Inspection Report - Interim

Leicester Fertility Centre
Leicester Royal Infirmary

Date of Inspection: March 4th 2008
Date of Licence Committee: May 21st 2008

CENTRE DETAILS

Centre Name	Leicester Fertility Centre
Centre Number	0068
Licence Number	L0068/14/b
Centre Address	Assisted Conception Unit Womens Hospital Leicester Royal Infirmary Leicester LE1 5WW
Telephone Number	0116 258 5922
Type of Inspection	Interim
Person Responsible	Jane Blower
Nominal Licensee	Alan Davidson
Inspector(s)	Ellie Suthers, Tony Knox, Steve Lynch
Fee Paid – up-to-date	Yes
Licence expiry date	30th September 2010
NHS/Private/Both	NHS and Private

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About the Inspection:
This inspection visit was carried out on 4th March 2008 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between 2007 and 2008

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

This small to medium sized centre was first licensed in 1992 and provides both private and NHS funded treatments to patients primarily from the local area. There has been no change in the types of treatment offered or in the number of patients seen or treated since the last inspection.
The centre is appropriately resourced and staffed to establishment: there has been no change in the number of staff employed since the last inspection.

The centre is a dedicated self contained unit with secure access within Leicester Royal Infirmary. The person responsible is Jane Blower who has been in post since 21st November 2007 and is appropriately qualified and experienced for the role. (PREP completed November 2007

Treatment at the Centre was stopped at the beginning of January 2008 in order to undergo refurbishment. Following an interim inspection and initial report submitted to the Licence Committee of 6th March 2008 treatment restarted on 10th March 2008

Activities of the Centre: Number of treatment cycles taken from 31/01/07 to 01/01/08

Licensed treatment cycles	IVF ICSI FET Egg sharing Egg donor (provider)	213 170 96 6
Donor insemination		36
Research	No	
Storage	Yes	

*"This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA on our website is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems."

Summary for Licence Committee

The Centre has undergone expansion and refurbishment of facilities since the last renewal inspection. The inspection team consider the centre to have been furbished to an appropriate standard and its general premises and clinical facilities are appropriate for licensed activities. Polices and protocols have been developed and implemented to reflect refurbishment changes.
Improvements should be considered in the following areas:
- Average time taken to pay required HFEA invoices;
- Staff compliance with University Hospital of Leicester NHS Trust Health and Safety policies;
- Potential breaches in patient confidentiality during counselling and or treatment sessions;
- Storage arrangements in the centres cryo-store
- Service user information must not offer “payment” for sperm donation:

The inspection team recommends the continuation of centres licence.
The centre has requested that the treatment of GIFT be removed from its licence.

Risk Assessment

Following the Interim inspection on March 4th 2008 with information and data available to the HFEA inspection team the risk score is assessed as 16%. This constitutes as low level risk status analysed by the HFEA Regulation Risk Assessment Tool Version 3

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		**X**	
2. Quality of the service		**X**	
3. Premises and Equipment		**X**	
4. Information		**X**	
5. Laboratory and clinical processes	**X**		

Breaches of the Act Standard Licence Conditions or Code of Practice: The table below sets out matters which the inspection team considers may constitute breaches of the Act, Standard Licence Conditions and/or Code of Practice and their recommended improvement actions and timescales. The weight to be given to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee

Breach	Action required	Time scale
1. For the year up to February 2008 the average time taken to pay HFEA invoices was 74 days. The HFEA Finance department noted prior to the inspection that there is an invoice in dispute with the Centre. *(CoP A.16.3)*	The PR should resolve the dispute with the Finance department of the HFEA	Within 3 months of this inspection date
2. It was observed by the inspection team that a laboratory fire door was wedged open for a period of time at the time of inspection. This represents a hazard to the safety of the staff and service users. *(CoP S.6.3.2)*	Staff must follow the available University Hospitals of Leicester NHS Trust Health and Safety policies and procedures	Immediately
3. During the inspection the inspector noticed that conversations at normal	A risk assessment should be carried out on the specified areas on the potential for	Three months from the date of this inspection

volume could be heard between the counselling room and the adjacent treatment room. This could result in breaches in patient confidentiality if counselling sessions can be over heard. *(CoP S.6.3.5 & S.7.2.1)*	breaches in confidentiality and remedial action taken.	
4. One of the information leaflets observed by the inspection team noted that "payment" was offered for sperm donation." *(CoP S.7.6.6 (b)*	The PR should withdraw the information leaflet immediately and remove the offer of "payment" from the information leaflets and amend to reflect a reimbursement of expenses for sperm donation	Immediately

