

## HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

### Sperm, Egg and Embryo Donation (SEED) policy review Findings of the clinic survey

#### 1. Introduction

In April 2004 the HFEA announced that it would be conducting a review of a number of its policies concerning the donation of sperm, eggs and embryos (SEED review). The review is being led by an HFEA steering group and consists of several stages. The first stage involved a survey of clinics in form of a comprehensive questionnaire, the results of which are the subject of this report. The aim of the survey was to assess systematically the current state, and perceived future trends, of provision of fertility treatment with donated gametes and embryos.

The findings of the survey will assist the HFEA in developing its guidance and policies on gamete donation and to ensure that these policies do not inhibit gamete donation practice without justification. The findings will also help the Department of Health to inform the measures it will undertake to support the change in culture surrounding gamete donation and to encourage known donations.

Prior discussions by the HFEA's SEED review steering group, as well as preliminary results from the clinic survey, have resulted in proposals for measures to secure and promote adequate, effective and safe donor gamete treatment services. These preliminary proposals were discussed by selected stakeholders at a meeting at the HFEA in July 2004. This meeting was attended by representatives from patient interest groups, clinic professionals and academics.

The proposals will be taken forward to the second stage of the review which will consist of a public consultation and will include a regulatory impact assessment. Finally, the recommendations formulated under this review, together with an analysis of consultation responses, will be presented to the HFEA and the Department of Health (Winter 2004-05).

This paper will present the main findings of the clinic questionnaire.

#### *1.1 Clinic questionnaire*

The first stage of the review was initiated in April 2004 when the HFEA sent out a questionnaire to all 99 centres holding a current HFEA licence to store gametes and/or to provide treatment. The questionnaire had two main objectives. Firstly, to gather quantitative information in order to establish a comprehensive account of the current status of gamete availability, donor recruitment and waiting lists. The second objective was to conduct a qualitative survey of the experiences and trends observed in the area of

gamete donation from the perspective of those providing treatment services and to benefit from their views and experiences.

The deadline for returning the questionnaire was at the end of May 2004. To date, 62 clinics have replied. Fifty-nine responses were received relating to sperm donations, 51 responses were received relating to egg donations and 49 for embryo donations.

## *1.2 Methodology*

All quantitative data was entered into a spreadsheet. As will be noted below, some questions and some questionnaires were not fully completed by certain clinics. In cases where this would have affected the overall result of the survey (*i.e.* especially in relation to any quantitative data) such responses were disregarded.

All qualitative responses were also entered into a spreadsheet. Once an adequate number of responses had been received, those responses which were more common than others could be identified and allocated to certain response categories (or groupings). However, in order to provide a broader picture of the types of responses received, less common responses were not excluded from the final analysis and some have also been included in this report.

Since not every clinic responded to every question, and since not every clinic returned the questionnaire, the results of this survey can only provide an indication of the current state of, and trends observed in, gamete donation and treatment. Moreover, it should be noted that qualitative responses in particular were provided by individuals (*i.e.* managers of donation programmes or other persons responsible) at clinics and may therefore represent their specific views rather than reflect clinic consensus. Unless stated otherwise, the number of total respondents to the questionnaire (n=59 for sperm donation, n=51 for egg donations and n=49 for embryo donations) was taken as 100%.

## **2. Sperm donations**

In total, 59 completed questionnaires on sperm donations were received. Ten questionnaires did not contain any quantitative (or useable) data regarding sperm currently in storage; this number rose further with regard to certain questions, *e.g.* the cost of recruitment (see below).

### *2.1 Gamete availability*

Of the 99 centres who hold a current licence to store gametes and/or to provide treatment, 49 responded to the quantitative part of the questionnaire. The results of the survey indicate that currently there is sperm from 2054 donors in storage available for the treatment of others, however, due to the level of responses received this may be an underestimate. Of these 2054 donors, 775 donors have reached the limit of ten live birth events for the use

of donor sperm from one individual and are available for sibling use only.<sup>1</sup> Therefore, according to these figures, the number of donors available for use with new patients is currently 1279. This number also includes 195 donors who have specified other conditions limiting the use of their sperm.<sup>2</sup> The results of the survey also indicate that currently there are 255 known donors with sperm currently in storage which is reserved for particular patients. However, from the questionnaire alone it is not possible to determine whether the number of donors whose sperm is available for the treatment of others (n=1279, see above) includes any of these 255 known donors. If it should be the case that the number of donors available for the treatment of others does include known donors, then the total number of donors available for general use would be reduced to 1024 (*i.e.* 1279-255=1024).

