Gaining consent to freeze spermatozoa from adolescents with cancer: legal, ethical and practical aspects

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Sperm banking for early adolescent cancer patients requires delicate, sensitive handling and, in the UK, consideration is required of statutory elements. No information at present exists about how adolescents with cancer are normally treated or counselled for sperm banking. Here we highlight the type of issues in relation to fertility preservation faced by clinicians and those faced by adolescents at a sperm storage laboratory. We explore the very real difficulties of bringing together these medical fields of assisted reproduction, oncology and the various pieces of legislation and focus specifically on gaining consent. Attention is paid to counselling and communication to help the patient reach an effective and informed decision to store spermatozoa. The role of parents in contributing towards communication and support, together with the legal constraints in decision making, is acknowledged. How absolute and fully 'informed' consent should be will always remain a contentious issue amongst the various specialists and disciplines. In relation to sperm storage, as a minimum the patients should understand the process that they are undertaking so that it is undertaken freely and without pressure. The practical approach to gaining consent that we are using seems a logical and practical method to help early adolescent patients to store spermatozoa.

Key words: adolescent/cancer/consent/sperm banking

Introduction

An increasing number of people are now being cured of cancer as improvements in diagnosis and treatment take effect (Richards *et al.*, 2000). The proportion of children and young adults who achieve long-term survival is greater as the cancers seen in these age groups are more amenable to treatment. However, there is a substantial cost as many such treatments result in permanent infertility.

Alongside this is increasing awareness of the potential for fertility preservation offered by improvements in assisted reproduction technology. Here we explore the very real difficulties of bringing together these medical fields to benefit young people with cancer, focusing specifically on consent.

The legal framework

Obtaining consent in early adolescence remains a contentious topic, with confusing legal precepts and advice (Bahadur and Hindmarsh, 2000). These have implications for the patient, parents or legal guardian and their involvement in the decision making process towards obtaining consent.

In England and Wales, persons over the age of 16 years can give consent to treatment according to the *Family Law Reform Act 1969 s8*. The consent of people under 16 years is legally valid if their doctor considers that they are competent to make

an informed and wise decision (Anonymous, 1985; Age of Legal Capacity (Scotland) Act 1991 s2,(4); Alderson, 2000; Hedley, 2000). The 1989 Children Act, and similar acts for Scotland and Northern Ireland, state that children deemed to be competent can 'refuse medical or psychiatric examination'. The United Nations Convention on the rights of the child emphasizes the best interests and welfare of the child, which includes adults listening respectfully to the child's views 'on all matters affecting the child' (United Nations, 1989, Article 12). Although this convention was ratified by the British Government in 1991, English law has since become more ambivalent about minors (Alderson, 2000).

Alongside this, the field of assisted human reproduction is governed by statute in the UK (HFE Act, 1990) including strict guidelines on the requirements for informed consent in respect of the storage of gametes and embryos and their use. Substituted consent is specifically excluded and there is a requirement to provide verbal and written information and an offer of independent counselling. The exclusion of substituted consent may be subject to further consideration under the UK Human Rights Act 1998, if this proves to be a hindrance in genuine cases to freezing and utilization of genetic material. The onus is upon those storing gametes and embryos to ensure that an informed and effective consent is in place before

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embarking on the cryopreservation procedure. The provider(s) of gamete or embryos thus always retains the right to control of their genetic material, the fate of which can be altered by a variation of consent which can occur at any time. Clearly, no gametes or embryos can therefore be obtained or frozen if the patient(s) has not understood the issues. In practice counselling by counsellors and support staff often follows on from the consultation with the oncologist at which the disease and treatment side effects have been revealed to the patient. This counselling seeks to enable the patient to consider the side effects with regard to fertility and the availability of facilities for gamete preservation.

Consent, assent and proxies

Storing spermatozoa gives patients future autonomy and choice by which they may form a family should they be both rendered infertile and survive. Particular difficulties of information and consent arise in those who have reached an age where sperm storage is physically possible (puberty) but are not yet deemed legally competent.

The transition through puberty includes significant biological developmental, emotional and cognitive changes. Combining these with the prospect of a serious disease such as cancer and the need to grasp the legal formalities can be daunting for those at any age but particularly the early adolescent patient. How absolute the consent has to be to fulfil the criteria of an informed consent is a moot point, which would apply equally to adult patients. It should be borne in mind that freezing ejaculated spermatozoa is a preventative process to overcome or alleviate potentially damaging side-effects of the treatment. It is not itself a treatment but a process which concerns two parts: the storage and the subsequent use. For most cancer patients the latter is the reason for storing spermatozoa but the choice of option at that stage by the patient and his future partner will be determined by a number of other factors which are unknown at the time of freezing. These include their prevailing semen quality, post-thaw sperm quality, whether further information on the genetic damaging effect of treatment is available, who the partner may be, her age and whether she is prepared for a more intrusive form of assisted conception technique. Fully informed consent is therefore not realistically possible.

Normally consent models refer to treatment, but as stated above the freezing of spermatozoa is preventative and normally requires no surgical intervention. The consent model which appears most appropriate to the needs of early adolescent cancer patients considering the storage of spermatozoa is that covered in the Gillick case (Anonymous, 1985). Significant remarks in relation to overriding a Gillick competents' decision have recently been recorded (Yate et al., 2000), although its application to freeze spermatozoa appears unlikely. Interestingly, in the USA the concept of 'assent' has been developed. Early adolescents are considered 'to assent' (or, its converse, 'dissent') when they have sufficient competence to have some appreciation of a procedure, but not enough to give fully informed consent. The age of assent is currently estimated as being twelve (Anonymous, 1977; Sigman and O'Connor, 1991; Committee on Bioethics, 1995).

If a patient is unable to produce semen by masturbation, the possibility of preserving testicular tissue arises (Bahadur and Ralph, 1999). Two issues are at stake. Where the patient is pre-pubertal, and therefore the testicular tissue does not contain 'gametes' as defined by the Human Fertilisation and Embryology Authority (HFEA), the legal, practical and ethical considerations are covered by the *Children's Act 1989* and the *Tissues Act 1961*. Under these circumstances parental consent is essential (Bahadur *et al.*, 2000). Secondly, where in the opinion of the medical practitioner, 'gametes' are present and the patient has reached Tanner grade 2 maturity, then under the provisions of the UK *HFE Act*, consent must come from the patient (Tanner, 1989; Deech, 1998).

A 'family rule' model (Foreman, 1999) of consent for early adolescents has recently been developed. The 'family rule' is a framework for obtaining ethical consent for medical interventions for children. The rule proposes that informed consent in children can be regarded as shared between children and their families, the balance being determined by implicit, developmentally based negotiations between child and parent – a 'family rule' for consent. It is claimed that consistent and operating procedures for ethically obtaining consent can be defined by this model and could be used as a unifying framework in developing new professional guidelines. It is felt that a 'guideline based' approach to gaining consent may offer a greater individuality than a 'rights based' approach.

When practitioners seek consent they usually want to perform some action and the subject therefore consents to experiencing an event. However, there are two broad classes of consent: consenting to an event and consenting to a rule and for children the most important rule is that set by their family. This 'family rule' is likely to promote the welfare of that child. The child's development requires repeated renegotiation of the rule's application from infant to adulthood. Acceptance of consent by the family rule implies that parents may inhibit their children's right to consent and thus diffuses the autonomy of consent. Whilst this model does seem appropriate to medical intervention it should be noted that any coercive influence affecting a decision on sperm donation by normal ejaculation and cryopreservation could be seen as contrary to the requirements of the HFE Act 1990 for autonomous consent. The specific requirement for autonomous consent in UK law may be opened to scrutiny and reinterpretation like all aspects of the HFE Act 1990 and its Code of Practice, under the new HR Act 1998 which comes into force in October 2000.