Non-Compliance

Area for improvement	Action required	Time scale

Recommendations	Time scale
1. The storage room is small, cramped and may have health and safety issues for staff working in this environment and/or in the case of emergency. Consideration should be given to reallocation of space within the centre to provide a larger space for cryo storage. *(CoP S.6.3.2)* **Recommendation:** The PR to arrange for a risk assessment to be carried out on the cryo store environment and recommended actions carried out.	Before the next inspection
2. A double magnetic door/access system is in place leading into the main hospital. It was suggested by the PR that this would stay open during working hours. The inspection team suggested this may be inappropriate as members of the public could access the unit unobserved by the staff, compromising security. **Recommendation:** Although not a specific requirement of the Act, Standard Licence conditions or the Code the PR should carry out a security risk assessment on how this door can be used for observable access while maintaining security.	Before the next inspection

3. Both the nurses and embryologist provide voluntary out-of-hours services which are based on the goodwill of the staff and are unpaid by the University Hospitals of Leicester NHS Trust. **Recommendation:** Although not a specific requirement of the Act, Standard Licence conditions or the Code I would recommend that the PR and Directorate Manager should risk assess if there were a change in custom and practice and this is not done voluntarily by the staff how would the out of hours requirements be met	Before the next inspection
4. It was noted post inspection that the reported OHSS rate was 8.93% which is higher than the national clinical acceptable rate of approximately 2%. On discussion with the PR the inspector was informed that many woman admitted to the gynaecology ward having undergone or undergoing infertility treatment may have a differential diagnosis of OHSS written in the notes and may be coded as such. **Recommendation:** Although not a specific requirement of the Act, Standard Licence conditions or the Code I would recommend that the PR assess the OHSS policy in terms of diagnosis and reporting in order to provide a clearer picture of OHSS incidence.	Before the next inspection

Proposed licence variations by last L.C.

None

Changes/ improvements since last inspection

All breaches, non compliances and recommendations from the Renewal Inspection report on the 7th of June have been addressed, action taken and issues resolved.

Additional licence conditions and actions taken by centre since last inspection

No additional licence conditions

Date	**Action taken**
	N/A

Report of Inspection findings

1. **Organisation**
Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees

Areas of firm compliance
Leadership and management: The Person Responsible has completed the HFEA PR entry programme and is considered appropriately qualified and experienced for the role. *(CoP: S.4.1.5: S.4.1.4)* Training logs are maintained by each member of staff which contained evidence of Continued Professional Development, competency assessment and mandatory training. The Centre appears to have sufficient numbers of staff, with the competence to perform their designated tasks. *(CoP 6.2.1)* **Organisation of the centre:** There are clear organisational accountability and reporting relationships which was demonstrated via an organisational chart and during interviews between the inspection team and centre staff. *(CoP:S.4.2.6)* The PR was present for the inspection and provided all the information requested both written and verbal. Each member of staff approached appeared to the Inspectors to know about the inspection process and provided information and comment when asked. *(CoP: S.4.1.3)* **Out of Hours:** The two senior nursing staff provides a voluntary out of hours service, and full weekend on call for service users who may be experiencing difficulties. Two senior embryologists provide a voluntary out of hours and full weekend on call service for contact in the case of dewar storage failure. **Risk Management:** Risk management and clinical governance strategies are employed following the University Hospital of Leicester NHS Trust policies and procedures.

Incident management:
The inspectors observed a documented procedure for the identification, investigation, control and recording of adverse incidents. The documentation was seen to be up to date and complete. Staff demonstrated their knowledge and understanding of the incident procedures during interviews with inspectors and in observed centre meeting minutes. Documented evidence was observed for the requirements of reporting to the HFEA.*(CoP S.9.4.1)*

Contingency arrangements:
Contingency arrangements are in place in case of emergency with Nurture and University Hospitals for Coventry and Warwickshire

Areas for improvement

For the year up to February 2008 the average time taken to pay HFEA invoices was 33 days. The HFEA Finance department noted prior to the inspection that there is an invoice in depute with the Centre. (*CoP A.16.3)*

Areas for consideration

The PR has been informed by the University Hospitals of Leicester NHS Trust that funding for mandatory training and CPD will be greatly reduced next financial year (2008/09). The PR should be mindful of the requirements of the Code of Practice in forward planning *(S.6.2.7 & S.2.11)*

Both the nurses and embryologist voluntary out-of-hours services are based on the goodwill of the staff and are unpaid by the University Hospitals of Leicester NHS Trust. The PR and Directorate manager should risk assess this practice. If there were a change in custom and practice and this is not done voluntarily by the staff how standards would be met?