This number is subject to a number of caveats. Firstly, it may include donors who have donated at more than one donor recruitment centre, in which case the number would be an overestimate. Since 1 April 1999 donation forms allow the donor to declare that they have previously donated at another centre, however, this information is dependent on the donor providing accurate information. Secondly, it may capture some donors with sperm held in storage at more than one clinic. If this were found to be the case it would further reduce the number of individual donors available. Information provided by the donor on whether he has been recruited at other centres is held on the HFEA's Register. The Register also holds information on donated gametes used at centres other than the recruiting centre and further research and analysis of data held on the Register is needed to establish these figures. Although this information was not available for the publication of this report, the HFEA is currently conducting this analysis and will publish the information in due course.

Thirdly, for many clinics the donor sperm in storage originates from donors recruited at other UK centres (1344 donors of the total 2054) and may be stored for specific use at clinics. Therefore, 1024 may not reflect the *actual* number of donors *available to every centre*.

In fact, the survey suggests that currently only eight centres supply sperm to other centres in the UK. The minimum number of sperm donors available from these centres is 388 (or maximum 490)<sup>3</sup> and according to the survey these are also the only centres that have donors on their 'available' list, *i.e.* donors that these centres make available for distribution. The survey suggests that there are currently a total of approximately 150 donors on such available lists. Interestingly, this number does not tally with the minimum number (n=388) of

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<sup>1</sup> The HFEA *Code of Practice* currently imposes a limit of ten live birth events per donor (twins and triplets counted as a single 'birth event'). The guidance allows exceptions to be made to this limit in certain circumstances.

<sup>2</sup> Thirteen clinics reported that these donors wanted the use of their sperm to be restricted to the treatment of heterosexuals. In one clinic the sperm was not to be used for the treatment of single women.

<sup>3</sup> The maximum number of sperm donors at distributive centres is determined by the number available for the treatment of others (n=741) minus the number of donors who have reached 10 live births (n=251) and equals 490. The minimum number is determined by subtracting from the maximum number the number of donors who are reserved for particular patients (n=102).

sperm donors that would theoretically be available from these centres. This suggests that centres that are recruiting sperm donors on a large scale, and that are also the only providers of donor sperm to other clinics, retain the sperm from over half of the donors they have recruited for their own use and do not make it available for further distribution.

## *2.2 Recruitment*

Of those clinics who commented on recruitment trends over the last year (n=36), half had not observed any changes to these trends. Of those clinics that had experienced a change in recruitment, nine clinics reported a reduction in donor recruitment for a variety of reasons. (It is worth noting that of the three centres who recruited the most donors over the last year, two had observed a fall in recruitment.)

There is no indication that any single recruitment strategy was overwhelmingly effective. Seven clinics found placing articles or adverts in the national press to be most successful, four clinics found placing posters at universities to be a successful strategy. No single approach could be identified as being clearly unsuccessful. Similarly, there is no clear indication that there is a specific type of donor that clinics are recruiting more successfully than others. However, four clinics found that they were most successful recruiting students. Twenty-five per cent of clinics noted difficulties with recruiting sperm donors from ethnic minorities.

Only a few centres were able to provide figures for costs for recruitment. For those centres that recruited more than 20 donors over the last year the cost of recruitment was between £1,300 and £5,000 per donor recruited, the bulk of these amounts was typically spent on laboratory screening costs and payments to donor for expenses. On average about 20% of donors who attend a clinic for an initial consultation go on to complete a course of donation but at one clinic, where 110 men attended an initial consultation, the figure was only 2%. The majority of donors who did not proceed had to discontinue due to positive lab results and/or unsatisfactory sperm quality.

## *2.3 Demand*

Forty-nine centres responded to a question on whether they were able to meet the demand for treatment with donor sperm. Half were able to meet demand for treatment with donor sperm. Of those unable to meet demand, nine experienced difficulties matching donors and recipients from ethnic groups. Other clinics (n=10) experienced difficulties matching donors with recipients in all categories. The reasons for this were heterogeneous but four clinics reported difficulties matching CMV status and one large recruiting centre reported difficulties in meeting their demand for Caucasian donors.

## *2.4 Trends affecting sperm donation*

The most frequently cited past trend, identified by 30% of clinics (n=15), was a reduction in demand for donor sperm due to the development of ICSI. Twenty-five per cent of clinics reported a trend of fewer donors coming forward. Also, 18% of clinics believe that the discussion preceding the legislative changes

concerning donor anonymity has already had an effect on recent sperm donation.

