Consent to tissue banking for research: qualitative study and recommendations

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ABSTRACT
Objective To explore how families of children with cancer experience giving consent for tissue banking and to produce recommendations on good practice.

Design 79 participants from 42 families (41 mothers, 18 fathers, 20 children and young people with cancer) took part in semistructured interviews to explore their experiences of being approached for consent to tissue banking.

Setting Tertiary care facilities for childhood cancer.

Results Families are generally supportive of tissue banking, although they report that it may be difficult for them to consider all the implications when asked for consent. They typically do not want detailed information when consent is sought close to diagnosis, preferring to see tissue banking as part of routine practice. Families often recognise that their consent may not be fully informed, but are content to give consent based on their understanding at the time. Some may want a chance to go over the information and revisit their decision when things have settled.

Conclusions Families’ views can inform practical recommendations for optimising the experience of consent for tissue banking. Current guidelines for obtaining consent should be revisited to take account of families’ preferences.

INTRODUCTION
In the past, children were often routinely excluded from much clinical research outside of highly specialised areas. Recent years have seen a greatly increased interest in children’s involvement in research, following policy changes in the USA, the European Union, the UK and elsewhere.1 Much of the evidence about recruitment to research, however, is based on adults. Though there are some interesting findings from that literature which are likely to be relevant in a paediatric context, there is currently not enough good quality evidence to inform recruitment practices for children and families. Tissue banking is an area of research which has often attracted considerable controversy, and where guidance on best practice would be very helpful for informing both policies and practitioner behaviour.

Tissue banking – involving collection and storage of human biological materials for research purposes – has grown in importance and scale worldwide. Study of human tissues enables improved understanding of the biology of serious diseases, including cancer, and is crucial in supporting the appropriate development and use of the new generation of molecularly targeted agents.2 Tissue banks typically store surplus material left over from clinical procedures such as biopsies and resections, as well as some samples taken during participation in clinical trials or other research.

Many childhood cancers are rare, and tissue banks provide a way of gathering enough samples to enable meaningful analysis. Since 1998, the UK Children’s Cancer and Leukaemia Group (CCLG) has operated a tissue bank to register tissues for research. Written information is given to parents, and age-specific information leaflets are provided for children.3 Consent is given for tissue to be used for research generally, not just paediatric oncology. Anonymised tissue samples registered in the tissue bank are available to researchers under a defined governance structure for biological studies using human tissue samples.4 This is a successful model which supports innovative research with over 1600 samples registered in a recent 2-year (2008–2010) period.5

Collection and use of human tissues has, however, become a fraught and often controversial area of research practice. In the UK, consent for obtaining, storing and using human materials from...
children remains an area of considerable legal complexity (box 1). There is evidence of widespread practitioner support for the principle of tissue banking, but anxiety and ambivalence remain about how the consent process can best be managed. Evidence about families’ own experiences and priorities is badly needed. In this paper, we report a qualitative study of the views of children with cancer, and their parents, on how consent to tissue banking might be optimised.

METHODS
Semistructured interviews about the experience of being approached for consent to tissue banking were conducted with children and young people with cancer and their families. Families were purposively sampled from seven tertiary care centres in the UK, which were located in diverse geographic regions and had varying rates of registration of tissues in the national CCLG tumour bank. We aimed to select families who had had a child diagnosed with cancer no less than 6 months previously, were not currently in a state of crisis, and represented a mix of social and ethnic background, different tumour types and age of child. These considerations guided the size of the sample. The majority of interviews were conducted in the families’ own homes.

The interview prompt guide was used flexibly in interviews, and was developed based on a literature review, discussions within the research team and pilot interviews. Interviews were, with consent, audio-recorded and transcribed verbatim. Data analysis was based on the constant comparative method. Initially, ‘open codes’ were generated to describe units of meaning. Through comparison across transcripts these were developed into higher order thematic categories, which provided a framework for coding. Coding was carried out by a single researcher (CS) with analysis assisted by the use of NVivo 7 computer software. The themes were reviewed independently by another researcher (CT) and any disagreements resolved by consensus. Ethical approval for the study was granted by Trent MREC.

