European Journal of Human Genetics (2016) 24, 30–36

www.nature.com/ejhg

ARTICLE

Regulating biobanking with children's tissue: a legal analysis and the experts' view

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Many current paediatric studies concern relationships between genes and environment and discuss aetiology, treatment and prevention of Mendelian and multifactorial diseases. Many of these studies depend on collection and long-term storage of data and biological material from affected children in biobanks. Stored material is a source of personal information of the donor and his family and could be used in an undesirable context, potentially leading to discrimination and interfering with a child's right to an open future. Here, we address the normative framework regarding biobanking with residual tissue of children, protecting the privacy interests of young biobank donors (0–12 years). We analyse relevant legal documents concerning storage and use of children's material for research purposes. We explore the views of 17 Dutch experts involved in paediatric biobank research and focus on informed consent for donation of leftover tissue as well as disclosure of individual research findings resulting from biobank research. The results of this analysis show that experts have no clear consensus about the appropriate rules for storage of and research with children's material in biobanks. Development of a framework that provides a fair balance between fundamental paediatric research and privacy protection is necessary.
European Journal of Human Genetics (2016) **24,** 30–36; doi:10.1038/ejhg.2015.59; published online 15 April 2015

INTRODUCTION

Biomedical research within the field of paediatrics focuses increasingly on the relationship between genes and environment, exploring aetiology, management and prevention of Mendelian and multifactorial diseases. Without the collection and long-term storage ('biobanking') of data and biological materials of affected children this type of research, which is essential to further develop paediatric health care, is merely impossible. There is a lack of knowledge about the causes of and proper strategies for prevention and treatment of diseases in childhood. Scientific research with children's biological materials is crucial to gain further insights in this field of medicine and to develop health care. However, long-term storage may also interfere with the child's right to privacy, in particular his or her (hereafter: his) right to an open future.[1,2] Biological materials contain highly personal information about an individual's health and future health prospects, such as late-onset risks for diseases.[3,4] Stored information could be used in an undesired manner, potentially leading to discrimination or stigmatisation and may also cause distress when disclosed.[5,6] In addition, once adulthood is reached, a participant may prefer not to be informed about the individual research results.

The current study focuses on storage of biological material left over from clinical care of young children (0–12 years) who are fully dependent on their parents. This age range was chosen because, in the Netherlands, children older than 12 years may decide together with their parents about storage and use of leftover tissue.[7] Young children, on the other hand, do not have the competence to provide informed consent or make decisions regarding test results, but they may become competent over the period that their material is stored. Once competency is attained, questions arise on the protection of the child's privacy interests.

Two issues are reported on in this current analysis: informed consent for donation of children's tissue to a biobank by parents and reconsenting of the child when he reaches adulthood; and disclosure of individual research findings to the child's parents as well the child's rights to know and not to know such information. Legal documents describe relevant principles and obligations concerning these issues,[8] but consequences for medical practice are often unclear and empirical studies have only addressed biobanking in general.[9–11] Thus, it is necessary to probe the applicable normative framework and the views of experts in paediatric biobanking on these issues by personal interviewing.

MATERIALS AND METHODS

Study of legal documents

The electronic databases Westlaw International, HeinOnline and Google Scholar were searched for relevant legal documents using combinations of the keywords: (child OR children OR paediatric OR pediatric), (biobank OR biobanks OR biobanking), (informed consent), (individual results OR incidental findings OR individual findings), (right to know OR right not to know) and (tissue OR biological material). The search was restricted to documents in English and Dutch. The reference lists of included studies were hand-searched to identify further relevant documents.

Experts

The experts in paediatric biobank research who were chosen for interviews were generally considered to be key figures in the field, had different disciplinary backgrounds, were living in various parts of the country and were working in different institutes or academic medical centres (Table 1). We invited 21 experts, purposively selected to represent all types of stakeholders and to cover a full variety of perspectives.[12] Two did not reply, two refused due to personal matters and one referred us to a colleague. A total of 17 experts were

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Received 26 September 2014; revised 20 February 2015; accepted 24 February 2015; published online 15 April 2015

interviewed, and based on the interviews, we concluded that data saturation was achieved.[12]

Interviews

We designed a semistructured interview of 14 open questions based on existing legal and ethical norms related to paediatric biobank research (Table 2). The semistructured nature allowed interviewees to express in-depth views and to address related themes. Two weeks before an interview, an introduction was sent to the expert to introduce the interview themes. The interviews were held individually and were tape-recorded. Each interview was conducted in person with a duration ranging from 45 to 75 minutes. Interviews were completed from June 2012 until June 2013.