Provided that the consent is given freely by the adolescent patient there are clearly merits in involving family members when early adolescent patients seek to bank spermatozoa. These merits may include parental help in simplifying complex language or relating a life situation to a context that they know to be familiar to their child. At home, the discussion may continue bringing closeness, openness and perhaps even a focus on positive life prospects in the face of the illness.

An agreement from an early adolescent by way of consent, assent, proxy consent or parent's permission often disguises the difficulties and complexities involved in the whole process. Guidelines for good practice are open to debate (Fleming *et al.*, 1994). The basic abilities required to give consent are

HFEA (00)6 FORM FOR CONSENT TO STORAGE AND USE OF SPERM AND EMBRYOS	
N.B. Do not sign this form unless you have received information about these matters and have be You may vary the terms of this consent or withdraw this consent at any time except in relation to which have already been used. Please insert numbers or tick boxes as appropriate.	
Full name (block capitals):	
Any other name by which you have been known:	
I. USE	
a. I hereby consent to the use of my sperm for the following purposes:	
i. in treating a named partner YES NO NO	
Full name of partner:	
ii. in treating others YES _ NO _	
iii. in any project of research YES NO	
Please state any particular conditions as to use:	
b. I hereby consent to the use of my sperm to fertilise egg(s) in vitro and to the use of embryo(s egg(s) for the following purposes: i. in the treatment of myself YES \ NO \	developed from these
together with a named partner	
Full name of partner:	
ii. in treating others YES NO	
iii. in any project of research YES 🔲 NO 🔲	
Please state any other conditions as to use (eg on the use of particular embryos):	
DAY MONTH Y	EAR
Signature: Date: LLL L	
II. STORAGE	
a. I hereby consent to the storage of my sperm:	
Storage period in years Maximum (10 years)* YES \ NO \ If less please state YE. *Centres are allowed to store sperm for longer periods for limited uses only.	ARS L
b. I hereby consent to the storage of embryo(s) developed in vitro from egg(s) fertilised with my	sperm:
Storage period in years:	
Five years YES NO Ten years YES NO More than ten	years YES└U NO└U
If less than five years or some other period please state the number of years: YE	ARS 📖
I understand that consent to storage of more than five years <u>must</u> be accompanied by a comwhich has been signed by a registered medical practitioner.** **This does not apply to donors.	pleted HFEA(96)8 form
c. If I die or become mentally incapacitated my sperm or the embryo(s) developed in vitro from my sperm should:	egg(s) fertilised with
i. be allowed to perish YES 🗌 NO 🗀	YES NO
ii. continue in storage for the purpose given in 1a. (for sperm) and 1b. (for embryos) above YES NO	YES LI NO LI
iii. continue in storage for other purposes (please specify below)	YES NO
d. Any other conditions of storage	ertilised with my sperm
will have to be allowed to perish at the end of the storage period specified at Ilb.	
DAT WONIN	1 1

Figure 1. HFEA (00)6 form for consent to storage and use of sperm and embryos.

developed by 2 years of age with understanding of basic requests and behaviour to others (Kagan, 1981; Nelson and Gruendel, 1981). By age seven, emotional factors are more important than developmental factors in predicting comprehension of medical procedures (Berryman, 1978; Turnbull and Turnbull, 1985), and the use of appropriate techniques can significantly improve younger children's comprehension of medical procedures. However, this comprehension in children is limited when compared to adolescents (Weithorn and Campbell, 1982); children between six and twelve can understand, for example, psychiatric hospitalization in general (Roth and Roth, 1984). This fits the modal age at which UK patients,

parents and practitioners think children can make decisions about surgery (Alderson and Montgomery, 1996), and the age of assent. On the other hand, early adolescents are perceived to lack the social independence needed to make a fully autonomous decision, being vulnerable to external pressures, and benefiting from firm guidance (Steinberg and Silverberg, 1986; Turner *et al.*, 1993; Shucksmith *et al.*, 1995).

Current practice

No information at present exists about how adolescents with cancer (Foley, 1989; Shields and Johnson, 1992) are normally treated or processed for sperm banking. Here we highlight the

HFEA (00)9 FORM FOR CONSENT TO THE LONG TERM STORAGE OF SPERM

Full name (block capitals)
Any other name by which you have been known:
STORAGE OF SPERM
a) I hereby consent to the storage of my sperm for years (not exceeding my 55th birthday) b) Date of 55th Birthday Month
c) Statement from a Registered Medical Practitioner verifying medical conditions for sperm storage for more than ten years*:
In my opinion the fertility of
Full name of Doctor:
Work address:
Signature: Date:
*this statement may also be in the form of a letter attached to the consent form
d) If I die or become mentally incapacitated, my sperm should
i be allowed to perish Yes No Continue in storage for the purpose specified in HFEA (00)6* Yes No
* a completed HFEA (00)6 must be attached
e) I have attached a completed form for the consent to storage and use of sperm and embryos Yes 🔲 No 🛄
Signature: Date:

Figure 2. HFEA (00)9 form for consent to the long-term storage of spermatozoa.

type of issues in relation to fertility preservation faced in the clinician's consulting room (before referral) and those faced at our sperm storage laboratory (after referral).

Before referral

Before referral for sperm storage the adolescent patient should be informed of:

- what might happen in the course of cancer treatment to his sperm quality and testicular function and information regarding risks of genetic damage imparted (Bahadur, 2000);
- how these could manifest in his future fertility prospects;
- the difficulty in predicting pregnancy success in the absence of a partner;
- what might happen if sperm storage is not considered;
- the prospect of choice of forming a family in the future;
- the opportunity to be counselled in-house;
- the prospective use of advanced assisted reproductive techniques to help achieve pregnancy (of lesser importance at this stage);
- the patient should be provided with some information about the laboratory.

After referral

After referral for sperm storage the early adolescent patient should be:

- allowed to come to know the staff and familiarize himself with the environment;
- given a chance to be alone with senior sperm banking personnel who will, apart from establishing a rapport, seek permission from the patient to involve any accompanying

persons such as parent, nurse or friend, thus respecting his right to confidentiality.

The staff member with responsibility for that patient should:

- establish that the patient has received some information about the sperm banking facility and about the reason for his attendance;
- establish whether the level of pain or medication are such as to obscure the patient's judgement;
- provide necessary information to help place their attendance into perspective. This may involve a simple biology lesson to establish the difference between semen and urine and may be assisted by visual examination of spermatozoa down the microscope if this is readily available (urine should be checked if patient fails to produce semen);
- explain about the special room and forewarn the patient of any content which may shock them (appropriate action should be considered for removing these if need be);
- the method of sperm production must be established with the patient and this is best done through one to one dialogue rather than by instruction;
- describe what happens to the semen once produced and discuss the issues of statutory consent, including how they wish the result to be disseminated now and in the future;
- offer the patient access to independent counselling;
- provide written information about sperm banking;
- explain and obtain statutory consent which is the UK HFEA (00)6 consent form (Figure 1). As an option, the form HFEA (00)9 (Figure 2) may be used to allow for situations where limited time factors for storage before treatment

G.Bahadur et al.

(Yes/No/Undecided)
(or, NAME)
the peripheral support staff members of the oncology team
(Yes/No/Undecided)
my GP(Yes/No/Undecided)
my wife/partner/next of kin (Yes/No/Undecided)
my wife's/partner's GP(Yes/No/Undecided)
to another licensed clinic considering treating my wife/partner
(Yes/No/Undecided)
for the purpose of financial audit(Yes/No/Undecided)
I do NOT wish information about by stored sperm to be given to.
Adularment notice to do not have to fill 4. 5. 6 or 7 (refers to internal hudget cetting)

Figure 3. Consent to disclosure of identifying information.

constrains a full and proper explanation, to enable the patient to reach an effective consent regarding the use of his gamete. The HFEA (00)9 (Figure 2) may become useful for adolescent patients. However, in the eventual use of sperm, form Figure 1 will need to be completed. Only the patient can sign these forms;