RESULTS
Participants
Interviews were conducted with members of 42 families of a child with cancer, and included 41 mothers, 18 fathers and 20 children and young people with cancer. The families were from socially mixed backgrounds, and nine were of minority ethnic background. Our analysis is organised around three themes: approaching the family; information and decision-making; and length of time needed to decide. For each of these themes, we provide illustrative quotations in the accompanying tables.

Approaching the family
The experience of having a child diagnosed and treated for cancer was stressful and upsetting for families (Box 2). Though views on the best time of approach varied, 16 parents and one child explicitly said that there was no ‘good’ time to ask for consent to tissue banking. Most did, however, want to be asked, and said there was not necessarily a ‘bad’ time either. Families felt that health professionals should use their knowledge of how well they were coping to time their approach, and should try to avoid approaching them when they were particularly distressed or distracted. It could be difficult for families if an approach to consent to tissue banking was made when they were struggling emotionally to come to terms with the shock of diagnosis, when they had just received bad news or when their child was acutely ill. However, families also accepted that health professionals could not always choose the timing of their approach: if their child required urgent surgery, any decision about taking additional samples would have to be made before the procedure. Nineteen parents and one child felt it was appropriate to be asked about tissue banking prior to the procedure to remove samples, although there were concerns that such a request could cause more anxiety where there was still uncertainty regarding the diagnosis. Six parents reported that they would be better able to consider tissue banking once treatment had started.

Box 1 Legal requirements relating to consent

Consent is required for:

- The procedure where tissue is removed and
- The storage and use of tissue for research.

Consent for the storage and use of tissue for research can be given by:

- A child who has task-specific capacity to consent, or
- A person with parental responsibility if
- A child with capacity chooses not to make the decision, or
- If the child lacks capacity to make a decision about the storage and use of tissue for research.

Therefore, different family members (ie, a child and a parent) may give consent for different parts of the process to remove and store tissue for research. In practice, parents are usually asked for consent both for surgical procedures and storage and use of tissue for research.

Box 2 Approaching the family

Timing and manner of the approach
“I think if we were getting bad news at the time it would’ve been difficult, the decision would have still been made, but obviously timing would’ve been quite crucial, as to when we were asked and what state we were in” (participant 6, parent).

“If they’d asked any sooner before we knew the results we would’ve been worrying, thinking ‘Well why do you want them, is there something wrong that we don’t know about?’” (participant 32, parent).

Who makes the approach
“Because the medical team down there knew what the diagnosis was, knew what they wanted it for, it’s sort of reassuring” (participant 76, parent).

“There were people queuing up to see us, so that as one person would leave the bedside the next would come and sit down, so you pretty much lose track of who’s done what” (participant 71, parent).
The quality of families’ personal relationship with the person seeking consent was seen as highly relevant. Eight parents reported that they needed to trust the person who approached them and to have confidence in their answers to any questions. Sixteen parents and three children felt that the most appropriate person was the consultant or surgeon who had responsibility for their child’s care and knew about their child. If families were being approached by someone with whom they were unfamiliar, they wanted to be assured that the person who approached them was known by, or linked to, the team caring for their child. However, 15 participants (13 parents and two children) had no strong feelings about who should take their consent.

Information and decision-making
At the time of approaching for consent to tissue banking, families were often under a great deal of emotional strain, and reported feeling bombarded with information about the child’s illness and treatment (Box 3). They wanted to be approached about issues like tissue banking in a sensitive and empathetic manner, but also wanted health professionals to avoid ‘beating about the bush’ and to be clear about what was being asked of them.

Families reported that they were focused on the child’s clinical condition, and on concerns about outcomes of surgery or progression of treatment: these issues overshadowed everything else. Most families accepted the idea of tissue banking in principle and did not feel they needed to understand the details of exactly what they were consenting to. For many (21 parents and one child), tissue banking was seen as a relatively minor issue in comparison with other issues they were dealing with, and one that they simply did not want, nor have the capacity, to worry about. Five parents and one child described consenting to tissue banking during a busy and stressful time during which they were seeing many different and unfamiliar health professionals; for them, consent to tissue banking was just another consent procedure of the many they were asked to undertake.

