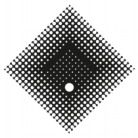

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ARTICLE

Clarifying ethical responsibilities in pediatric biobanking

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ABSTRACT

Background: The creation of biobanks for storage of human specimens and use in health and medical research is expanding globally. Biobanks hold significant potential to facilitate such research. However, important ethical questions arise, particularly in the pediatric setting, in relation to consent, future use, and the balance of benefits against potential harms. To date, these ethical issues have been undertheorized and underresearched in the biobanks domain. The aim of this study was to examine stakeholder attitudes regarding the ethical responsibilities of researchers, biobank custodians, Human Research Ethics Committees (HRECs), research institutions, and parents. **Methods:** A qualitative study using semistructured interviews with a purposive sample of key informants ($n = 14$) with relevant expertise was conducted. Participants were interviewed about their pediatric biobank experiences, the main ethical issues observed as an HREC member, researcher, or custodian, and future needs. **Results:** Participants expressed concerns about consent processes in the biobanking context, including issues regarding the provision of information, level of understanding, voluntariness, and the point at which children have a role or can consent for themselves. Other major issues raised were biobank quality management, the return of results, and the idea of human tissue as a scarce precious resource. Key informants also highlighted uncertainties about the custodianship of biobank samples and reasonable limits on the custodian's role. **Conclusions:** Pediatric biobanks are a valuable resource, presenting unique opportunities to advance children's health and well-being. Properly run pediatric biobanks entail responsibilities for institutes, custodians, researchers, and research ethics committees. We discuss ethical implications for pediatric biobank policy and practices, as well as future information needs in light of the study findings.

KEYWORDS
ethics; biobank; pediatric biobank; informed consent; parental consent

What is a biobank?

Biobanks have some defining features, but there is no consensus on what is a "biobank" (Gibbons et al. 2007; National Health and Medical Research Council [NHMRC] 2010). Our working definition of a biobank includes large-scale or smaller scale population collections of samples, and disease-specific collections. Samples within these collections are generally linked to other personal and health information, but some are not. Our definition includes research collections and nonresearch collections. Nonresearch collections include those established for diagnostic, therapeutic, treatment, quality assurance, or public health purposes or as teaching materials. Samples include blood, saliva, cheek scrapes, cord blood, feces, biopsy material, placenta, urine, bronchial lavage, images, and pediatric tumor cells.

Project rationale

Collecting and storing tissue and information from children provides a resource and unique opportunities to learn more about children's health and well-being. Benefits may be for children in general or children with a specific disease. The success of biobanks depends on the support of the community and their willingness to contribute to biobanks (Gurwitz et al. 2009; NHMRC 2010). It is crucial, therefore, that we identify ethical issues and clarify ethical responsibilities around children and biobanks. Public trust is essential for the collection of tissue and data from children to proceed. It is recognized that scandals such as the unauthorized retention of children's organs by researchers in the United Kingdom have undermined public trust (Williams and Schroeder 2004; Williamson and Smith 2004), and adversely affected the donation of tissue for legitimate research—even research not directly linked to the scandal (Seal et al. 2005).

Consent is the most frequently discussed ethical issue in relation to biobanks generally (Budimir et al. 2011). While there is debate about whether consent is needed at all in biobank research when consideration is given to the "public interest" or the "common good" (Forsberg, Hansson, and Eriksson 2011), there are also persuasive critiques of the uncritical thinking that sometimes underlies the idea of the "common good." For instance, critics challenge "unquestioned assumptions" such as the idea that seeking consent comes at the cost of the public interest and that dispensing with or relaxing consent requirements serves the "common good" (Arnason 2011, 563; Rommetveit 2011, 585).

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Most of the discussion around consent and biobanks focuses on the consent form and the type of consent that is required (Budimir et al. 2011). Types of consent include consent limited to a specific project; consent for future research related to or in the same general area for which the original consent was given; and consent that is for any future research purpose (NHMRC 2007; Organization for Economic Cooperation and Development [OECD] 2006; 2009).

