



Additional Inspection Report

Centre Name	London Women's Clinic
Centre Number	0105
Name of PR	Geetha Venkat
Name of Inspectors	Parvez Qureshi Andrew Leonard
Date of Visit	12 February 2009
Focus	Information received at the HFEA indicating that payments made to sperm donors by London Women's Clinic centre 0105 were not compliant with SEED review requirements.

With notice	
Short Notice	
Unannounced	✓

Purpose of Visit

This was an unannounced inspection following up on information received at the HFEA that suggested that payments to sperm donors made by the London Women's Clinic (centre 0105) were not compliant with Direction 2006/1.

A renewal inspection of the centre's licence was undertaken in September 2008, during which it was noted that the information for patients donating gametes suggested that payments made to sperm donors were not compliant with the SEED review. It was recommended that the PR review the payments made to donors to ensure that they are compliant with the requirements of the SEED review. This was discussed by the inspection team with the centre staff during the course of that inspection and the PR agreed to amend the patient information to ensure it reflected practice.

The focus of this inspection was to ascertain the centre's compliance with the SEED review requirements, as detailed in Direction 2006/1.

Inspection Activities

The following documents were reviewed during the course of the unannounced inspection to ascertain how payments are made to sperm donors by the centre.

- All information provided to donors by the centre, to verify that its content indicated practices at the centre were compliant with HFEA Code of Practice, 7th edition, requirements and Direction 2006/1.
- The Centre's procedure for assessing and providing donors with compensation for expenses and lost earnings, to ensure that payments are made in compliance with Direction 2006/1 and the Seed Review.
- Records for 10 donors, enrolled approximately 14 months prior to the inspection, and records for 10 donors enrolled in the last 2 months, were reviewed and the dates on which donations were made were listed. Each donor record contained a sheet detailing all payments made to that donor. Payments in these log sheets were reconciled against donation/attendance dates to determine if additional payments had been made. Donor payments were also reconciled against the laboratory sperm processing log book, to ensure that payments made for attending for donation were linked to a laboratory record of processing of the donor sperm.
- An electronic copy of the log of all payments made to all donors on the day of attendance from December 2007 to date and a copy of the electronic log of all payments made to all donors from January 2008 to date, on release of samples from quarantine, to verify that all payments to donors for expenses and lost earnings were compliant with Direction 2006/1 and other HFEA requirements.

In addition to the review of the above documents, discussions were also held with the PR, Donor Bank Manager and Nominal Licensee to discuss compliance and actions to be taken to ensure compliance.

Inspection Observations and Findings

The centre has a log sheet in each sperm donor record recording all payments made to the donor. The centre also has a computer-based general donor payment log noting payments made to all their donors after they have provided their donations. They also maintain a log of secondary payments made subsequent to the samples being released from quarantine for use.

The inspectorate reconciled the dates of payments made to donors in their individual payment record sheet against the laboratory sperm preparation log book, which listed the sperm preparation results for each donor by date. This indicated that most payments matched the dates of donations. Some additional payments were made when the donor had attended to provide blood for screening, for tests on sperm, counselling or a visit to the doctor. These occasions were listed on the donor's payment sheet and in the donor records. The remaining additional payments noted were made when donated samples were released for use after 6 months quarantine.

Electronic records of donor payments were reviewed: no discrepancies were observed between the electronic payment log and the records of individual donor payments reviewed in the course of the inspection.

The centre does not differentiate between recompense for loss of earnings, which is capped at £55.19 maximum per donation and £250 per course of donation, and recompense for legitimate, justifiable expenses, which are unlimited as long as incurred within the UK and 'reasonable'. This is non compliant with directions D2006/1.

A review of donor information and the contents of the email sent out by the centre to potential donors was conducted. An email sent to potential donors stated that donors are paid £20 per donation, then £20 more when a sample is released for use after quarantining. It also stated that over 24 donations, a donor can earn £480, then receive up to another £480 when screened samples are released. This is unlikely to occur as many samples (approx. 60% in the records inspected) are discarded after processing due to quality issues; thus the post screening payment over 24 donations would average around £200.