Analysis

Interviews were transcribed verbatim and coded. We used a framework approach in content analysis: interview data were systematically analysed based on the main themes of 'informed consent' and 'disclosure of individual research findings'.[13] Data were coded equally to the themes of the interviews to obtain a consistent uniform set of categories, followed by detailed subcoding to select subthemes. Subsequently, we interpreted codes and quotes to detect similarities and differences between interviewees.

Table 1 Specialty of expert interviewees

(n = *17*)	n	%
Donor		
Patient support group representatives	2	11.7
Manager		
Biobank administrators	2	11.7
Physician		
Paediatricians	2	11.7
Paediatrician-researchers	4	23.5
Clinical geneticists	4	23.5
Physician-researcher-REC	1	5.9
Expert		
Ethical expert	1	5.9
Legal expert	1	5.9

Table 2 Topics within the semistructured interviews

1. Informed consent for donation

1.1 To what extent should parents decide about collection and storage of their child's material?
1.2 Should that be an explicit informed consent or an opt-out?
1.3 Is there a chance of different interests between parents and child?
1.4 Should a child decide on collection and storage of its material itself?
1.5 How should a child's right to withdraw be specified?
1.6 Should there be a child's right to destroy its material?
1.7 Should the child be asked to consent to continuation of storage and use of its material?
1.8 Who should re-contact the child?
1.9 What should be the scope of research with a child's biological material?

2. Disclosure of individual research findings

2.1 What should be the biobank policy on disclosure of individual findings?
2.2 Is there a possibility of different interests between parents and child regarding (not) to know individual findings?
2.3 At what age is a child capable to decide about disclosure of individual findings?
2.4 Is there a chance to stigmatisation with knowledge about a genetic deviation?
2.5 Should an independent committee advise about disclosure of individual findings?

RESULTS

We describe first existing normative frameworks and the expert's views regarding informed consent and subsequently disclosure of individual research findings. Main findings are summarised in Table 3.

Informed consent for donation

Analysis of legal documents. The Convention on Human Rights and Biomedicine of the Council of Europe[14] aims 'to guarantee everyone's rights and fundamental freedoms and, in particular, their integrity and to secure dignity and identity of human beings' in the sphere of human medicine and biology.[15] The Biomedicine Convention is signed by all Member States of the Council of Europe, but has not yet been ratified by the Netherlands and several other European countries. Regarding paediatric biobanking, the Convention provides general principles on informed consent. Biological material that is removed in the course of an intervention may be stored or used for other purposes, 'if this is done in conformity with appropriate information and consent procedures' (Article 22). The explanatory report to the Convention explains that this must be consistent with a free and informed consent based on appropriate information and a right to withdraw at any time (Article 5). For children, this should be authorised by parents or representatives (Article 6). The report emphasises the necessity of informed consent in storing human material, 'because much information on the individual may be derived from any part of the body (…). Even when the sample is anonymous the analysis may yield information about identity.' (para 135). These norms are flexible, however. In some cases, it may be sufficient to duly inform the individual, while in other situations, particularly if sensitive information is collected, express and specific consent is necessary (para 137).

The United Nation Convention on the Rights of the Child contains general provisions on the child's position: 'the best interests of the child shall be a primary consideration in all actions concerning children' (Article 3).[16] The UN-Convention states: 'States parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child' (Article 12). The UN Committee on the rights of the child stresses the importance of 'the right of the child to be heard and taken seriously as one of the fundamental values of the Convention'.[17] For research this implies that physicians and health-care facilities '(…) should provide clear and accessible information to children on their rights concerning their participation in paediatric research and clinical trials. They have to be informed about the research, so that their informed consent can be obtained in addition to other procedural safeguards' (Consideration 103). According to the Convention, children have the right to express their views as much as possible, and, if they have sufficient capacity, should be enabled to exercise their rights on their own behalf (Articles 5, 12, 13 and 17).[16,17] Finally, Article 24 of the Convention emphasises 'the right of the child to the enjoyment of the highest attainable standard of health (…)'.[16] Storage of and research with children's tissue can improve knowledge about prevention and treatment of diseases in childhood and with that it can contribute to progress of medical science and optimal health care.

