Journal of Adolescent Health 58 (2016) 474–480

ELSEVIER

JOURNAL OF ADOLESCENT HEALTH

www.jahonline.org

Original article

Opinions of Adolescents and Parents About Pediatric Biobanking

Cynthia C. Kong, M.D. [a], Tamsin E. Tarling, M.Sc. [b], Caron Strahlendorf, M.B., B.Ch. [a,b,c,d], Michelle Dittrick [e], and Suzanne M. Vercauteren, M.D., Ph.D. [a,d,e,f,g,*]

[a] *Faculty of Medicine, University of British Columbia, Vancouver, British Columbia, Canada*
[b] *Department of Pediatrics, University of British Columbia, Vancouver, British Columbia, Canada*
[c] *Division of Hematology/Oncology/Blood and Marrow Transplant, British Columbia Children's Hospital, Vancouver, British Columbia, Canada*
[d] *Child and Family Research Institute, Vancouver, British Columbia, Canada*
[e] *Department of Pathology and Laboratory Medicine, Children's and Women's Health Centre of British Columbia, Vancouver, British Columbia, Canada*
[f] *Department of Pathology and Laboratory Medicine, University of British Columbia, Vancouver, British Columbia, Canada*
[g] *Division of Hematopathology, Department of Pathology and Laboratory Medicine, British Columbia Children's Hospital, Vancouver, British Columbia, Canada*

Article history: Received August 19, 2015; Accepted December 8, 2015
Keywords: Biobank; Pediatric; Adolescent; Parent; Consent; Assent; Reconsent; Biospecimen; Opinion; Clinic

A B S T R A C T

Purpose: A biobank is defined as "a facility for the collection, preservation, storage and supply of biological samples and associated data, which follows standardized operating procedures and provides material for scientific and clinical use." The practice of biobanking must consider the best interests of participants, which is especially complicated in the pediatric setting, where parents or guardians are responsible for consent of their children. Age of participant assent, consent, and reconsent at the age of majority are some of the issues which need to be addressed.
Methods: We conducted an exploratory survey of four cohorts: (1) adolescents aged 14–18 years treated at British Columbia Children's Hospital, Vancouver, British Columbia, Canada, in the Division of Oncology, Cardiology, or Orthopedics. (2) Parents of the adolescents described in (1). (3) Adolescents aged 14–18 years from high schools in Vancouver, British Columbia, Canada. (4) Parents of the adolescents described in (3).
Results: We show that clinic participants rated a higher willingness to donate specimens versus school participants. Furthermore, clinic participants felt assent was more important and parental consent alone was insufficient. The median suggested age for assent was 14.5 years among adolescent responses and 16 years from parental responses of both groups. School parents were the most conservative in their responses toward their child's participation in a biobank.
Conclusions: Adolescents, who were seen in clinics and their parents, had a more altruistic approach toward pediatric biobanking than those surveyed in the school setting. Additionally, parents are less comfortable making decisions regarding biobanking than their adolescent children.

IMPLICATIONS AND CONTRIBUTION

This survey assesses the opinion of adolescents and their parents from different settings in regard to biobanking. Although this research is exploratory, it provides a basis for further investigations and initial evidence for future policy making.

Conflicts of Interest: S.M.V. is the Director of the British Columbia Children's Hospital BioBank and T.E.T. is the Administrative Manager of the British Columbia Children's Hospital BioBank. C.C.K. is a medical student from the Faculty of Medicine, who performed this research study during a summer project.
Disclaimer: The study sponsor was not involved in the design of this research study, the collection, analysis, or interpretation of data or the writing of this report. Finally the decision to submit the manuscript for publication was determined by the authors and was independent of the sponsors.
Terminology: For the purposes of this article, we have chosen to use the term biospecimen or specimen when referring to the biological specimens that are obtained for biobanking. However, in our consent forms and in the survey we conducted, we use the term "sample" as we feel that this is easier for a lay person to understand. Therefore, the terms biospecimen, specimen, and sample may be used interchangeably in this document.

* Address correspondence to: Suzanne M. Vercauteren, M.D., Ph.D., Department of Hematopathology, British Columbia Children's Hospital, 4480 Oak Street, Room 2K51, Vancouver, British Columbia, V6H 3N1 Canada.
E-mail address: svercauteren2@cw.bc.ca (S.M. Vercauteren).

1054-139X/
http://dx.doi.org/10.1016/j.jadohealth.2015.12.015

A biobank is defined as "a facility for the collection, preservation, storage and supply of biological samples and associated data, which follows standardized operating procedures and provides material for scientific and clinical use." [1] The number of biobanks has significantly grown over the last decade, and best practices for the operation of biobanks have been developed by a number of organizations such as the International Society for Biological and Environmental Repositories [2]. These guidelines provide best practices for participant recruitment, biospecimen collection, and clinical data collection and are guided by the Declaration of Helsinki [3] and the Belmont Report [4]. Participant recruitment and the subsequent collection of biospecimens and clinical data should be conducted in a way that respects the individual and maintains privacy and confidentiality [5].