During the course of the inspection the centre could not provide evidence of a documented rationale for payments made to donors. However, the PR and the Donor Bank Manager explained to the inspection team that in their opinion, prior to September 2009, they considered that the cost to a donor for each donation was £20. This was made up of travel to the clinic and loss of earnings. Since September 2009 the payments were changed to £40 per donation to take into consideration the recent increases in cost of living and the change in centre's interpretation of a course of sperm donation to 6 donations.

The written patient information pack states that a patient is paid £20 per donation, and the centre prefer the patients to donate once a week for a period of 6 months. The post screening £20 payment per released donation is also discussed. There is little discussion

in the patient information about these payments being recompense for lost earnings and legitimate expenses. The centre makes no attempt to justify the money provided to donors against receipts for expenses or a donors lost pay. Therefore, the information provided to patients suggests that payments are non-compliant with Direction 2006/1.

On discussion of the apparent non compliance it was reported that the £20 + £20 rate of payment was instigated in early September 2008: prior to this the centre were paying at a £10 + £10 rate. No records from September 2008 were sampled in the course of the inspection carried out in September 2008. In the course of the inspection the PR reported that it is centre's intention to make payments in future in line with directions D2006/1.

During the course of the inspection, discussions with centre staff showed that they were interpreting a course of donation as lasting 6 donations. Each individual donor payment log sheet logged 6 donations and was annotated with Course 'X', where 'X' is an empty space presumably in which staff were meant to insert the course number. Review of donor records indicated that donors started another 'course' of 6 donations soon after the previous course of 6 had finished. In many cases, donation courses ran consecutively separated by only 1 -2 weeks.

Subsequent to the inspection the PR reported the following:

- The email sent to potential donors has been amended to remove reference to a schedule of payment over 24 donations which was non-compliant with Direction 2006/1. The wording has been changed to reflect practices which are, in the opinion of the inspectorate, broadly compliant with SEED review requirements. The centre should however note that they can pay reasonable expenses (for guidance on what constitutes reasonable then the centre is referred to the guidance notes on the HFEA website that support D2006.1) up to an unlimited sum, as long as incurred within the UK. Donors may also be compensated for loss of earnings (but not for other costs or inconvenience) up to a daily maximum of £55.19 but with an overall limit of £250 for each course of sperm donation. Wording in the patient information email is inaccurate on this point. The PR should also consider informing potential donors in donor information that centre staff may check receipts for expenses, as it is suggested they might make such checks by information on the donor payment log sheet (as discussed below).
- The individual donor payment log sheet, signed by the donor on receipt of all payments, has now been updated and states: 'The payments received above (to a maximum of £250 per course of donation) are to cover expenses, such as travel, child care and loss of earnings. When signing above you are agreeing that this money is reimbursement and not payment. You may be asked to provide proof of this spending to comply with the SEED Review 2005.'
- The PR considers that the requirement for a six month quarantine period for samples provided during a course of donation, does not mean that six months need to elapse before a further donation cycle can be initiated, provided the donation courses are defined and the 10 family limit is observed.

Conclusions

Observations made on inspection suggest that the centre has been making flat-rate payments to donors which have not been justified or documented as being appropriate compensation for loss of earnings and/or expenses. The centre does not differentiate between recompense for loss of earnings, which is capped at £55.19 maximum per donation and £250 per course of donation, and recompense for legitimate, justifiable expenses, which are unlimited as long as incurred within the UK and 'reasonable'. These practices are potentially non compliant with Direction D2006/1.

The donation payment log sheet infers a course of donation as lasting for 6 donations. The centre allow donors to start a new course of donation within 1-2 weeks of the donation which terminated the previous course of donation. This definition of a course of donation varies with the definition provided in Direction 2006/1, which states: "course of sperm donation" means the period beginning at the first consultation and ending once the sample has been released for use in treatment. The centre's alternative definition of a course of donation from that provided in Direction 2006/1, means that their donor payment procedures are potentially non-compliant with Direction 2006/1.

Information provided to individuals considering donation did not inform potential donors that the donation of gametes is voluntary and unpaid with compensation being restricted to expenses and inconveniences in line with the requirements of COP Standard S.7.6.6.