Table 3 Results

	Patient representative	*Biobank administrator*	*Paediatrician*	*Paediatrician/ researcher*	*Clinical geneticist*	*Physician, researcher, REC*	*Expert (legal/ethical)*	*Total, n = 17*		
								Yes	*No*	*Unknown*
1. Informed consent										
Explicit consent										
Yes	2	2	2	1	3	1	2	13		
No (opt-out)				2					2	
Unknown				1	1					2
Broad research goals										
Yes	1	2	2	3	4	1	2	15		
No (disorder-specific)	1			1					2	
Unknown										0
Specific age thresholds (years)										
12–16		1	1			1		*Total 12–16:* 3		
12–18	2	1	1	4	4		1	*Total 12–18:* 13		
14/15							1	*Total 14/15:* 1		
Ongoing obligation to inform										
Yes	2	2	2	2	3	1	2	14		
No				2	1				3	
Unknown										0
Re-consent										
Yes	1	1	1	1	3	1		8		
No	1	1	1	3	1		2		9	
Unknown										0
2. Individual research findings										
Disclosure actionable findings										
Yes	2	2	1	4	4	1	2	16		
No									0	
Unknown			1							1
Disclosure actionable findings with relevance to family										
Yes	1	2	1	1	2		1	8		
No									0	
Unknown	1		1	3	2	1	1			9
Disclosure of late-onset findings										
Yes	2							2		
No		2	1	4	3	1	2		13	
Unknown			1		1					2
Advise REC or colleague										
Yes					1		1	2		
No									0	
Unknown	2	2	2	4	3	1	1			15
Parental right (not) to know										
Yes								0		
No	1	2		2	2	1	2		10	
Unknown	1		2	2	2					7
Age threshold child's right (not) to know (years)										
12			2	1	1			Total 12 years: 4		
16/18	2	2		2	2	1	2	Total 16/18 years: 11		
Unknown				1	1			Total unknown: 2		

The (non-binding) OECD-Guidelines on Human Biobanks and Genetic Research Databases (OECD-Guidelines HBGRD) include several relevant principles such as informed consent for establishing, accessing and making use of human biobanks and genetic research databases.[18] They include 'best practices', which provide guidance to the more fundamental 'principles' and state that prior, free and informed consent should be obtained from each participant (Principle 4B). The importance of sufficient, accessible and written information about the most relevant elements of participation is underlined (Articles 4.1–4.4). The consent may be broad to facilitate the use of material for unforeseen research questions, but participants should be aware of this. The guidelines recommend development of a clear policy on involving children in biobanking, including whether, when and how to obtain their assent (Article 4.7) and on steps needed once such participants become legally competent to consent (Article 4.8 and Annotation 31). In young children, parents, as representatives of their child, should decide whether or not the child's material may be stored in research biobanks. When the child reaches the age of majority, it is also necessary to obtain the child's consent for ongoing storage and use of his material (Annotation 32).

The Recommendation (2006)4 of the Council of Europe is a non-binding but still important framework for member states, influencing legislation and regulations.[19] This Recommendation applies to biomedical research involving human biological materials removed for research purposes and materials removed for purpose(s) other than research (Article 2). The Recommendation provides general principles regarding informed consent (Articles 21 and 22). According to the Recommendation, an important requirement is approval of the research protocol by an independent ethics committee (Article 24). Article 15 section 3 states that as soon as a child has the capacity, he should have the opportunity to withdraw or change the scope of the consent for storage of stored materials given by his parents.

In summary, prior voluntary consent based on sufficient information is a basic requirement in paediatric biobank research. Furthermore, children have a right to express their own views and should have the opportunity to exercise their rights on their own behalf as soon as they are able to do so.

Expert's view. All experts agreed that parental consent is needed for storage of children's biological materials in biobanks. Their view differs on whether this should be an explicit consent, or opt-in approach, or whether an opt-out approach would be sufficient. In the opt-out approach, experts distinguish between biobanks with anonymous human material and those with identifiable material. The majority of the experts considered an opt-out system as sufficient if the blood, tissue or DNA samples are stored completely anonymously, for example, without preserving the possibility to recontact the family. (It is important to note, however, that as biobanking is rarely useful with completely anonymous material owing to the almost universal need to correlate findings in samples with clinical data, an opt-out system, therefore, is often not appropriate.) In storing identifiable material, the majority of experts were in favour of obtaining explicit consent. Informed consent should also involve communication of individual research findings. However, two paediatricians strongly involved in research activities expressed preference for an opt-out system in all situations, including for identifiable materials.

> *'I'd be very happy with an opt-out system. That makes it easy for us. (...) We don't do anything extra, we just store something'.*

They argued that in an academic setting every patient should contribute to biomedical research.

Most experts stated that on the basis of consent, children's material should be available for broad research purposes, provided this is discussed in advance with parents, and as long it does not involve entirely unrelated research topics. They argued it is not feasible to describe *all* specific research questions in advance, or to recontact the family to explain new research purposes.

> *'In 2012 you can't argue any more that it can only be used for a very specific purpose. Because if we start using sequencing to look at things like the causes of deafness or blindness or intellectual impairment or new risk factors for cardiovascular disease, then you can run into all kinds of things where specificity gets nullified by the nature of the techniques'.*

Some experts said that the use of children's material should be disorder-specific or be focused to the disorder of the child himself. The experts with a clinical genetic background did not favour broad storage goals, as it is often impossible for parents to oversee all implications for their child. One interviewee (a clinical geneticist) differentiated between storage and use: the explicit consent is particularly important if individual findings need to be discussed with the family. Most experts stressed that it is essential to provide proper information to parents and the child, depending on his understanding, about aspects such as research goal(s), the way the material is stored now and in the future, the disclosure policy regarding individual research findings, and finances. It was stated this was possible through information leaflets, letters, websites, and oral explanations.

Finally, most experts were in favour of specific age thresholds for the child in providing consent to biobanking. They stated that the age thresholds of the Dutch Medical Research Involving Human Subjects Act (12–18 years) or the Dutch Medical Treatment Contract Act (12–16 years) should be applied. Most were in favour of using 18 years as the threshold to a child to make decisions independently of the parents.

Re-contacting grown-up children. Almost all experts stated that biobank managers have an ongoing obligation to provide information to families about the storage of biological material and the research carried out with this material. Biobank managers should approach them actively through information leaflets, letters, or websites to keep them informed. Parents and children should be notified of the possibility to recontact the biobank administrator if they have questions.

> *'If researchers want to keep the trust of the public, then they're going to have to make special efforts. Claiming that they're just asking you for a bit of material and that you'll never hear anything again and that they just want to do scientific research and that they'll leave your interests out of the picture – all of that will be less and less valid, I think. When more and more predictive information can be found, especially from DNA material, then that just won't work anymore'.*

Three interviewees (two paediatricians-researchers and one clinical geneticist) argued biobanks should operate pragmatically because actively releasing information to parents and children has significant logistic and financial consequences, which can hinder research activities. However, the clinical geneticist stated actively contacting families may not be feasible and achievable in practice, but would still be preferable:

> *'I don't think it's feasible to contact everybody again. I do think it's the responsibility of the biobank to do things that are reasonable, within their power. They can't just hide behind the fact that it's a little more work'.*

Two interviewees (the paediatrician-researcher and clinical geneticist) stated that parents are responsible to inform their child about biobanking his material and to discuss future storage and use of materials. One paediatrician-researcher believed the subject should only be recontacted if medically relevant individual findings are found, and at that time should be asked whether he wants to receive the information.

There were different views among experts regarding recontacting the child in adulthood. Nine experts were not in favour of such obligation, because of the possible logistic and financial problems. They argued that if biobank managers provide continuous information about the biobank to parents and child, the older child will be capable of re-contacting in case of questions. Eight experts stated that at a certain age, the child should be asked for his consent to continuation of storage and use of materials.

> *'I think kids over 12 years old are pretty much capable of judging that, if you give them the time to think about it. But okay, you do have to*

use your judgment. Some kids between 12 and 18 are so mixed up as far as the world or themselves or their parents are concerned, that there's not much point asking them 'What do you think about this?' But you can always throw out the question and come back to it later sometime'.

Two experts stated re-consent should be asked first at 12 years and again between 16 and 18 years, whereas six experts felt this should only be done when the child is 16–18 years old.

Disclosure of individual research findings

Analysis of legal documents. A basic right of the Convention on Human Rights and Biomedicine is the right to privacy including a right to know as well as not to know information about one's health (Article 10). These rights are not absolute. As to research, guidance is provided by the additional protocol on Biomedical Research (2005): 'If research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them. That shall be done within a framework of health care or counselling. In communication of such information, due care must be taken in order to protect confidentiality and to respect any wish of a participant not to receive such information' (Article 27).

The Council of Europe's Recommendation (2006)4 also applies this provision of the additional protocol to research with stored materials (Article 25). The Explanatory Report to this additional protocol defines that a '[…] researcher may seek the advice of the ethics committee as to the potential relevance of the information in question to research participants'.

The OECD-Guidelines HBGRD recommend biobank administrators to develop a clear policy on involving children in biobanking, particularly regarding the feedback of individual findings (Articles 4.9 and 4.10). They recommend development of a policy on informing donors about options regarding disclosure of individual findings and the consequences for the donor and family members (Article 4.14). Also, the donor should be informed about the right to opt out from receiving such results. Non-validated results should *never* be disclosed to donors (Article 4.14), but should be explained in the informed consent process. Disclosure of such information would only serve to harm the donors involved.[20] Finally, the United Nations' Convention on the Rights of the Child states that a child has a right to privacy (Article 16), and may request access to information and material from different sources (Article 17).

The international normative framework underlines the importance of research participants' right to know and not to know research results, and emphasises the need for a clear policy on disclosure of individual research findings. During the period where the child is not considered competent, his rights may be exercised by the parents.

Expert's view. Almost all experts stated it is essential to distinguish between validated findings, relevant to the child's health and with actionable options, meaning treatment or prevention is possible (actionable), *versus* findings without clear significance for the child's health. Most experts agreed it would be irresponsible not to inform parents and child about actionable findings. Medical practitioners stated it is their professional duty to warn parents (and, depending on age, the child) about actionable findings. Some experts stated this duty extends to findings that are important to the health of family members. Most experts indicated that relevant results should be disclosed by a physician. The majority of interviewees stated that information about late-onset disorders for which no treatment is possible should not be disclosed to parents or child.

'But I also think that some other things oughtn't be disclosed in this context. Imagine that more becomes known about genes affecting autism. I don't think it's the place of scientific research to disclose information that wouldn't immediately benefit the child'.

The patient-representative experts had a different opinion: individual research findings should be disclosed to the parents, allowing parents to decide about disclosure of information to their child.

'I would want to know that. Because then I might be able to look for different methods. (...) Or keep an eye out for whether a new medicine is being developed or whatever.(...) As a parent, or as a human being, I'd want to know what she can expect'.

Many experts stated that options regarding disclosure of individual findings should be addressed during the informed consent procedure. Some interviewees argued that a colleague or ethical committee should be consulted when in doubt about disclosure of findings to a family.

Right to know or not to know. Most experts stated that parents should not have the right to decide about the right to know or not to know on behalf of their child.

'We also felt that parents didn't have the right to say they didn't want to know it. Children are vulnerable human beings, they don't have the responsibility for their own health care. So if you find a serious health condition that you can take immediate preventative action against, then you've got to disclose'.

Individual findings for which treatment options are available should be reported regardless of parental wishes. According to most experts a child from 16 to 18 years of age can and should be allowed to decide independently about being informed. For younger children knowledge about such findings would have many consequences that the child cannot oversee.

'That's one reason why being informed after age 18 is such a good thing. Then they already know as young adults that they're in there, and so they also know they could be confronted with a letter in the future that says, 'Look, there's something you need to know, something that's important'. Once children reach 18 years, they should be clearly informed of that'.

Some interviewees had a different view: children from 12 years on should be able to decide about this together with their parents. They felt that, at a minimum, the child should be informed about the presence of his material in a biobank and, on request, be able to obtain information regarding individual findings.

DISCUSSION

By interviewing experts, we explored their opinions regarding the issues of informed consent and disclosure of individual research findings in the context of paediatric biobanking. We stress that the limited amount of purposively selected interviewees may limit the generalisability of our findings, because they may not be representative for the population.[12] Still, we believe our intention to gain insight into the variety of perspectives and to represent all types of stakeholders was achieved. The results of this study show that there is consensus about several basic principles, but a clear consensus about practical implications is lacking.

Informed consent for donation

All experts consider informed consent of the young child's parents a basic requirement to store children's materials in a biobank and using it for research. Whether this should be explicit or implicit, or a broad or specific type of consent is a topic of discussion. The international documents leave room for both approaches.[18,19] The current literature emphasises the vulnerable position of young children in biobank research, stressing consequences of information that can potentially be derived from the biological material.[6,21,22] Therefore, we argue that explicit consent is to be preferred over implicit consent.

Experts take different positions how consent should be asked from parents: broad or specific. Most support a broad consent, but a few experts favour disease specific consent that focuses on the disorder of the child. Hens *et al*[23] have been opposed to 'full broad consent to any possible future research', especially for more sensitive research with more privacy risks, due to the child's right to express his own values. Furthermore, Giesbertz *et al*[24] have concluded that different biobank characteristics lead to a different involvement of children in the consent process. The OECD-Guidelines leave a broader consent open to national regulations, provided that additional safeguards are at hand, such as oversight mechanisms. In our view, a broad consent approach is most suitable because defining all research questions in advance is not feasible.[25,26]

All reviewers agree that biobank managers have an ongoing obligation to provide sufficient information continuously to the child and parents about the storage and intended use of materials and data, as well as the consequences for parents and child.[6,27–29] These requirements are shared by the Public and Professional Policy Committee (PPPC) of the European Society of Human Genetics (ESHG).[30] They underline the necessity of consent and age-appropriate information. Research suggests that there is lack of understanding regarding the informed consent process by parents,[10] which emphasises the need for providing appropriate and sufficient information.

Children are considered temporarily incompetent but acquire with time the capacity to provide consent and decide on biobanking independently of their parents. There is disagreement among experts on children's rights when reaching a certain age. Several authors have argued that young adults must have the option to re-consent or to withdraw earlier parental consent.[23,27] Proxy consent and consent of a participant him/herself are not considered the same: consent provided by parents is based on protection of the best interests of their child, while consent of an adult child expresses his own wishes and autonomy.[31–33] The PPPC of the ESHG underlined the importance of re-contacting the child at the age of majority to allow for reconsenting or withdrawing consent.[30] The Dutch experts differ in opinion about this. Some state this is the responsibility of the parents, provided they obtained sufficient information about storage and research. Others state the child should be re-contacted at a certain age. In our opinion, re-contacting the mature child is an essential requirement in paediatric biobanking regulations. The exact age for this is primarily a matter to be debated at national level. If recontacting the mature child is impracticable, for instance, if the child is deceased, there should be room for exceptions.

Disclosure of individual research findings

The interviews demonstrated that disclosure of individual research findings is one of the most problematic aspects of paediatric biobanking, and that further guidance is necessary in this respect. International documents do not provide this guidance. Empirical research shows that a motivating factor for parents to provide consent to biobank research is the hope and expectation to receive individual findings, even if dealing with untreatable diseases.[10] The Public Population Project in Genomics and Society (P3G) International Paediatric Platform recommended the possibility for disclosure of individual findings should be discussed during the informed consent procedure.[34] Most experts agree with this recommendation.

According to the majority of experts, actionable findings must be disclosed to parents and/or child.[30,35] There is no consensus about parents' right to know or not to know findings on late-onset disorders for their child or on findings with uncertain consequences. Some experts argue that such information should not be communicated to parents, whereas others believe that parents should decide for themselves about being informed or not.[36] In literature, it is most often argued that parents can exercise their right to know or not to know as long as this is in the interest of their child. This means that they cannot refuse to be informed about immediately clinically relevant findings, and cannot ask to be informed about findings which are not relevant for the current health of the child.[30,35,37,38] We agree with the latter approach because it best supports the interests of the child.

Finally, several experts discussed the possibility for consultation of an ethics committee when uncertain about the disclosure of individual findings. The Additional protocol on Biomedical Research and the Council of Europe's Recommendation (2006)4 include a possible role for an ethics committee; however, they do not specify how such a committee should be involved in the case of individual research findings.

CONCLUDING REMARKS

We conclude there is no clear consensus about the practical application of the basic principles concerning informed consent and reporting individual research findings in paediatric biobanking. There is agreement on a general normative level, that is, parental consent is a basic requirement for their child's participation and that biobank managers have the responsibility to duly inform parents and the older child about storage, use and disclosure policies. Re-contacting the mature child to ask for consent as well as the parental right to know or not to know are still debatable topics. In our view, the adult child must be re-contacted for consent and parents should not be able to refuse information about clinically relevant findings, or receive information that is not relevant for the current health of the child.

Discussions about appropriate and well-balanced privacy rules for paediatric biobanking should continue. We hope this will result in a clear set of responsibilities and rights to which biobanks, researchers, parents and children all agree. International organisations, such as the OECD or the Council of Europe, and regulators on a national level, are in the best position to take the lead.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

This study was funded by the Netherlands Organisation for Health Research and Development (ZonMw). We thank the interviewees for offering us their insights and experiences.

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