- ensure that the disclosure of information form is completed (Figure 3). This gives the patient the right to choose to whom information about his spermatozoa can be transmitted;
- ensure that accompanying persons, especially parents, are privately sectioned off before the patient produces a sample.
 From experience this has been psychologically helpful to patients in successfully producing sperm samples;
- discuss the results of the semen and how the spermatozoa will be stored with the patient; he should be forewarned of this;
- a copy of his consent form together with written information should be provided in a large envelope, together with any future appointments;
- provide a contact telephone number for the laboratory.
 In summary whilst full attention must be given to complying

with the statutory and medico-legal requirements care must be taken to provide the information that the patient requires to make a meaningful choice of treatment, to avail himself of the facilities on offer and to make his participation in the treatment as stress free as possible. Particular attention must be

given in the case of adolescents to supplementing information provided with counselling and providing a proposed line of action. Likewise, every effort must be made to elucidate the wishes of the patient in matters on which there is a choice. Important steps which may be taken are for example simplifying verbal and written information on a case by case basis which does not devalue the young person's level of intelligence. The message may have to be repeated until the patient has understood each point, and ample time should be allocated in order that the patient may feel comfortable and reach an effective decision. Sketches in delineating the meaning of biological parenting and genetic lines could be useful in some instances although this is often easily understood by most young patients from the outset. Where the young patient declines to proceed with the cryopreservation process it is important to understand the reasons, talk them through and record them. It is highly unlikely that a parent may consider overriding their child's decision not to provide genetic material. In this unlikely event it should be borne in mind that the actions would be contrary to the HFE Act 1990 and possible assault charges could be levied on the takers of the genetic material. There may however be a difference in opinion between parent and child and this is best narrowed by open dialogue and support counselling.

Discussion

The models used so far in childhood and adolescent consent concern treatment or medical intervention. Research consent models are different, as the purpose of such intervention is to gain information rather than benefit or improve the patients' condition immediately. When so little information is available on adult cancer patients and their fertility, research involving children and adolescents should be conducted cautiously as they are a group prone to persuasion under the banner of progress and advancement. In relation to non-intrusive and preventative sperm storage perhaps the closest consent model is that of Gillick, but for the opposite reason as this arose from a contraception issue. How absolute and fully 'informed' a consent should be will always remain a contentious issue amongst the various specialists and disciplines. In relation to sperm storage, at minimum the patients should understand the process that they are undertaking and it must be undertaken freely and without pressure. In relation to the requirements of the HFE Act 1990 and sperm storage, the practical approach to obtaining consent that we are using seems a logical and practical method for early adolescent patients and can be mirrored for all age bands.

It should be remembered that in the UK, the statutory storage period for spermatozoa can be extended, for medical reasons, from the 10 year limit up to when a patient is 55 years old (HFEA, No. 1540, 1991). Adolescent cancer patients would qualify under these circumstances. Our offer of counselling, care and follow-up remains for all this period. From the financial perspective we offer this facility to all cancer patients on the UK National Health Service without charge and with no annual maintenance charge levied to patients. This considerably lessens the pressure on patients to reach a hasty decision on a

year by year basis, which may be counterproductive, especially when they have several decades of life ahead of them.

Conclusion

Whilst not concerning medical intervention *per se*, sperm banking for early adolescent cancer patients requires delicate, sensitive handling and in the UK encompasses statutory elements. We also have a duty of care to the patients' relatives and guardians, who should ultimately respect the confidentiality aspects bestowed by statute to the patient if he so chooses.

There is a minimal risk to the adolescent in giving consent for storing spermatozoa produced non-surgically which is to be cryopreserved and possibly used several decades later. They make apparently adult-like decisions (Sigman and O'Connor, 1991) and, in so doing, demonstrate their maturity and understanding of the subject of sperm storage in relation to their disease, their treatment, their rights and their prospect of genetic continuity. Persons taking such consent should be reflective of the process and methods by which it is taken.

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