Consent is also identified as "the most widely discussed issue" in a review of the ethics literature and guidelines about children and biobanks (Hens, Levesque, and Dierickx 2011, 406). However, where children are involved, the issues are more complex. Children need someone else to consent on their behalf (parent or guardian), making the "value" of the consent "fundamentally different" (Hens, Levesque, and Dierickx 2011, 404). According to Hens, Levesque, and Dierickx, the literature and the guidelines are "fairly unanimous" about who should consent. The "need for and the validity of parental consent" is not questioned in the literature, nor "the right of a child to give his or her own opinion on the matter" (Hens, Levesque, and Dierickx 2011, 407). But there is no consensus on whether parents have the right to consent to future unspecified research on the stored tissue samples of their children, and there is "uncertainty" about the age at which children can be involved in decisions about participation (Hens, Levesque, and Dierickx 2011, 407). There is "some agreement" that "children should be able to renew their consent when they reach the age of competence" (Hens, Levesque, and Dierickx 2011, 407).

In the literature about pediatric biobanks, one prominent argument is that researchers can collect DNA samples and data from children but that they should wait until children are old enough to give their own consent before researchers can share the children's samples with other researchers. The underlying idea here is that while children are vulnerable in the sense that they need others to decide on their behalf, their "vulnerability is temporary" (Gurwitz et al. 2009, 818). Others strongly oppose the view that sharing children's samples should wait until they can consent for themselves—they claim that the wait is "too long" (Brothers and Clayton 2009, 798).

The question of whether to return individual results from biobank-based research is an issue that figures prominently in the literature. Returning results can be a benefit but it can also be a harm (Wolf et al. 2012), and it raises different issues where children are involved. We can ask adults whether they want to receive information that may emerge about their health, and they can elect to be informed or they can choose not to know. Where children are concerned, it is not clear that parents should be provided all information about their child that becomes available (e.g., the child's genetic makeup) or that parents should have the right to say they do not want to receive results that could contain information that is of benefit to their child (Hens, Levesque, and Dierickx 2011).

A considerable part of the literature on biobanks is made up of stakeholder opinions, mostly participant attitudes (Budimir et al. 2011). While participant attitudes have an important role, others suggest that "opinion sampling" is not an adequate substitute for informed discussion and debate (Williams and Schroeder 2004, 271). To illustrate, studies show that parents agree to have their children's samples stored in pediatric biobanks even though they do not "fully" understand risks, confidentiality, the aims of the research, and the experimental nature of the research (Budimir al. 2011, 272; Klima et al. 2014). What is more, there is a lack of research demonstrating effective processes for gaining valid consent in pediatric biobanks (Klima et al. 2014).

In their content analysis of the literature on biobanks, Budimir et al. (2011) identify issues of importance that have received little attention. These include commercialization, the "role of ethics boards" as opposed to the "opinions" of ethics boards, and international collaboration or "data exchange" (267, 271).

Others argue that in addition to the central ethical issue of consent, there are other important issues regarding the ethical acceptability of biobanking. For instance, it has been argued that custodians of large-scale biobanks should actively take on the following responsibilities (Williams and Schroeder 2004):

- Encourage public debate about the use of tissue and data.
- Sponsor research that "reflects publicly agreed priorities and provides public benefit" (89).
- Guard against problematic uses of tissue and data.
- Provide "regular public reporting" on "actual benefits obtained"—not only "the speculated benefits" (99).

While some of the matters mentioned here are not specific to children, they are equally relevant. We argue they are more pressing and there is more at stake when biobanks include children—children who need other people to consent on their behalf. As well as the potential gains for children's health, children may suffer the effects for longer if anything goes wrong. The ethical responsibilities that are generated for researchers, biobank custodians, Human Research Ethics Committees (HRECs), research institutions, and parents are areas that are underresearched in the area of pediatric biobanking.

Capron et al. (2009) note the "lack of empirical data" on "specific ethical concerns" in the area of genetic databases and biobanks and have sought the views of international experts (101). Nevertheless, their research does not address or refer to the collection of tissue and data from children or pediatric biobanks. We believe that issues affecting children and ethical responsibilities in the context of pediatric research biobanks warrant special consideration.

The central aims of this study were to identify the main ethical issues and clarify the ethical responsibilities of researchers, biobank custodians, HRECs, research institutions, and parents that are generated by the collection, storage, and use of children's biological samples and data. This is the first such study to examine these issues in the Australian context.