The requirements for pediatric participant recruitment are not clearly defined, and there are significant gaps in the literature in regard to the unique issues associated with the collection of biospecimens from children and adolescents [6]. The specific issues that are pertinent are (1) the consent process; (2) the age at which children should be involved in assent; (3) whether parental consent is sufficient for the longevity of the biobank; and if not (4) whether biobank participants should be recontacted at the age of majority for reconsent [7]. Additional issues that require further resolution are the return of secondary findings; this topic will not be discussed in the article.

In Canada, Research Ethics Boards are governed by the Tri Council Policy Statement [8] which recommends that the participation of children in research studies is allowable when direct benefit to the child can be demonstrated. In the context of biobanking, there is usually no direct benefit to the participant, but because the results of research, having used biobank specimens may benefit other children with the same condition, pediatric biobanks are considered permissible [9].

For children to be involved in research, the parents or legal guardians consent on behalf of their child. Biobanks often use a broad consent, which allows specimens to be stored for long periods and used in undetermined studies [10]. Ethically, the family values and wishes should be respected, but as the child develops with age, it is not always feasible to accurately reflect current values at the time of specimen use. Children are expected to be involved in the discussion about research participation to the level that they can understand [11]. The age at which the child is involved and their agreement documented varies widely. If a child dissents, then this must be documented and respected. Appropriate age and methodology for obtaining pediatric assent for biobank participation remains a continuous topic of discussion. Although wishing to include children in the decision-making process, the age at which different individuals are able to understand all aspects of the assent varies significantly. Kaufman et al. [12] reported that most studies using age as a metric of the ability of children to assent have suggested ages between 7 and 14 years. Staff carrying out biobank consent must be perceptive about the child or adolescent's cognitive ability such that consent and assent are explained fully but at the comprehension of the potential participant [6].

In addition to the issue of appropriate age for assent is the lack of legality surrounding assent and the rarity of young children signing other documents in everyday life [13]. The assent process requires children or adolescents to sign a document which approves their participation in research. Assent is not considered to be a legally binding agreement; however, it is plausible that the child or adolescent may feel that their assent is legally binding because of the act of "signing." Subsequently, the individual providing assent may feel that they are unable to break that contract because of the perceived legal nature.

The Tri Council Policy Statement indicates that "children may lack the capacity to decide whether to participate in particular research initiatives." When children are recruited for research studies, the design of the study should account for the possibility to obtain consent from the child at a time when they do have the capacity to consent for themselves. Biobanks are often obligated to recontact participants when they reach the age of majority and obtain reconsent at this time for the continued use of the stored specimens in research. Keeping participants informed and providing them with the opportunity to reassess biobank participation are both important; however, reconsent may not be feasible for all biobanks from an operational and financial perspective [14]. Previous studies which aimed to recontact research participants (adult) found that recontacting participants was time consuming and expensive [15,16]. From a participants perspective, opinions about reconsent vary; Rush et al. [17] report that 60% of young adults thought that they should be asked whether they wished to continue to store their biospecimens for unspecified research and 40% thought it was unnecessary to ask.

In summary, there is a lack of clarity around the issues of consent, assent, and reconsent for pediatric biobank participation. We, therefore, developed a survey to explore the opinion of adolescents (aged 14–18 years), both healthy and in the hospital clinic setting, and their parents regarding biobank participation and related subjects. In particular, we addressed willingness to donate biospecimens, appropriate age of assent and the perceived importance of reconsent when they reach the age of majority.

Methods

Participant recruitment

Adolescents aged 14–18 years, inclusive, and their parents were invited to participate in this survey. Participants were recruited from outpatient Hematology/Oncology/Blood and Marrow Transplant ('Oncology'), Cardiology, and Orthopedics clinics at British Columbia (BC) Children's Hospital, and from three Vancouver high schools. The three clinics were chosen to compare patients with potentially life-threatening conditions (Oncology), versus chronic diseases (Cardiology), and short-term medical conditions (Orthopedics), although some heterogeneity and severity of diseases among the clinics was noted. Three schools within different socioeconomic areas of Vancouver were chosen to represent diversity of participants.

Hospital participants and their parents were approached in clinic waiting rooms and provided with a letter describing the study. Consent for participation was considered implicit with survey completion. Completed surveys were deposited into an anonymous drop box at each clinic.

School students were given a take-home package containing an informational letter, parental permission form, a parental survey, and an adolescent survey. Parental surveys were completed at home, whereas students completed their surveys at home or at school. In accordance with Vancouver School Board requirements, only students with signed permission forms were