Need for clear and simple explanations
“You don’t like to be messed about. (…) Some doctors come in with the, they try and be all … they’re not telling you exactly what they want to know. And I think the best way is just to come out and say it” (participant 42, child).

“You ask the questions but at the time I think there are so many other things going on. Provided you accept that it’s going on, you understand vaguely what’s happening, it wasn’t a big priority” (participant 56, parent).

“If you started asking people in that situation in-depth questions of ‘Oh well we might just take some … I might just take that’, I think you’re probably more likely get a negative answer because people just think ‘I can’t cope with this’” (participant 65, parent).

Research as normal and valuable
“I think approaching somebody straight away enhances the fact that research is going on all the time, so you’ve always got it in your mind” (participant 2, parent).

“I wouldn’t bring it up as a special issue, it just should be part of telling you what’s going to happen anyway and ‘would you mind if we do this at the same time’,” (participant 48, parent).

Nonetheless, families made several suggestions on how to ensure the consent process best met their needs. Many families struggled to take in information at what was often a stressful time, and wanted simple explanations, absent of jargon. They particularly appreciated professionals being sensitive to their difficulties in absorbing information, and being willing to go over the same information more than once. For many, the technical details of tissue banking were unimportant. Instead, families generally wanted to know more about the research that the tissue might be used for, and the way it would benefit families in the future. Families wanted to be kept informed over time about research on tissues within the childhood cancer community and to be told about the value of this research in developing treatments.

Families felt that they would be better prepared to make a decision, and that the burden of the decision-making process could be reduced, if they were made aware at an early stage that research was a normal activity in the hospital and that they might be approached about it. Families also felt that the stress of the decision would be reduced if the approach for consent to tissue banking was treated as a routine procedure, rather than something extraordinary.

Length of time needed to decide
Families varied in their views on the amount of time they needed to make the decision about whether to consent to tissue banking (Box 4). Fourteen parents and one child said that they had made their decision to consent quickly based on a general belief that tissue banking would help others. These families did not feel the need to take time; they just wanted to make the decision and move on. However, four parents did feel that taking time to make the decision had been important for them and wanted the opportunity to discuss information with staff, and ask questions. Even if they did not want to take time to make the decision, families appreciated being offered time. They equated this with not being pressured into making a decision to consent: it could be distressing for families if they felt rushed.

Time to decide
“You’ve just got to understand that people need to have time. You need, the staff need, time to sit and chat to you about these things. Some people can’t make the decision straight away, they do need to go away and think about it” (participant 2, parent).

“There’s never been any, ‘You’ve got to do it within 10 minutes’. And I think if that’d been the case I think we would’ve taken a step back and thought twice about it. But there’s been no pressure whatsoever” (participant 76, parent).

Opportunity to review their decision
“I signed that many papers, I couldn’t honestly say whether I had or I hadn’t” (consented to tissue banking) (participant 1, parent).

“You’ve got so much going round in your head, and people do make rash decisions when they’re under a lot of trauma and stress. So yeah, that might be an excellent idea once the operation’s been a success, to say ‘Oh by the way, do you remember you said we would take the tissue, do you still feel the same?’” (participant 2, parent).

Box 3 Information and decision-making

Box 4 Taking time
Thirteen parents reported being aware in retrospect that they had been unable to take in information properly at the time of consent and that they had given the decision about tissue banking little thought. As a result, three parents were not sure of what it was they had consented to and this caused them anxiety: one parent described having to seek reassurance that she had only agreed to tissue sampling and not to organ removal. Ten parents and one child could not remember whether they were approached about tissue banking; the interviewer did not know whether they had not been asked about tissue banking or whether they did not recall.

Having written information that they could refer back to was useful, but some families also felt it would be helpful if, at a later stage, they were given the opportunity to review the consent that they had given and to reconsider their decision if they so wished.