Methods

Sample

As the goal of this study was to identify ethical issues and clarify responsibilities in pediatric biobanking, we sought the views of experts in the field. We employed a purposive sampling approach to identify and recruit a diverse range of expert informants (Sarantakos 1998). We compiled an initial list of twelve potential expert informants through multiple sources, including keyword searches of websites and word-of-mouth referrals.

Our aim was to recruit people with current and direct experience in pediatric biobanking, such as biobank custodians;

researchers who collect, store, or use children's biological samples and data; people who review a significant number of biobank research studies involving children's samples and data; and others with relevant expertise, such as members of biobank advisory boards and informants with education and ethics expertise in pediatric biobanking and research.

Recruitment and interview

Initial contact with identified experts was made via an e-mail letter providing an overview of the study aims and methods, and an invitation to participate in a semistructured interview. Of 12 potential participants whom we emailed directly, nine agreed to take part in the study. We also sent an e-mail invitation to participate in the study via secretariats of selected HRECs and an electronic bulletin at a Children's Research Institute, which resulted in a further five people recruited to the study.

Semistructured interviews were conducted with 14 participants (six female, eight male) selected for their current expertise relevant to pediatric biobanking. Participants had multiple roles and positions (current and past) and training in fields that gave additional weight and relevance to their contributions. Participants were made up of researchers and custodians (some with their own lab or who were in charge of lab services); those who review biobank research involving children's data and samples; those developing guidelines and policy for pediatric biobanks; those involved with research governance; and a member of an international biobank scientific advisory board. Six of the 14 participants have been involved in setting up biobanks and/or biobanking processes. Eight participants have significant current or past roles with research ethics committees and at least half of these are also researchers or custodians. At least four participants have formal ethics qualifications or training.

Participants have experience with the following biobanks and biobank research: disease-specific biobanks; tumor biobanks; large population biobanks; nonresearch collections (e.g., for diagnostic purposes); population research; longitudinal cohort studies (birth, child, and adolescent); international consortia of child and birth cohort studies; twin studies; studies involving data linkage; genetic research; and establishing cell lines.

The method of data collection was semistructured interviews. We asked participants about their involvement with pediatric biobanks, what they see as the main ethical issues, and things they have found to be problematic in their role on a HREC or as a researcher or custodian. Participants were also asked about their attitudes on future needs and issues they would like to see investigated further.[1] Author MS conducted individual semistructured interviews in person or by telephone and took detailed notes during the interviews. Permission was sought to recontact informants for clarification if necessary.

Data analysis

Interviews ranged from between 25 to 65 minutes with an average of 40 minutes. Data were analyzed at two levels: (i) inductive (or interpretative) content analysis to clarify content categories (organizing relevant data around interview questions where appropriate), and (ii) thematic analysis to identify main issues and themes (Manning and Cullum-Swan 1994; Strauss and Corbin 1990). During the analysis phase, the study team held a number of meetings to discuss and agree on the method of analyses. Rigor of analysis is evidenced by our inclusion of examples from the data demonstrating the context of themes or content categories identified (Hansen 2006).

The findings are in accordance with COREQ criteria for qualitative research (Tong, Sainsbury, and Craig 2007). Findings are arranged according to the four main ethical issues identified by the expert informants. See Figure 1 for a summary of the main findings.

Ethical approval

Study ethics approval was obtained from the Royal Children's Hospital, Human Research Ethics Committee.

Results

Consent

The most commonly discussed ethical issue was consent. Key elements of informed consent were the basis of many concerns—crucial matters such as the provision of information, level of understanding, voluntariness, and the point at which children have a role or can consent for themselves.

Validity of consent was a major concern for some informants, and this concern had a number of sources:

- What information and how much information should be disclosed so that consent is informed? (Experts 1, 9)
- Information may be unavailable, unknowable, or uncertain because "you don't know the specifics of the research" at the time tissue is collected. (Expert 5)
- People may not be getting relevant information. According to one informant, information on how insurance could be impacted may be available, but researchers are not explaining it. (Experts 13, 14)
- The person providing information for consent may have conflicting interests. For instance, researchers often say "it's completely anonymized, but it's re-identifiable. … In order to encourage participation, they don't accurately inform." (Expert 13)
- There may be difficulties in understanding information. Potential participants may not really understand where the data are going and what they are consenting to. (Expert 4,7)

The function and the value of consent in pediatric biobanking came under scrutiny (with a focus on the role of the child and the parent):

> Is it OK for parents to consent? (Expert 8)
>
> At what point should the child have a role and at which age? (Expert 4)
>
> At some age … you need to get independent consent from the child. (Expert 8)

Some informants worried about the voluntariness of children's participation due to possible pressure from parents—even though the children may agree to participate (Experts 14, 7).

[1] A copy of the interview questions is available from the authors upon request.

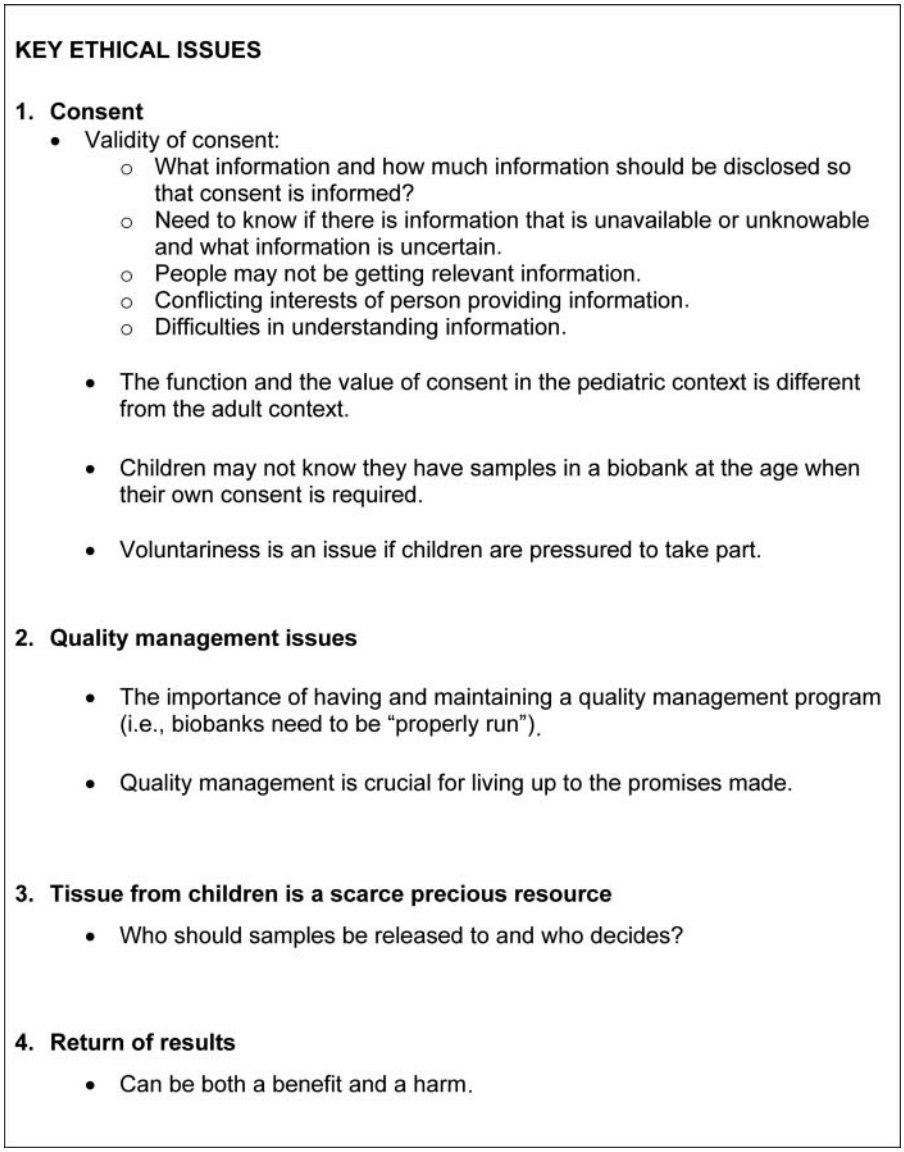

Figure 1. Summary of main findings.

There was also concern that when children reach an age where they can consent for themselves and parental consent no longer applies, they may not know that their samples have been stored: "Most children at 18 wouldn't know about samples" and there is "no onus to inform people" (Expert 2).

Waivers of consent were an area of difficulty for researchers and HRECs because of the requirement that a review body must be satisfied that "it is impracticable to obtain consent" (NHMRC 2007, 21). This requirement was thought to be getting "more stringent" and "more and more" researchers are being told they have to try to get consent (Expert 2). Another view was that "sometimes" it is just that researchers "can't be bothered," not that consent is "impracticable" (Expert 14).

