [22].

Today no data exist on the attitudes of the Belgian population towards research on stored tissue samples from minors. As such attitudes may be dependent on cultural context, we found it useful to query these attitudes and opinions [36]. Since we wanted to explore these questions into some depth and find out whether there were any issues that did not come up in the existing literature, we chose focus groups as our modus operandi [37, 38]. Considering the fact that we did not find any empirical studies based on the opinions of young people on the verge of majority (within the range of 15–19 years), and as we also wanted to check whether their opinions were different from those of adults, half of the focus groups we conducted were with participants in this age group.

Table 1. Overview of focus groups

Focus group	Age range	Location of discussion	Duration of discussion	Recruitment method	Additional information
FG1	15–16	restaurant	60 min	One teenager was asked to gather mixed group of different schools	Mixed group: Catholic and public schools, secondary and technical education Participants from Leuven and surroundings
FG2	24–48	researcher's home	1 h 45 min	Internet forum (about motherhood) and women's organization	Group composed of mothers Participants from Leuven and surroundings
FG3	16–17	school premises	50 min	Recruitment through teacher from public school	Pupils from one class in a public school in Aarschot
FG4	26–73	university premises	1 h 30 min	Recruitment through the Flemish platform of patients' organizations	Group composed of members from different patients' organizations Participants from Antwerp, Leuven and Aarschot
FG5	16–19	researcher's home	60 min	Recruitment through board of Steiner school	Pupils from different classes of a Steiner school in Wilsele
FG6	31–52	researcher's home	1 h 30 min	Recruitment through internet fora and local community organizations	Mixed group: participants from Antwerp and Leuven
FG7	61–77	community room	1 h 15 min	Recruitment through organization of senior citizens	Senior citizens; participants from Leuven and surroundings
FG8	28–49	online	60 min	Recruitment through parents' internet fora and the national cystic fibrosis organization	Parents of children with a medical condition Participants from Gent, Leuven and Westerlo
FG9	16–17	school premises	45 min	Recruitment through board of Catholic school	Pupils from different classes from general secondary education in a Catholic school in Leuven
FG10	16–19	school premises	45 min	Recruitment through board of Catholic school	Pupils from different classes from technical secondary education in a Catholic school in Leuven

Methods

We conducted 10 focus groups to investigate the concerns of a Belgian population with regard to research on stored tissue samples. An overview of these focus groups is given in table 1. We provided food and beverages for the participants so that, even when the focus groups were conducted in environments such as schools, people would feel relaxed. One focus group with parents from children with a medical condition was performed online through a chat room; we thought that the travel distance would be an impediment for participation in this group [39]. We developed standard qualitative focus group procedures [37, 38]. The topics the moderator (Kristien Hens) introduced during the discussion were the willingness to donate samples for biomedical research, the need for consent and information, the possible dangers they saw associated with such research, the role of ethics committees, and the need to return incidental research findings. The discussion guide, for this part of the debate, was developed based on a literature study we conducted before [40] and on a pilot focus group with specialists in medical law, medical ethics and social sciences. The content of the discussion guide was revised based on the outcome of this pilot study.

A considerable amount of time (approximately one third of the discussion) was spent on the use of samples of minors for research. For the general discussion we used 3 different scenarios: the use of surgical waste, the use of blood that was collected in the context of a medical examination and a longitudinal cohort study. These scenarios were also continued in the discussion on the use of tissue from minors. The discussion was started with a general question about how partakers felt about the participation of children in such research. Based on the answers we got, we further inquired about consent, assent, risk, return of results, and genetic information. In the adult groups, we inquired about the willingness of donating tissue from their (potential) children or enrolling children for longitudinal research, whereas the teenage groups discussed how they felt about participating in such research themselves. Also, in the teenage groups, we enquired about the sensitivity of certain medical and nonmedical information, as we wanted to know how they felt about the fact that researchers and/or their parents would also be informed.

The discussion groups were conducted with Kristien Hens (K.H.) as a moderator. Kris Dierickx (K.D.) was assistant-moderator in most of the groups. At the beginning of each discussion, the participants were told that the conversation was audio taped and that we would process our findings in a publishable report. They were assured that this report would contain only anonymous data, no one objected. Audiotapes of the sessions were transcribed but not corrected for grammar in order to capture the oral nature of the discussion. Selected quotes were translated in English during the write-up of this paper.