Four clinics also identified a sense of confusion and uncertainty about the implications of the release of identifying information among potential donors. One clinic attributed this uncertainty to lack of information on the subject.

Another trend, identified by eight centres, was an increase in single women and lesbian couples coming forward for treatment.

A trend identified by three clinics concerned the provision of sperm from larger centres. It was noted that there are now fewer centres than in the past and that it was difficult to obtain sperm from larger recruitment centres.

As far as future trends are concerned, the majority of clinics (n=37, 62%) predict that the removal of donor anonymity will have the greatest effect on sperm donation over the next five years. The same number of clinics predict that the loss of donor anonymity will have an adverse impact on recruitment. By contrast, 11% predict it will have little or no long term effect. Approximately 10% of respondents believe that the changes in legislation will increase demand for imported sperm and that it will affect the matching of donors and recipients. One centre also mentioned the EU Tissue Directive as a factor that will be affecting sperm donation over the next ten years.

Thirty-three per cent of clinics stated that they had already prepared for the forthcoming changes in the law and were changing their literature and consent forms in accordance with these changes.

### *2.5 Options to increase gamete supply*

Thirty per cent of respondents believe that raising the awareness of the general public, including the promotion of better understanding of legislative changes among prospective donors, would help to increase the willingness to donate. Nineteen per cent believe that an increase either in direct payment to donors or in the amount allowable for expenses would help to increase availability. Some clinics (10%) suggest that the limit of live births could be raised to increase availability and three clinics suggested an extension to the current 10 year storage period. There were some suggestions to increase the number of sperm imports (n=5, 8%) and to make changes to current recruitment practice (n=5, 8%). The changes suggested were to recruit more donors locally or to target specific groups of potential donors, such as men who had completed their families or men who were about to undergo vasectomy. There were also suggestions to centralise gamete provision in form of a national recruitment program or a central donor bank.

Some clinics found the current requirements for CMV screening too restrictive and in this context there was one suggestion that in order to make available the CMV positive donors to CMV negative recipients, the CMV status of potentially suitable donors could be matched to that of the patient's partner.

## *2.6 Views on HFEA policies*

Four centres said they had no complaints regarding HFEA policies. Thirty-two per cent of respondents believe that an increase in donor remuneration should at least be considered. Only one clinic registered its explicit opposition to this idea, but four centres said they were satisfied with all HFEA policies which would include its policy on remuneration. Twenty per cent of centres were in favour of an increase to the current limit on live births, but 13% want to see the current limit remain in place. Most centres were satisfied with current screening requirements, but four specifically noted that they were not and found the CMV screening requirements too stringent. Thirteen centres commented on whether there should be an increase in the age limits of sperm donors but they were split evenly on this issue. One centre suggested that the HFEA might consider an extension of current storage limits and one centre registered their concern regarding the EU Tissue Directive.

## **3. Egg donors**

In total, 51 completed questionnaires were received on egg donations. Three did not contain any quantitative data.

### *3.1 Gamete availability*

The survey suggests that from 1 April 2003 to 31 March 2004 a total of 94 altruistic, anonymous egg donors were recruited. In addition, 47 donors were recruited by individual patients and placed in a donor pool. The category with the highest number of egg donors (approximately 176) is that where the donor is known to the recipient.

In the same time period there were 628 egg sharers. Most egg sharers (73%, n=464) had never previously had IVF treatment. Sixteen per cent (n=101) of patients in egg sharing agreements had previously had self-funded treatment.

### *3.2 Recruitment*

From 1 April 2003 to 31 March 2004, 308 women had attended an initial consultation with a view to becoming an anonymous, altruistic egg donor. Of these, 72% (n=222) took advantage of counselling, 33% elected not to continue, 8% were ruled out due to positive lab results and 7% were ruled out due to an unsatisfactory medical history. Therefore, according to the results of this survey, 32% (n=95) of women who had attended an initial consultation with a view to becoming an altruistic, anonymous egg donors went on to complete one cycle of donation.

Sixty per cent (n=31) of questionnaire respondents reported that the recruitment of (anonymous) altruistic egg donors was following a similar trend to previous years. Of the 13 respondents who reported a change in recruitment patterns, eight had observed a negative trend.

It is difficult to estimate the average cost of recruitment since only a few clinics were able to provide an accurate breakdown of their costs. Moreover, the cost

of recruitment seems highly variable and can range from approximately £300 to in excess of £5,000 for a single altruistic egg donor. The reasons for this vary: some clinics have high advertising costs, which raises their total expenditure, for others the majority of the cost is spent on staff time.

The two most successful recruitment strategies for egg donors (reported by 23% of respondents) were adverts placed by patients themselves or recruitment by word of mouth as well as articles or adverts in the local press. However, 10% of respondents also found articles or adverts this to be unsuccessful. Articles in the national press generated mixed success rates with 11% of clinics having success with this method but 17% reporting it to be unsuccessful. Posters in hospitals and clinics were found to be less successful with only 4% reporting this as successful and 11% reporting this method as unsuccessful. Two clinics also reported success in recruiting women who were undergoing sterilization and three clinics found TV and radio adverts successful. Two clinics found publicity surrounding special events to be successful, e.g. patient information evenings or special events held at the clinic.

Twenty-one per cent of clinics reported that they were most successful recruiting egg sharers and 30% of clinics experience difficulty with the recruitment of donors from ethnic minorities.

### *3.3 Supply and demand*

Of all respondents (n=39) to the question on whether they were able to meet demand, 90% said they were unable to meet demand (n=35). Of these, half were unable to meet demand specifically for ethnic minorities whereas the other half reported shortages across all categories.

The results obtained also indicate that the number of patients receiving treatment within an egg sharing agreement is approximately twice the number of patients who undergo treatment with altruistically donated eggs.

Not all clinics completed the questionnaire and some of the percentage data shown below has been adjusted to the number of clinics that provided useful data.

When asked about waiting times for treatment with altruistically donated eggs only 22 centres replied to the question in a quantifiable format. At these centres a total of 172 patients were treated with altruistically donated eggs for the first time between 1 April 2003 and 31 March 2004. Of these 38% had to wait between 12-18 months for treatment, 8% waited between 18 months to 2 years and 17% of these patients had waited for more than 2 years. Overall, 62% of clinics, including those that had not provided useful data regarding waiting lists, attributed waiting times of longer than one year to the *general* shortage of altruistic donors.

A similar distribution of waiting times was seen for treatment provided within an egg sharing scheme. Again, only 18 centres completed the questionnaire fully and were able to be included in the analysis. At these centres, a total of 372 patients, *i.e.* egg recipients who took part in an egg sharing scheme, were treated between 1 April 2003 and 31 March 2004. Of these, 28% waited between 12-18 months, 35% waited 18 months to 2 years and 11% waited for

more than 2 years. According to thirteen clinics waiting times can be attributed to a shortage of sharers egg sharers. Another reason for these waiting times, identified by seven clinics, was the inability to match donors and recipients.

### *3.4 Trends in treatment and recruitment*

Over the last 10 years, 25% of respondents perceived the increase in egg sharing arrangements to have been a significant trend (25%). Twenty-five per cent of clinics also observed either a reduction in altruistic donors or reported difficulties in recruiting altruistic donors. In addition to this decrease in the availability of donated eggs, four clinics explicitly noted an increase in demand for treatment with donated eggs.

Three clinics noted an increase in media coverage and one clinic noted that staff time is increasingly taken up by administrative procedures

The removal of donor anonymity was the most frequently cited factor anticipated to affect egg donation (56%). The majority of respondents (82%) believe that the removal of anonymity will have the greatest effect on these trends. However, 17% believe that this will have little or no effect.

Four clinics predict that NICE guidelines, which recommend free treatment cycles, will result in a decrease in egg sharing.

In view of the forthcoming changes to the law, 33% of clinics said they would make changes to patient information. Ten per cent said they would offer more counselling. Three clinics said they would close their waiting lists and three clinics said they would increase their advertising and/or try different approaches.

Three clinics said they would make changes to their current policy. One clinic is considering a policy which would allow donors to know the result of their donation and numbers of offspring, another clinic was looking into accepting donations from known donors, which had not previously been their policy. Another approach was to use one recipient per donor to allow the waiting list to clear.

### *3.5 Options to increase gamete supply*

Twenty-one per cent of respondents believe that increasing payment or expenses to egg donors would help to improve availability. Some respondents envisage increased payment to reflect compensation for inconvenience whereas others feel they should be used as an incentive to donate. Some (21%) also hold the view that increasing public awareness and more publicity would assist the recruitment of donors.

### *3.6 Views on HFEA policies*

Seventeen per cent of clinics were satisfied with HFEA policies.