Consent figured significantly in the things that informants nominated for further investigation. They wanted to know the type of consent that is appropriate in pediatric biobanking (e.g., specific, extended or unspecified); whether research can continue without young people's reconsent; and where consent or reconsent is required, what information and options should be provided (Experts 3, 4, 5, 6, 9, 13, 14). A member of an ethics committee spoke about the need for clear and accurate information on biobanking and behavioral genetics research: "Researchers can be a bit cavalier at times … tend to get irritated when asked about the division between genetic testing and genetic studies" (Expert 13).

Quality management

Quality management emerged as a major theme in this research. It was referred to in some form or other by almost all of the expert informants (Experts 2, 3, 4, 5, 6, 7, 8, 10, 11, 13). The quality management issues they talked about included ideas such as having and maintaining proper processes, living up to promises, and being trustworthy—"Sticking to what you've told the patient you will do" (Expert 3), and what at least one informant referred to as "properly run" biobanks (Expert 8).

According to this informant:

> It's not so much about informed consent, but biobanks living up to the promises they make in relation to protecting privacy and

> advancing health. And, if they can't do something, don't suggest they can—don't promise. (Expert 8)

This informant went so far as to say that the "main issue" is "properly run biobanks and reporting back findings without causing harm … it's not a consent thing. Can't just rely on consent" (Expert 8).

Another suggested that "individuals' welfare could be affected" if, for instance, confidentiality is not protected, or there is access to materials by those who should not have it, loss of biospecimens or identifying information, inaccurate results, and giving wrong information (Expert 11).

> Sustainability is a related concern:
> What happens in 20 years? (Expert13)
> What if the research institute ceases to exist or is taken over by someone else? (Expert 8)
> Does the researcher's responsibility end when the money runs out? (Expert 4)

These are important questions, and expert informants are raising them because they do not have answers. These questions are clearly not receiving the attention they deserve.

Tissue as a scarce precious resource

Tissue as a scarce precious resource was a significant issue for some informants: "Such a precious resource is often irreplaceable" (Expert 10). There was concern about whom the samples should be given to: "Brain tumors, if 100 samples, there is only so much you can do with it. Which research should get the sample?" (Expert 1). In addition to which research gets the sample, there is also the matter of who should get access to samples for collection and storage. One informant described "competition from multiple groups wanting to access the samples from the same population sample" as a significant challenge: "six groups wanting to access blood from healthy children having minor surgery. To date it has been cordial—one will have it one day and another the next" (Expert 5).

In terms of this scarce precious resource, there was a lack of clarity amongst the expert informants about the role and responsibilities of research ethics committees and custodians: "Because it is an important resource, you have to be careful about who they are released to … the project has to be valid, worthwhile to get maximum benefit from the resource" (Expert 10).

Return of results

The question of whether to return individual results was another significant issue (Experts 4, 8,12, 13). One informant asked, "What if we identify information that is important for their health … if you find information inadvertently?" (Expert 12). Another postulated that "feedback of results to individuals is a possible harm. First stipulation is that there are really clear plans about whether information will be fed back and if it will be, how it will be done" (Expert 8).

Discussion

This is the first study to examine stakeholder attitudes about the key ethical issues that arise in the Australian pediatric biobanking context in relation to consent, future use, and the balance of benefits against potential harms. The expert key informant participants of this study expressed concerns about current consent processes in the biobanking context, including issues such as the provision of information, level of understanding, voluntariness, and the point at which children have a role or can consent for themselves. Other major issues raised were related to biobank quality management, the return of results, and the idea of human tissue as a scarce precious resource. Key informants also highlighted uncertainties about the custodianship of biobank samples and the role of the custodian.

In what follows, we discuss how the major issues identified reflect what is at stake where children are concerned and how that translates into responsibilities for pediatric biobanks. To demonstrate what is important about these ethical issues and the ethical responsibilities they generate, we again draw attention to what is different or special about pediatric biobanks—namely, the collection, storage, and research use of biological samples and data from children.

The findings in this study reflect what it is that makes consent problematic when children are involved. Because of their vulnerability (limited cognitive capacity), children need others (proxy decision makers, generally parents) to look out for their interests and to make decisions on their behalf—but that is not a situation that lasts forever.