The executive recommends that a condition is applied to the centre's licence requiring the submission of all logs and or records of payments made to donors for a period of 9 months.

The Licence Committee is asked to consider what, if any regulatory sanction or further action should be taken in consideration of this breach.

Agreed outcomes / actions to be take

Recommendations	Timescale
<p>The PR should ensure that payment is made to donors in compliance with Directions 2006/1 and section 12 (1) (E) of the Human Fertilisation and Embryology Act 1990. The PR should review the guidance notes provided in support of D2006/1.</p> <p>All information including email correspondence should be reviewed to ensure that before individuals consider donation, those individuals: have received all the required information; understand that the donation of gametes is voluntary and unpaid, compensation being restricted to expenses and inconveniences in line with the requirements of COP standard S.7.6.6.</p>	<p>Non compliant payment of donors to cease immediately and the HFEA to be provided with copies of revised standard operating procedures for payment of donors and donor information by 12 April 2009.</p>

The PR should review the way payment to donors is logged in consideration of guidance provided at G.4.11 of the COP which recommends that centres procuring gametes or embryos from donors should maintain a central log of all expenses and compensation paid to donors containing information about the date, amount, recipient and reasons for each payment.

Complete the box below only if conditions will need to be imposed, varied or removed

As a result of this visit the following recommendations are made:

The executive recommends that a condition is applied to the centre's licence requiring the submission of all logs and or records of payments made to donors for a period of 9 months.

Date (where applicable)

Next action

Review of response from the PR regarding the findings of the unannounced inspection.

Report completed by

Signed _____

Name **Parvez Qureshi**_____

Designation **_ Inspector**_____

Date **27 February 2009**_____

Appendix C: Response of Person Responsible to the inspection report

Centre Number.....0105.....

Name of PR.....Dr Geetha Venkat.....

Date of Inspection.....12 February 2009.....

Date of Response.....08 April 2009.....

I have read the inspection report and agree to meet the requirements of the report.

Signed.....

Name.....Dr Geetha Venkat.....

Date.....08 April 2009.....

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

N/A

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

Background and HFEA Recommendation

We are in receipt of the Additional Inspection Report issued after an unannounced inspection on 12 February 2009. The report states that we did not differentiate between loss of earnings (capped at £55.19) and recompenses for legitimate, justifiable expenses. It further stated that ‘...practices are potentially non compliant with Direction D2006/1’. In addition, our understanding of a ‘course of sperm donation’ varies from the definition in Direction D2006/1. The report recommends that the centre ensure that payments to donors should be in compliances with Direction D2006/1.

Analysis

I have reviewed the guidance notes provided by supporting document D2006/1. Meetings between me and senior personnel followed and revised protocols were discussed. As the meeting progressed there was growing recognition that the functioning of the sperm bank, which is already under pressure, could become even more difficult.

Response

However, we decided on the following course of action. Any inconvenience, including loss of earnings suffered by the donor will be compensated to a maximum of £250 per course of

donation. At no time will that exceed £55.19 per donation.

The information provided to potential donors has been revised, so that it is clear that donation of gametes is voluntary and unpaid. Compensation will be limited to reasonable expenses the donor incurs. Available receipts will always be requested and stored. In addition, in future donors will also be requested to confirm in writing the money spent whilst attending the bank.

With effect from 12th April 2009, we have improved the format of the central log of all the payments. Expenses and 'compensation' are logged separately.

Concerns

In response to what constitutes a course of donation we have again studied the SEED Review in conjunction with the Direction D2006/1. Technically the interpretation of a course of donation provided in the report is clear and we wish to abide by it. However, we are concerned that such a rigid interpretation is potentially counterproductive. Consider the example of a volunteer donor, recruited after considerable expense and effort, who is happy to donate on a regular basis but may only be able to donate one course of samples over many months. Supplies of sperm, already historically low in the UK, could further reduce the options available to patients

3. Please state any actions you have taken or are planning to take following the inspection with time scales

See above

We welcome comments about the inspection on the inspection feedback form, a copy of which should have been provided at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF