



## **British Fertility Society**

response to the

**Human Fertilisation and Embryology Authority**

public consultation on

**The Regulation of Donor-Assisted Conception**

February 2005

## Summary of Opinions and Questions

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**Interest in the SEED Review:** The British Fertility Society is a multi-disciplinary organization representing professionals with an interest in reproductive medicine. The objectives of the society are:

- To promote high quality practice in the provision of fertility treatment.
- To provide a common forum for members of various disciplines having an interest in the science and treatment of infertility.
- To promote high quality scientific and clinical research in the causes and treatment of infertility.
- To provide professional leadership in the provision and regulation of infertility services.
- To promote the increase of NHS funding for and equity of access to fertility treatments.

The provision of assisted conception using donor gametes is an important part of the workload of BFS members and as such the society has an interest in policy developments in this area.

The society **agrees** to the making its responses publicly available by the HFEA in accordance with the Cabinet Office Code of Practice on Written Consultation. In addition the society will be making this response available on its website (<http://www.fertility.org.uk>).

## Background

Following the announcement of the SEED consultation, the Executive committee of the British Fertility Society decided that the society should respond on behalf of its members. Therefore, in January 2005, the BFS secretariat made e-mail contact with over 700 members and invited them to submit their views. A total of 13 members of the society responded as follows:

Member Category	No of respondents
Clinician	7
Counsellor	3
Nurse	2
Scientist	1

Whilst this cannot be taken as a representative sample of the society membership, the views of these members have been taken to form the core of this response. However, as might be expected there was often significant differences between individuals and where possible this has been reflected in this response.

### Screening of gamete and embryo donors (paragraphs 12 to 17)

The opinion of respondents was either for option 1 (that the HFEA should rely upon guidance produced by the relevant professional bodies) or option 3 (that the HFEA should continue to produce its own independent guidance taking into account advice from professional bodies). There was a slight majority view for option 1 and so this is taken as the BFS view. There were no respondents in favour of option 2 and so the BFS would view that this option should be rejected.

Comments from members on this point included the views that:

- The professional bodies were the most skilled to provide an assessment of the literature and undertake an evidenced based assessment of medical and laboratory screening.
- The current British Andrology Society and BFS guidelines needed urgent revision and it would be proposed that with agreement of the two societies that these should be merged into a single document.
- Any revised guidelines should consider only medical and scientific aspects of screening and issues relating to the counselling of candidate donors should be considered separately (presumably by the British Infertility Counselling Association?).
- The HFEA through its inspection process should continue to police through its inspection process any guidance provided by the professional bodies.

*Summary: Option 1 is the BFS view*

### **Selection of donors by clinics and recipients (paragraphs 18 to 20)**

There was an overwhelming view by respondents that the selection of donors for treatment of a particular recipient should be left to clinics and patients. This was based on a variety of views including:

- The multi-disciplinary team involved in the patient's treatment was best placed to provide practical support and advice in reaching this decision. However,
- The desire to consider matching on the basis of physical characteristics was now out of date given the move to greater openness and the fact that from April 2005 only identifiable donors can be used in treatment.
- The recognition that there needed to be some degree of connection or 'fit' between patients and donors was desirable but that this was based on more criteria than just physical characteristics.
- The pragmatic view that in reality most patients currently do not have a choice given the shortage of suitable donors and that further regulation may further inhibit an already difficult service.

*Summary: Option 1 is the BFS view*

### **Limiting the number of children per donor (paragraphs 23 to 25)**

Respondents were split equally between the option 1 (gametes from a single donor should not be used in the treatment of more than 10 families) and option 2 the maximum number of families who may receive treatment with gametes from a single donor should be fewer than 10). Four respondents did not answer this question and one preferred option 3 (that the maximum number of families who may receive treatment with gametes from a single donor should be greater than 10).

The split of opinion was largely between those who had a pragmatic view about the ability to deliver donor treatment services with a limited number of donors as opposed to those who with psychosocial interests in the welfare of donors and their families / donor conceived individuals and their families, when contact is being made in 18 years time.

Members were clearly of the view that the setting of the current maximum limit of 10 live birth events was an arbitrary number, based on a poor evidence base, and designed to prevent the incidence of consanguineous relationships in a society where secrecy in families and donor anonymity were the norms. Now that this situation has moved on to one of more openness, there seems to be little basis in maintaining this limit and other arguments should be used to re-establish it.

Those respondents who were of the opinion that the maximum number of families should be less than 10, all stated that in their opinion this should be set at a maximum 4 family groups. Again, however, this is a clearly arbitrary decision, although it would align the

position of sperm donors more with that perceived to be the case for egg donors where for pragmatic reasons fewer recipient family groups are involved.

*Summary: There is no consensus view among BFS members, but any decision to reduce the maximum number of families who may receive treatment with gametes from a single donor should be taken in the full knowledge of what this will mean for the provision of treatment unless donor number can be increased significantly.*

### **Payment of Expenses to Donors (paragraphs 31 to 32)**

There was a clear and almost unanimous view among respondents that the current system of payments/expenses was unfair and discriminated against egg donors and as such rules should be in place to ensure that donors should not lose out financially from donating. Whilst some of the respondents were of the view that any expenses were reasonable as long as they were justified and adequately accounted for, there was a larger majority that were of the opinion that maximum values should be set by the HFEA (and reviewed regularly) to provide a 'secure framework' and prevent the establishment of a 'donor's market'.

*Summary: Option 1 is the BFS view*

### **Compensation for Inconvenience – Sperm Donors (paragraphs 36 to 37)**

The views of the respondents to this question were split equally between those who felt that sperm donors should receive no payment for inconvenience (option 1) and those who felt that compensation should be offered with an agreed maximum value that is a realistic value of the inconvenience (option 2).

Arguments against payment for inconvenience to sperm donors included:

- The notion of compensation for inconvenience seems to be indistinguishable from overt payment.
- Compensating gamete donors for inconvenience is inconsistent with the fact that blood donors are not compensated for the inconvenience of giving blood
- The introduction of such a payment would detract from the value ascribed to donation and could appear to be a commercial payment in effect.
- Additional money to encourage men to donate is contrary to the non-commercial tradition of donation in the UK and contrary to the EU Tissue Directive.

Arguments in favour of payment for inconvenience to sperm donors included:

- The fact that most donors would have to take time off work to make their donation by virtue of the fact that sperm banks are rarely open out of normal office hours.
- The fact that there will be some unaccountable losses/costs associated with donation

and a payment for inconvenience with a sensible maximum would help to compensate for this.

Of those who supported a payment for inconvenience, suggested levels of compensation ranged from £30 to £50 per visit.

Finally, it is interesting that among members there was no clear distinction of views between the different types of members submitting responses. Whilst all counsellor members supported option 1, other members expressed both views.

*Summary: There is no consensus view among BFS members,*

### **Compensation for Inconvenience – egg donors (paragraphs 38 to 40)**

The views of respondents were identical to that given above for ‘Compensation for Inconvenience for Sperm Donors’ but were supported by arguments that reflected the obvious difference in the process of egg donation. Again, there was no clear polarisation between different categories of members and their views, although all counsellor members supported option 1 (no compensation). Where respondents supported a payment for inconvenience, the proposed level ranged from £50 per clinic visit to £500 per donation event. Again, all counsellor members who responded supported option 1, whereas other members expressed both views.

*Summary: There is no consensus view among BFS members,*

### **Benefits in kind (paragraphs 42 to 45)**

There was a clear and majority view among respondents that benefits in kind in the form of discounted treatment services may be given to donors providing gametes for the treatment of others. However, opinion was more divided as to whether these should be accrued in the same cycle/procedure as the donation and no additional compensation for inconvenience should be given (option 1) or whether these benefits need not be taken advantage of in the course of the donation cycle (option 2). Since there was a slight majority for the former then this is taken as the BFS view.

*Summary: Option 1 is the BFS view*

As to whether the answer to this question might differ if the benefits in question were sterilisation rather than fertility treatment, there was a slight majority in favour of this (i.e. answering yes to the question). However, because the individual’s response depends on how the respondent answered the above question initially these are difficult to summarise.