Added to that, consent by proxy is a challenging concept in the research context. It raises the question of whether one person can volunteer another person. Furthermore, in the context of pediatric biobanks, the proxy decision maker may be making an irreversible decision, forsaking the child's ability to withdraw from the research. Withdrawal from research is effectively not possible once samples and data are shared with other researchers (e.g., via a research collaboration).

While it is accepted that parents make irreversible decisions for their children that are not in their strict best interests, according to some, this is a decision that "could just as well" be a reversible decision "at the point when the child reaches decisional competence" (Gurwitz et al. 2009; Holm 2005, 21). Some go as far as suggesting that "there can be no reason, apart from the convenience of the researchers, to renounce withdrawability at the proxy consent stage" (Holm 2005, 21−22). Considerable importance is placed on children's ability to renew their consent when they reach the age of competence and their ability to withdraw from research (Hens, Levesque, and Dierickx 2011; Holm 2005). What this all boils down to in the pediatric context is that parents need to understand exactly what they are consenting to on behalf of their child. This also generates a range of ethical responsibilities. See Figure 2 for a summary of ethical responsibilities.

It can be taken as a given that it is the parents' role and responsibility to understand what is involved in pediatric biobanking before they give their consent. That includes details about the potential benefits, risks, and the implications of participation. While full information is not a realistic goal, parents do need information that makes a difference to whether they want to enroll their child or not. That includes knowing whether there is information that is not known, uncertain, or unavailable. They also need information about contentious issues and debates relating to specific types of research they are