The issue of remuneration was much commented on and 30% of respondents are of the view that payment to donors could be increased. In many cases it is not clear whether the increase is meant to capture 'incentive' payments or 'compensation' payments. Ten per cent of respondents believe that current payments to donors are reasonable and should not be increased; again, it is



not clear whether all of these clinics would also be opposed to increases in 'compensation' payments.

Twenty-one per cent of clinics believe that a higher age limit for egg donations could be set. Eleven per cent found current screening requirements for CMV restrictive and believe that they should be removed.

#### **4. Embryo donations**

In total, we received 49 responses.

##### *4.1 General responses*

The number of detailed responses in this category was fairly small; most centres have only limited experience of using donated embryos. However, depending on the centre, there seems to be a reasonable demand for donated embryos. Half (n=17) of all clinics who responded to a question on availability reported that they were not able to meet the demand for treatment using donated embryos. The most common reason cited for this was lack of donated embryos: 23% of respondents report that couples waiting to receive treatment have waited for more than one year.

Eleven per cent (n=5) of clinics report that couples who are initially interested in donating their embryos are subsequently deterred by screening procedures and/or following counselling. Many clinics anticipate that the removal of anonymity of embryo donors will further adversely affect this form of treatment.

#### **5. Conclusions**

This survey has provided a valuable insight into the current status of gamete donation practice in the United Kingdom. The quantitative results generated by this survey and the experiences and views of those involved in the gamete donation process and treatment provision with donated gametes will form an important component of this policy review.

The survey clearly indicates that for both sperm and egg donations the demand for donated gametes continues to be greater than the supply. This is despite some clinics reporting a reduction in demand for donated sperm due to improved medical technology (e.g. ICSI), and suggests that, for sperm donations, at least some of this demand is created by a new class of recipient, *i.e.* single women and lesbian couples. Indeed, this trend has been observed by some clinics. However, a more significant factor contributing to the continuing shortage of gametes seems to be a reduction in the number of donations over recent years. The survey suggests that this trend is more pronounced for egg donations, for which waiting times for treatment of longer than one year is caused almost exclusively by a shortage of donors. By contrast, not many clinics providing treatment with donated sperm were attributing waiting periods of longer than one year to the shortage of sperm,

and the quantitative data received for this survey indicates that waiting times longer than one year are unusual for sperm donations.

The majority of clinics predict that as a result of the removal of donor anonymity the observed trend of fewer donations will continue for at least the foreseeable future. However, other factors, such as the difficulty of matching patients who are CMV negative with suitable donor gametes, were also noted. The demand for donor gametes is great among all population groups but it seems to be proportionally more difficult to find suitable egg donors for recipients from ethnic minorities.

Many clinics believe that it may be possible to improve the provision of treatment services by raising public awareness of gamete shortages and a better understanding of the implications of the removal of donor anonymity in prospective donors. The HFEA will take this opinion into account when making its recommendations under the current review. About a quarter of respondents feel that an increase in remuneration would help to increase the number of both sperm and egg donations. Thirty per cent of respondents also feel that an increase in remuneration should at least be considered as part of the HFEA's policy review. However, for egg donations in a particular there was also some opinion opposing such a change in policy.

The HFEA is aware of the need to take into account the range of opinions that exist with regard to the issue of donor remuneration and of the need to approach this ethically difficult area sensitively. Such concerns would include the difficulty in accounting for income differentials in compensation payments for 'time lost', the danger that differences in expenses payment might create a market place for donations and the concern over higher inconvenience expenses providing a possible incentive for donation, especially perhaps for women from poorer countries. The HFEA's SEED review steering group took into account the results of this survey when it discussed a number of possible options regarding its future policy on payments to gamete donor. These options have already been presented at a recent stakeholder meeting, which helped to confirm and further define these options. In this regard, the survey has already made an important contribution to the HFEA's forthcoming consultation document.

One of the main objectives of this survey was to inform sustainable changes in HFEA policy on the provision of treatment services. The results of the survey indicate several areas which merit further research. For example, the survey indicates that for some clinics national adverts for sperm donors were a successful strategy in the recruitment of donors and further research might reveal the type of advert that would capture potential donors most effectively. By contrast, a successful recruitment strategy for egg donors seemed to be word of mouth or personal adverts placed by patients themselves. In this context, it may be worthwhile to further explore why this strategy is successful as this also might provide further insight into the motivation of such donations.

The survey indicates that many practitioners expect the removal of donor anonymity to have a negative impact on the provision of treatment services with donor gametes. This policy review is designed to support the implementation of appropriate measures to counteract this trend.