DISCUSSION

Families of a child with cancer are, on the whole, supportive of tissue banking, they want to be asked, even though they recognise that having the discussion may be difficult. This finding is consistent with recent research on recruitment of children to clinical trials in leukaemia. However, thinking deeply about tissue banking is not a priority compared with other issues families have to deal with, and families want to minimise the burden of the decision. Families want health professionals to be sensitive about the timing of the approach, and to avoiding raising the issue when they are particularly distressed or having difficulties in coping. Some families also want to be offered time to make the decision. It can be challenging for families to take in a lot of complex information or engage in weighing up pros and cons. The decision is made easier if families are already aware of tissue banking and its value in research to advance childhood cancer treatment, understand it as part of routine practice and know in advance that they may be approached. At the time of making the decision, most just want simple information, reassurance that tissue banking is a ‘good thing’ and want someone to take the time to answer any questions they might have. Families also find it helpful to have full written information to take away and read, and a chance to review their decision at a later stage when they are in a better state of mind.

This study reinforces the need for information about tissue banking to be kept simple. It adds to the growing recognition that participants may not recall or understand information given to them about research, especially at a time of emotional strain. Families accept that they may be unable to absorb much information at the time of consent, but are happy to proceed on this basis: they do not feel that their consent needs to be ‘fully informed’. However, if consent is given on that basis, families may sometimes want the opportunity to find out more and to review their decision.

Families’ views on optimising the consent process concur to a great extent with the views of professionals, but highlight some additional considerations, including the importance to families of being able to rely on an understanding that tissue banking will be of benefit to the childhood cancer community as a basis for making the decision, rather than having to engage in complex information processing. This is in keeping with recent work showing a decline in the level of support for using donated tissue as the research focus moves further away from the field of children’s cancer. It suggests a need to recognise that families may wish their contribution to be recognised and valued over a long period of time through provision of feedback and regular updating on the uses to which tissue is being put and how science has advanced through use of tissue. Families may thus want to be engaged as members of the research community long after the moment they sign the consent form.

Currently, the only guidance for health professionals on approaching families for consent to tissue banking is provided through formal guidelines on consent to research. These guidelines set out universal notions of what ‘informed consent’ and optimal decision making processes should involve. Although driven by ethical ideals, these notions do not always fit well with the views and preferences expressed by families. Given the convergence of families and health professionals’

Box 5 Suggestions for optimising the consent process for families

Normalise the research process

- Raise families’ awareness of ongoing research in childhood cancer (through magazines, posters, clinic information and discussions with staff).
- Make research more visible to families and normalise research as part of the day to day business of the unit.
- Inform families at the earliest stage possible that they may be approached about research (including tissue banking).

Approaching families

- Be sensitive to the emotional state of the family.
- If possible avoid asking for consent to tissue banking when the family has just received bad news, are particularly distressed or not coping well.
- Consider who would be the most appropriate person to approach the family: if the family have built a relationship with a particular doctor or nurse, they may prefer the approach to come from this person.

What information to give to families

- Approach families in an empathetic manner, but be direct and clear about what is being asked.
- Give a simple verbal explanation of tissue banking, avoiding jargon.
- Provide concrete examples of research that the tissue will be used for and how it might contribute to advancing science relevant to childhood cancer.
- Ensure that a member of staff is available to discuss tissue banking with families and answer any questions. Be prepared to go over the same information more than once.
- Offer families time to make the decision and make it clear there is no pressure to consent.

Follow-up

- Provide full written information about tissue banking for families to take away and read, and emphasise that families can talk over the decision again at a later point if they wish.
- Make sure there are opportunities for families to be informed about research done using donating tissues, for example, through websites and newsletters.
views on optimising consent to tissue banking, we suggest that new guidance on optimising the process of consent is required. This should acknowledge the need for health professionals to exercise discretion and sensitivity in timing their approach to families, and allows for consent that is not ‘fully informed’ at the moment it is given. Our findings suggest practical ways in which the process of consent to tissue banking could be optimised from the perspective of families (see box 5).

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REFERENCES

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