We used NVIVO8 to do a detailed coding of the transcripts and to compare between focus groups and participants. We created cases for each focus group participant with attributes containing demographic values. During a first-pass analysis, we performed descriptive coding to assign each piece of text to a case. During a second-pass analysis, we did a detailed coding according to the various topics in the text. We then reorganized these topics under the categories attitudes, consent, return of results, and risk. These broader categories were inspired by the literature and discussion guide, whereas the subcategories reflected the issues brought up by the participants. Subsequently, we did a more analytical coding to find recurrent themes across the different topics. This part of the coding was done by K.H. and K.D. separately and then compared to match themes. The themes were coded under a separate tree, independent from the topical categories. In a last pass, we reorganized these recurrent themes. Based on our literature study, we assumed to find concerns about genetic information obtained from samples and, especially amongst the teenagers, a right to make their own decisions. Instead, the broader themes that occurred throughout the discussion were parental involvement, growing autonomy and need for information, and benefits and burden.

Results

Our focus groups discussed attitudes towards stored tissue samples from minors, the willingness to participate and issues of consent, risk and return of result. The categories that attracted attention throughout the whole discussion were the requirement that such research should not pose any burden on children and that it should benefit other children, the trust people had in the role of parents, the need for information, and the growth towards autonomy.

Burden and Benefit

The major theme that recurred throughout the different discussions was the fact that nontherapeutic research on children should not burden a child in any way. The combination of the fact that research might be distressing for children and not be of direct benefit to them was quoted as a major problem and was the one reason why people would not enroll children in research or why teenagers would not choose to participate. One participant stated the conditions under which she would enroll her child in biobank research as follows: 'If there is no fuss, if it happens, for example, at school and it is no burden for the child (for example through a mouth swab), if we know the benefit of the research, then I would probably not mind.' (table 1, FG8P2, female, 28).

The burden that was quoted most was the physical discomfort of venipunctures. Research should be as minimally intrusive as possible and preferably hidden behind diagnostic procedures that should have to happen anyway. Some even considered the taking of an extra tube of blood as a burden, which would not require an extra puncture, because this would stretch the time a child would spend in an uncomfortable situation. Also, the risk that a child may be afraid of researchers and the research environment was quoted as a potential undesirable outcome.

The willingness or desirability to enroll children also in primary, nontherapeutic biobank research, with associated phenotypical examinations, was strongly linked to the preferences of the children themselves. Both adults and most teenagers thought that such could only be performed if it was 'fun' for the children. Strikingly, the adults were less inclined to allow (small) children to participate in research that would require the taking of extra samples than the teenagers were. In the teenage groups, some people stated that needles were part of life and that a child would need to learn to deal with them anyway.

The physical or emotional burden was also linked to the age and the character of the child. The older children would be, the better they would understand the reason for the discomfort. Also, people stated that some children were more cool-headed than others and would be more willing to cooperate. In the group of parents with children with a medical condition, it was considered important that the research would not put additional load on children that were already burdened by medical treatment.

The risks associated with genetic information were seen as problematic by 2 participants: one was a representative of a patients' organization for people with a genetic disease and another was a parent of a child with a medical condition. The former made a link to genetic testing: 'Yes, I know, but the question is if those parents in England cooperate with their children. Do they give permission or can they also put limitations on that? For example, the things that were mentioned here, from my point of view this is very innocent, but whichever way you look at it, if they take blood samples, these will contain DNA. That is a full DNA profile, and we defend that children

should not be tested, but if the DNA material is there …' (FG4P2, female, 54). So, although she understood the nontherapeutic nature of the research discussed, she still thought the fact that the DNA is stored in itself is an item to be considered, and she thought the same guidelines as those regarding genetic testing of minors should be applied [41]. Overall, however, participants did not regard the genetic nature of the information that can be obtained from stored tissue samples as more problematic than other medical information.

People agreed that the use of stored tissue samples from children could be useful to understand and find treatment for typical childhood diseases, such as ADHD, autism, leukemia, progeria, and childhood cancers. Especially in the group composed of parents of children with a medical condition, research on the disease the children had themselves was preferred. One participant stated this as such: 'No, but I would like to find out first whether this can be used for … [the medical condition of her child]' (FG8P2, female, 28). Some partakers remarked that parents from healthy participants would be less inclined to give consent to participate in research than parents of children with a condition or parents belonging to a family with a condition. It seems that implicitly, people assumed that such research, even though nontherapeutic, might in the end be beneficial to the child or to the community of children with the same disease. This opinion, that research should preferably be done on children with a specific disease for a specific disease, was far less explicit in the teenage groups.

Parental Responsibility and Trust in Parental Decisions

We found a great trust in the responsibility of the parents in making the right choices for their children, both amongst adults as well as amongst teenagers. This trust was seen in different contexts. First, there was acceptance that parents could and should make decisions about research participation for children who are still unable to do so for themselves, and there was confidence that they would make the right balance. We also discussed with the teenagers whether they would blame their parents if they had decided to donate tissue for medical research when they were small and they unanimously stated they would not do so. It was accepted, both in the groups with adults as well in the groups with teenagers, that it is part of life that parents make decisions for children who cannot decide for themselves. In one teenage group (FG5), an analogy with baptism was drawn: as baptism in Belgium typically happens when a child is only a couple of months old, he or she has no say in the ritual, but this was not estimated as a great problem, even for children who would later lose their religion. Some teenagers did say that they would refuse to participate if parents were to force them without further discussion. No teenager, however, thought this was a realistic scenario, as they had faith that parents would discuss this with them. They showed trust that their parents would make the right decisions and would also involve them in these decisions.

Overall, the impression amongst adults and teenagers was that the parents were the most suitable persons to convey information about research participation to their children, because they knew their children best. They were hence seen as intermediaries between scientists and their research subjects, the children. As we shall discuss in the section 'Autonomy and the Need to Be Infromed', some people also thought that it was the task of the parents to inform their children in due time about the fact that their tissue was used for research and that they could consent to further uses or not.

Trust in the parent-child relationship was also apparent when the return of incidental research findings was discussed. Both teenagers and adults thought that medically important information should be told to the parents and the minor together. Teenagers found it logical that this would be shared with parents: 'You can then object to the fact that parents know it first, and some people will push this very far, but the real problem is really not with the parents if you have cancer.' (FG5P8, male, 19).

In some of the teenage discussion groups, we also debated the scenario of a 14-year old with a high amount of alcohol in his or her blood. The participants considered this to be private and nonmedical information that should not be shared with parents, although in one group it was stated that if this drinking habit were so severe that it would affect the child's health, researchers would have the right to inform the parent. Hence, both teenagers and adults thought medical information is something that should and could be shared between children and their parents, and they did not consider this as information that should be kept private. Moreover, they considered it advisable that parents and children would also receive this information simultaneously.

Autonomy and the Need to Be Informed

Although we found much trust in parental decisions, the fact that children might not be able to autonomously decide on research participation was quoted as a major ethical difference between stored tissue samples from mi-

nors and from adults. One participant expressed this very clearly: 'Yes, so, you take your baby to the doctor and you say, I want from my child blood to be taken so that it can be used for scientific research. OK no, I would think that wrong, that is really completely wrong, look that child cannot choose for himself, they would have to have a reason for that, at least done some proper thinking.' (FG10P8, male, 16). This teenage boy stresses the relation between the lack of autonomy of the child and the fact that something potentially burdensome is done to him/her (venipunctures). In the last part of this quote, he suggests that such actions could be done but only with a solid (medical or research) reason.

A considerable portion of the discussion time was spent on the children's right to have a say in the decision as well. Both teenagers and adults seem to agree that children would have to be allowed to decide for themselves once they reach the age of understanding: 'No, from the moment that I can decide myself I want to decide myself, but I would not mind too much either. Let's say my parents consented, and I know that now, yes for such a research I would not really mind.' (FG1P2, female, 16).

There was much discussion in most of the groups about the specific age on which a minor would be capable to make his or her own decision about donating. The age proposed ranged from 10–18 years. Remarkably, the age that was most quoted in the groups with teenagers (15–19 years) was higher than that in the adult groups: often the former thought 16 was the minimum, although they all thought they themselves were capable of deciding for themselves on the matters discussed. In the teenage groups, the fear was also expressed that other teenagers would refuse because they were in puberty, but they themselves believed they would not refuse if asked to contribute to research. In the adult groups, ages quoted where more fluid and ranged from 10 to 18 years. In adult groups, the remark was made that children with a medical condition were more mature than healthy children and would hence be able to understand better what was at stake, something that was not mentioned by the teenagers. This did not, however, automatically imply that this would make them more suitable as research subjects than 'healthy' participants.

The groups also discussed participants' attitudes towards the duty to recontact persons when they reached the majority age, which is 18 in Belgium and many other European countries [42], to ask for renewed consent for research on stored tissue samples. There was agreement amongst adults and teenagers that recontacting people to ask for consent to the further use of their samples was a good practice, but they also acknowledged the fact that this would be on a 'best-effort' basis. On the one hand, focus group participants thought the initiative should come from the biobank participants and their parents; parents should make their children aware of the fact that their tissue was used and that they should contact researchers to (re)consent to the use. Again, a great role was attributed to parents and trust was placed on the relationship between children and parents. On the other hand, some thought researchers should try to contact participants when they turned 18 on a best-effort basis. They did however think this could pose an administrative burden. If it was not possible to find the person in question, they thought tissue could still be used and would consider the throwing away of samples as wasteful. Hence, they saw the duty for recontact not as an absolute requirement but something that needs balancing with the potential benefits of research. When we asked the teenage participants whether they would expect a phone call when they were 18 years old, some said they would not. They thought it would be too much trouble for the researchers and did not consider investigation on their stored tissue samples as too big a deal. Others, however, said they would like to know about the study done on their sample. Some teenage participants mentioned 'curiosity and respect' as the main reason why they would want to be informed, rather than the desire to have the final say. Others saw such recontact as a token of respect: 'I think if you turn eighteen, well, I hope you are briefed by your parents but that they send also a mail or a letter out of politeness, like, look, now you can decide yourself on your blood, can we continue or not.' (FG10P7, male, 17).

Discussion

General Findings

In much of the literature about research on children, a reference is made to their special vulnerability [22]. Children deserve, because of their limited autonomy, extra protection from harm. Also, our study shows that many people's primary concern when enrolling children in nontherapeutic research, be it only on their biological samples, is that this should not pose any burden on these children. This is consistent with the focus group study by Kaufman et al. [24] and with interviews with 7-year-old children participating in a clinical cohort study by Gammelgaard and Bisgaard [43]. Children in the latter study mentioned the venipunctures as the part of the research they disliked most. A solution to reduce the burden would

be to reuse materials that are gathered in the context of diagnosis or to use nonintrusive techniques if such reuse is not possible. A study by Bartington et al. has shown that collecting oral fluid is a feasible and nonintrusive method [44] and could be done in a familiar atmosphere at home with the help of the children's mothers. In the same way, mouth swabs could be used for genetic research. In the ALSPAC study, which is nontherapeutic only, a local anesthetic is used when blood is taken and the children are shown videos to distract them [45].

Next to physical risks, the literature on stored tissue samples also quotes privacy issues. Such samples contain genetic information which is considered potentially dangerous if accessed by the wrong people, such as insurance companies or potential employers. Only 2 of our participants mentioned the specific nature of genetic information as a reason why children would be in need of extra protection. However, as these 2 participants had been in closer contact than average with the medical world, and were therefore more informed, the sensitivity of genetic and medical information is not something that should be disregarded. In the study by Williamson et al. [21], where parents were already involved in the study through their children, some parents did mention fear of the long-term use of genetic information, although this was not a major concern of many [46]. When the issue of return of incidental research findings was discussed, both teenagers as well as adults did not see major privacy issues in the fact that parents would know their child's medical data. Teenagers were, however, more sensitive to certain nonmedical information that could be retrieved from tissue. For example, they considered their drinking habits to be private. Only if this were to become a 'medical condition', researchers would be allowed to communicate this to parents. We recommend that, especially if longitudinal studies with minors are designed that investigate certain types of information that is not strictly medical, it is good to reflect on these privacy issues and discuss them with the children.

Adults and teenagers thought that research on stored tissue samples from children could be useful. They all quoted diseases that occur in childhood as important areas of study. People were willing to allow their (sometimes hypothetical) children to participate in such research, but there was a preference to enroll children in research on conditions they themselves had. This seems to imply that the requirement that is quoted in some guidelines on investigation on stored tissue samples that research on children should benefit other children or children with the same condition [3, 29–31, 33–35] has some ground in moral intuition. However, longitudinal research, such as the ALSPAC study, typically follows children from birth onwards to create a research resource for many different diseases. Policy makers should consider how to balance access to pediatric resources with protection of vulnerable subjects.

Both adults and teenagers we interviewed thought parents had an important task in safeguarding their children's interests and in judging the best course of actions. However, a trust in parental decision-making does not contradict a need for a gradual increase in the need for children to be able to decide themselves. Our participants did not agree on the age as of when children would be able to understand research enough to decide themselves. This is in accordance with the existing literature. In this respect, the study by Avard et al. states that the geneticists they interviewed considered 12 as a crucial age: children over 12 were consulted about willingness, those below 12 were involved as much as possible [22]. Goodenough et al. state that the age between 9 and 11 is a crucial age, because then the balance of decision-making is shifting and people are making more and more decisions for themselves [20]. In our groups the suggestion was often made that children would gradually receive more information, and this would imply a growing impact of the opinions of the children. It was thought that children have a right to be told in their own language about research. In one group the need for protection of children through 'extra' ethical committee oversight was mentioned, as there may be a limit to the knowledge and expertise of parents, and an extra aid in making the right decision would be helpful. This is also mentioned in some guidelines on stored tissue samples [3, 28, 29, 31, 32, 35, 47, 48]. As the ethical issues associated with stored tissue samples from minors are different from those with adults, and as children are considered vulnerable subjects [22], we think that extra ethics committee oversight is indeed necessary. But this is complementary to a good relationship of researchers and medical staff with both parents and children.

Differences between Adults and Teenagers

One of the aims of this study was to see if, when talking about stored tissue samples from minors, adults and teenagers would emphasize different aspects. We found that they agreed on most issues. However, there were 2 striking differences. First, teenagers often quoted a higher age (around 16) when asked at which point children were able to make their own decisions. They also referred to 'puberty' as a reason why teenagers would refuse to co-

operate more often, but they thought their own judgment would be clouded by this condition. Indeed, all teenagers we interviewed were well spoken and had clear opinions on the matter. As such, they were examples of the fact that children can (and should) be heard. The fact that these teenagers put the age of consent relatively high could also suggest that they are not entirely comfortable making such decisions. They may want guidance considering the complexity of the question. A qualitative study by Boddington and Gregory also shows that teenagers, when confronted with explanations about genetics and carrier testing, sometimes did not entirely understand what was said to them and, when questioned as adults, would have preferred more guidance [49]. These findings would suggest that teenagers should not and do not want to be left alone with questions concerning genetics. However, it could also mean that they consider these decisions as relatively harmless and as having no direct bearings on their own lives and are therefore happy to relinquish the responsibility.

Another difference was that some (but not all) teenagers thought children could be convinced to cooperate to research even if this would cause them discomfort, for example because syringes were used. In the adult groups, participants were overall less inclined to allow such research on their children. As such, these teenagers took a more deontological approach to research and thought it was more important than any discomfort it might cause. We can only guess at what could be the reason for this difference. A possible explanation is that these teenagers identify themselves more with the children in research and perhaps, having had similar experiences in the past, would consider the burden 'not so bad after all'. The adults, on the other hand, took the positions of caretakers and defenders of the (vulnerable) children. In this position research goals are secondary compared to any possible negative impact these could have on children.

Limitations

We admit that our study has several limitations. The fact that it is a focus group study, on a voluntary basis, also implies that the participants might have been biased, either in the positive or the negative sense, and may not be entirely representative of the Belgian population. The original discussions took place in Dutch, and quotes were translated in English, which means that some of the nuances of the responses may have been lost. Our teenagers questioned had, as far as we could assess it, no underlying medical conditions. We do not know if the inclusion of such a group would have changed our general findings.

Our focus group study shows that both the adults and the teenagers we interviewed thought that the inclusion of tissue samples from minors in research had ethical implications. A major concern was that nontherapeutic research would pose no extra burden on children, which would assume the use of nonintrusive methods of gathering samples and the use of these in a diagnostic context. Participants, however, also understood the necessity of such research. The overall impression was that parents would be the best persons to make decisions on behalf of small children and that the same parents would engage their children in the decision-making when they grew older. People thought that there was a duty to recontact minors when they reached the age of competence but on a best-effort basis.

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