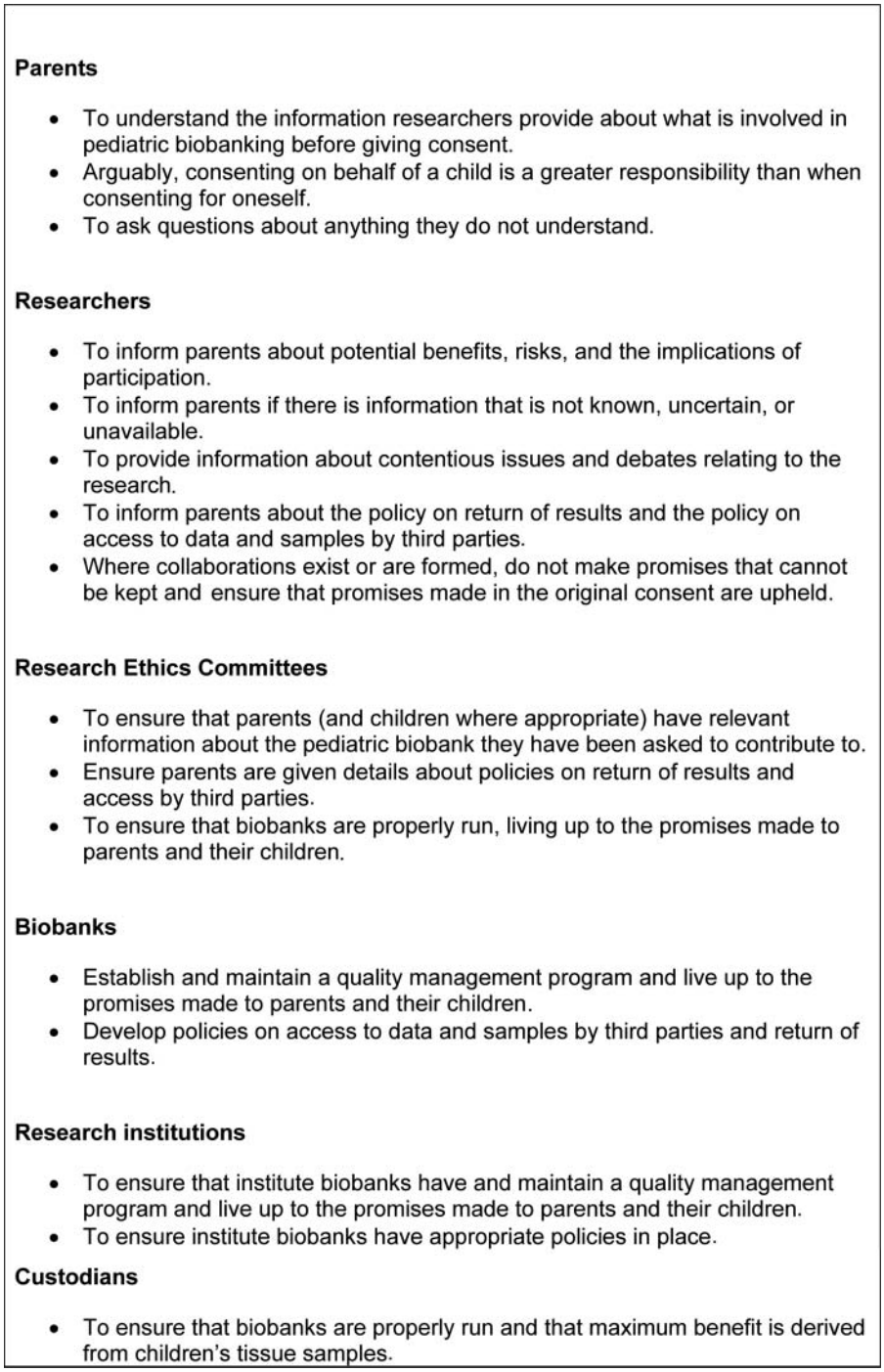

Figure 2. Ethical responsibilities in pediatric biobanking research.

being asked to enroll their child into. They also need to know how promises made by the biobank and researchers will be upheld, particularly in the setting of international collaborations between biobanks and researchers (Birmingham and Doyle 2009).

A current issue relevant to consent is the data protection reform that is underway in the European Union and the accompanying concern about what it may mean for biobank research. According to some, "broad consent" may no longer be a "lawful option," and a requirement for specific consent will make research unworkable (Kay et al. 2015; Wellcome Trust 2014). While there are international initiatives to find a set of principles to improve governance and interoperability around the sharing of data and biospecimens (Mascalzoni et al. 2014), there are others who complain that "huge lobby groups are trying to massively influence the regulatory bodies" and weaken data protection (Signatories 2013, 180).

A 2015 fact sheet issued by the European Commission addressing the question of how the reforms will affect scientific research states that scientific research "stands to benefit from the proposed data protection reform" (European Commission 2015, 5). Clearly, conflicting views currently exist. This highlights the need for further research and analysis of how data protection reform may affect biobank research, in particular

pediatric biobanking research with its complex consent issues—but that is beyond the scope of our study.

The responsibility to inform parents about the things that matter to them (things that affect their willingness to take part and enroll their child) belongs to researchers, and it is for research ethics committees to ensure that researchers meet that responsibility. Arguably, parents' responsibility is greater when consenting for a child than when consenting for themselves. Studies show that many adult tissue donors give unspecified consent for future research, and they are unconcerned about detailed information (Lipworth et al. 2009). While that may be acceptable for competent adults consenting for themselves, it is not when they are consenting on behalf of a child.

When children need someone else to make decisions on their behalf, they need someone who takes note of the details. Details in addition to those already listed here include privacy protections—whether information can be accessed by other researchers (including researchers outside Australia), third parties such as police or government departments, or even parents (or children themselves when they are older) through freedom of information laws. Parents also have the responsibility of asking questions about things they do not understand.

Although consent was the topic that received the greatest amount of attention from expert informants in this study, not all informants were saying that consent was the most important thing. Nearly all talked about quality management issues or what was sometimes referred to as "properly run biobanks." Quality management is not typically considered an ethical issue, but in this context it is ethically very important. Parents need to know what they are consenting to, and that crucially depends on properly run biobanks.

Biobanks also need to be "properly run" in order to live up to the promises on which consent is given. This is clearly articulated by one informant who claimed that "if the tissue is not usable down the track, you have breached the ethical agreement you had with the people you got consent from" (Expert 5).

Quality management also matters in terms of the risk/benefit calculation. If benefits are unrealizable or undermined because of poor procedures, risk of any level cannot be justified—the risk is for nothing. The opportunity to advance children's health is lost, and it will damage the public trust that is essential for pediatric biobanks to function. Quality management issues, therefore, take on a special importance in pediatric biobanking research.