However, there was a clear majority view that benefits in kind to women about to undergo sterilisation were not the same as women who were undergoing their own fertility treatment. This is because:

- Sterilisation is a procedure that is normally provided on the NHS and therefore it is difficult to see what benefits in kind can be offered.
- Providing benefits for gamete donation during sterilisation is an explicit trade-off.
- Female sterilisation is not considered to be the best form of long-term contraception for women now that the Mirena coil is available.
- Younger women who might be approached as potential donors would need to be younger and with younger families and may donate without fully considering all implications of sterilisation.
- Some of the inherent risks in donation (i.e. compromising future fertility, loss of hoped for genetic child, psychological impact of failure) are not the same between women undergoing sterilisation as opposed to a cycle of IVF.

*Summary: It is the BFS view that to offer any benefits (direct or indirect) to women undergoing sterilisation in exchange for eggs is inappropriate and should be discouraged.*

### **Supply of gametes and embryos by one licensed centre to another (paragraphs 46 to 48)**

The opinion of respondents who answered this question was equally divided between the two options presented in the consultation document. As such, it is impossible for the BFS to take a view on this question. However, the following comments from respondents may assist the HFEA in reaching a sensible decision.

In support of option 1:

- It should be recognised that the current price of sperm being ‘sold’ between clinics is far below the actual procurement, processing and distribution costs.
- For genuine economic reasons (see above point) there are only a small number of centres who are able to economically recruit gametes therefore they must be allowed to set their payment tariffs **to meet their costs incurred** – not a figure HFEA have come up with.
- It is unethical for centres that are good at recruiting donors to lose out financially by distributing them to other centres. The current system is inhibitory to the free supply of gametes between centres and as such should be changed.
- The supplying centre’s costs and expenses should always be met. Some centres have reported a loss in providing this service - there appears to be no real incentive for centres to continue to supply others or for centres with a tradition of recruiting, to resume their activity and to pool resources with others.

In support of option 2:

- Assuming this can be done without excessive bureaucracy, it seems important that a balance needs to be struck between a centre's ability to recoup the expenses involved in donor recruitment and obtaining gametes or embryos and avoiding a commercial market in gametes and embryos
- The maximum cost in this situation should fairly represent the huge amount of work that goes into the recruitment and workup of donors. A fair maximum would prevent a commercial venture into sperm donation for profit making purposes, which should be avoided.

*Summary: There is no consensus view among BFS members,*

### **Obtaining gametes from abroad (paragraph 49)**

Amongst respondents there was an almost unanimous support for the view that the HFEA should authorise all licensed centres to import gametes at their discretion (option 2). There was a strong view that the current arrangements were overly bureaucratic. Although some respondents expressed concern about the need to maintain quality standards on imported gametes and the need for the inspection process to make sure that the use of the donor had been carried out in accordance with current UK law specifically with regard to any limits on the number of children born per donor and the provision of counselling to the donor. One respondent raised the issue of possible difficulties that may be encountered in the future with UK born individuals trying to trace a donor recruited overseas.

*Summary: Option 2 is the BFS view*

### **Best practice in recruitment of gamete donors (paragraphs 56 to 59)**

BFS members had a variety of views relating to best practice in the recruitment of gamete donors and what practical measures they considered could be implemented to make the process of gamete donation less burdensome for donors. These are summarised in point format below:

- There was an urgent need to review the standards for medical and laboratory screening methods as set out in question 1. Concerns included:
  - The need for donors to attend GUM clinics for their screening alongside people using that service for their own treatment;
  - The possible use of rapid PCR based testing for infection to allow the quarantine period for semen to be omitted.
- The need for centres to have opening hours that are convenient to donors (including evenings and weekends). This is not withstanding:

- The view by centres that the majority of have worked very hard over the years to adopt flexible working hours and in making the donation process as efficient as possible.
- The criticism that centres are inflexible does not recognize the many other pressures that they face and the fact that the economic reality of providing staffing outside core hours can make donor recruitment uneconomic.
- The image of sperm, egg and embryo donation needs to be raised to similar levels and publicized alongside blood, bone marrow and organ donation. This included the view that donors should be treated with dignity and respect and should be formally thanked for their donation.
- Good quality counselling should be available prior to donation and centres should consider counselling sessions on a home visit basis or use of telephone counselling which is particularly relevant for those prospective donors caring for children.
- It is essential that from April 2005 donors are given clear and direct information concerning the provision of counseling and future support services including the:
  - Availability of follow-up counselling and the information that is available to them and how it can be obtained.
  - System by which donors can provide updated information in the future;
  - System for informing the donor of the outcomes of their donation - if that is what they wish
  - Plan for counselling and support service in place for future enquiries, including services around times of information sharing and/or contact with donor-conceived offspring;
  - Availability of counselling and support service for a donor's partner and/or other family members;
- Detailed help should be provided for donors to complete the 'pen portrait' since experience shows that donors, especially young males, find it extremely difficult to write about themselves.
- Efforts should be made to investigate the possible advantages of recruiting own known donors - both egg and sperm donors.

Finally, BFS members were opposed to the view that a National Recruitment Service should be established. Although there may be perceived political benefits to this, members were generally of the view that this would simply lead to increased costs and bureaucracy associated with providing gametes to licensed centres for treatment. In preference to this was the view that efforts should be focussed to re-skill centres where the skill base had appeared to have been lost and give practical rather than theoretical assistance to centres to begin donor recruitment activities to be able to capitalise on the publicity generated from National Recruitment Campaigns.

### **Effect of Options Chosen**

The single most common view of respondents, from all professional groups represented by the society (i.e. not just the clinical members) was that the options presented in this document would only have a minimal effect on the availability of donor gametes

available for treatment in comparison to the effect of the forthcoming change in legislation which would allow donors recruited from April 2005 to be identified. A small number of respondents (mostly clinical members) were very critical of the consultation processes that have led to the current position and asked most strongly that the BFS represented this view in its response. Most, however, acknowledged that the effect of the decisions implemented in this consultation would do little to encourage the actual process of donation but were of the opinion that the donation which did occur could potentially take place in a framework that society would find more ethical.

Unfortunately, for some questions posed in this consultation, the BFS is unable to give a definitive response because its membership provided conflicting views in almost equal numbers. These include questions relating to: (a) Limiting the number of children per donor; (b) Compensation for inconvenience (of both egg and sperm donors); and (c) The supply of gametes and embryos by one licensed clinic to another. Interestingly, these differences do not simply reflect the conflicting views of those involved in providing treatment (e.g. clinicians) against those with perhaps more interest in the psychosocial wellbeing of donor conceived families (e.g. counsellors). It is clear from the responses that some views are shared by individuals in both groups and as such probably represent the range of opinions in society as a whole.

In spite of the differences of opinion between members, for some issues (e.g. limiting the number of children per donor) it was evident from the responses that to reduce the number of children per donor from 10 to 4 would be to both exacerbate further the availability of sperm donors and also increase the cost of those patients who were able to receiving treatment. Whilst some members found this acceptable and others did not both groups recognised it as a natural consequence of such a decision. However, it was recognised by all that to reduce from 10 to 4 the number of children born would align more closely the position of sperm donors with that of egg donors.

The suggestion that clinics be allowed to pay actual expenses to donors (up to a maximum set by the HFEA) was seen as a positive step forward by members in as much as it again recognises the fundamental differences between the processes of egg and sperm donation. However, it remains controversial within the BFS as to whether payments for inconvenience is appropriate, although benefits in kind were considered acceptable (as long as those benefits accrue in the same cycle/procedure as the donation). The latter view, if adopted, would ensure that egg sharing in its current form is acceptable to members.

A major step forward was considered the need to remove unnecessary bureaucracy and regulation surrounding the movement of gametes between centres both within the UK and from centres overseas. A natural consequence of this decision would be to immediately allow for more freedom of choice.

Finally, there was a general desire to reverse the uncertainty felt by clinics over the past few years as to the direction that policy makers were taking with regard to the recruitment of donors and the use of donor gametes. It was considered by many

respondents that it was now time to reach a period of stability where clinics can invest in developing robust protocols, staff training initiatives and in some cases make bids for badly needed staff resources or infrastructure to underpin their donor recruitment activities.