There is a growing international push to accept the sharing of samples and data with other researchers as a necessary way to optimize use and value (Mascalzoni et al. 2014). We hold that sharing of samples and data is different for pediatric biobanks because of the issue of withdrawability. Voluntary participation is a fundamental aspect of ethical research, and that includes the ability to withdraw from research. Proper procedures are needed for that to be possible, for example, procedures and processes to identify and withdraw samples and information. As noted earlier, some people argue that sharing of samples with other researchers may need to wait (Gurwitz et al. 2009). This is an area of intense debate that only occurs in pediatric biobanking (Brothers and Clayton 2009; Gurwitz et al. 2009; Holm 2005). While this is partly a consent issue, it is also a quality issue.

Tissue as a scarce precious resource is also different in pediatric biobanking in the sense that it involves "additional and unique barriers" such as fewer investigators, fewer subjects, a preponderance of rare illnesses, difficulties in sample collection methods, and small tissue sample volumes (Brisson et al. 2012, 154)—and there is more at stake: more to gain and more to lose.

Pediatric tissues can be analyzed to tell us more about the earlier prevention and treatment of high cost, high prevalence, high burden conditions, or diseases where earlier intervention is possible because we are dealing with children. Because of the potential for early intervention and avoiding conditions/diseases developing into chronic problems with high population prevalence, it is more important to get the decisions right around collection and use of the scarce resource of children's tissues. Biobank advocates certainly argue this (Brisson et al. 2012).

The idea of tissue as a "scarce precious resource" raises questions about the release of samples and questions about who should be deciding. For instance, is a well-designed study that has ethics approval an adequate reason to give out a scarce precious resource like children's brain tumor samples? Can the person who collected the samples say "no"? Can the person who is in charge of the samples say "no"? Could the HREC choose not to approve the study even though it is well designed?

It is noteworthy that responses of experts in pediatric biobanking reveal a lack of agreement or at least uncertainty about who is the custodian of biobank samples and about the role of the custodian. Some think the custodian is the researcher, some suggest it is the person in charge of the samples, and some suggest that it is a role for the research ethics committee. It is possible that the causes of this uncertainty may be discipline dependent. The scientific community tends to see the hands-on manager as the custodian, while lawyers would regard the custodian as the one with legal responsibility and control, usually the institution that "owns" the biosamples.

Nevertheless, this is an area that needs clarification (and harmonization for collaborative research) in biobank policy. Key questions are: (i) Who should be the custodian? (ii) What is the role of the custodian? (iii) What is the extent and what are the limits of the custodian's role?

Regardless of who the custodian is, there is a need for biobanks, research institutes, and HRECs to have policies and procedures about who can get access to samples and who should be making the decisions on these matters. There is also a need for policies and procedures to determine when, if ever, third parties can access biobank data and samples, and when, if ever, and on what criteria, a child's results can be given to parents. As mentioned earlier, return of results has the potential to cause harm and the issues are different where children are involved.

There remains one unallocated responsibility, that is, the responsibility to inform children (who may not know that they have samples stored in a biobank) when they are old enough to give their own consent for research to continue. Most likely, this is an oversight that will become outdated as new biobanks and studies get set up.

Conclusion

Pediatric biobanks are a valuable resource, presenting unique opportunities to advance children's health and well-being.

Consent of the parent and, where appropriate, consent of the child, are very important, but they are not the only important things. A key finding of this project is that quality management has major ethical implications that affect consent, risk, and public trust.

Pediatric biobanks (like any biobank) need to be properly run to achieve anticipated benefits. That means they need a clear quality management program, and they need to live up to the promises made to parents and children who provide their samples and information. If they are not properly run, there is a potential for harm and a lost opportunity to advance children's health. Properly run pediatric biobanks entail responsibilities for institutes, custodians, researchers, and research ethics committees, as we have outlined here.

Areas for future research include identifying levels of risk in collecting, using, storing and sharing samples in different types of pediatric biobanks according to the type of research being undertaken, and determining the implications for return of individual results in the pediatric context.

Author contributions

Both authors made substantial contributions to the conception and design of the study and analysis of data. M. Spriggs undertook the data collection and drafted the article with input from C. Fry. Both revised and finalized the article.

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Conflicts of interest

The authors have no relevant financial or other material, professional, or scholarly relationships to disclose that would constitute real or perceived conflicts of interest.

Ethical approval

This study was approved by the institutional review board at Royal Children's Hospital, Melbourne, Australia.

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