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

Business planning

Evaluation

Some improvements required

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates

Live Birth Rates
Data obtained from the HFEA registry shows that for the period April 01 2003 to March 31st 2006: Relative live birth success rates for DI/FET and IVF/ICSI were no different to the national average in all age ranges *except* IVF/ICSI > 35years which was significantly below the national average.
Areas of firm compliance
Quality Management System: The PR and staff within the unit have demonstrated a commitment to the establishment and maintenance of a Quality Management System (QMS) The PR is the centres consultant embryologist and also the quality manager. The QMS was considered at the time of inspection to be appropriate. A comprehensive Quality Manual has been established using the Centres electronic system; protocols etc are readily available in paper format located in the central corridor of the centre. The inspection team saw evidence of version control and review. The Centre has successfully achieved ISO 9000 certification. *(CoP: S.4.2.1)* **Monitoring and resolution of complaints:** The Centre has a written procedure in place for the acknowledgment and investigation of complaints, as well as collecting suggestions and compliments from service users. The complaints process followed is as per the University Hospitals of Leicester NHS Trust policy. Inspectors observed that records of complaints and their investigation together with the corrective action are kept in the centre. *(CoP S.9.2.2).* A service user suggestion box was observed in the main waiting area and the centre staff informed the inspection team that suggestions are reviewed and discussed at centre meetings. An audit of 25 HFEA patient questionnaires showed a high level of service user satisfaction and no complaints were raised. **Staff Suggestions:** Staff suggestions and participation in day to day changes and new developments are demonstrated in meeting agendas and minutes. This was corroborated by staff interviewed by the inspection team. *(CoP S.9.2.3)*

Areas for improvement
It was observed by the inspection team that a document about sperm donation was available to centre staff which did not appear to be accurate or to be version controlled. This was discussed with the PR who assured the inspection team that this would be rectified immediately. *(CoP S.5.2.5)* It was noted post inspection that the reported OHSS rate was 8.93% which is higher than the national clinical acceptable rate of 2%. On discussion with the PR the inspector was informed that many woman admitted to the gynaecology ward having undergone infertility treatment may have a differential diagnosis written in the notes and may be coded as such.
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection

Evaluation
Some improvement required

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Areas of firm compliance
General suitable premises: The Centre is a dedicated self contained unit with secure access within Leicester Royal Infirmary. Recent refurbishment and extension of premises has increased space substantially providing a new embryology laboratory: three additional consulting rooms; new counselling room; and an additional production room. The PR assured the inspection team that all new rooms have been risk assessed according to University Hospitals of Leicester NHS Trust risk management requirements by the Centre staff in accordance with the Trust Risk Management requirements and apart from the confidentiality issues in the counselling room found to be fit for purpose. All laboratories have key pad locks and self close doors: The external doors to the Centre have magnetic locks and open into an adjacent outpatient department. The inspection team consider the centre to have been furbished to an appropriate standard and its general premises and clinical facilities are appropriate for licensed activities. *(CoP S.6.3.2)* **Laboratory facilities:** The laboratory environment was observed "at rest" as the treatment had not yet begun following refurbishment. The inspectors observed that the laboratory facilities were appropriately maintained to suit intended purposes. An environment has been provided in order to protect the quality and safety of gametes and embryos, appropriate monitoring had demonstrated the required air quality. *(CoP S.6.3.6)* Storage of gametes and embryos is in a designated security area with controlled access is well ventilated, all dewars were seen to be individually locked equipped with independent radio frequency alarms and are on an auto dial facility. *(S.6.3.8)* **Control of records:** The centre is part of a larger organisation University Hospitals Leicester NHS Trust and follows the policies and procedures in order to ensure information provided in confidence by service users is kept confidential. *(CoP S.7.2.1)* Health records were seen to be stored securely in well organised lockable cupboards in the main administrative area. *(G.10.2.1)*

During interview the member of staff responsible for maintaining the records library demonstrated a practical knowledge and understanding of records management, storage and confidentiality.

Staff facilities:
The centre provides suitable and appropriate facilities for staff including basic catering facilities. *(CoP S.6.3.13)*.

Areas for improvement

Confidentiality:
During the inspection the inspector noticed that conversations at normal volume could be heard between the counselling room and the adjacent treatment room. This could result in breaches in patient confidentiality if counselling sessions can be over heard. *(CoP S.7.2.1& S.6.3.5)*

Health and Safety:
It was observed by the inspection team that a laboratory fire door was wedged open at the time of inspection. This represents a hazard to the safety of the staff and service users. Fire safety protocols were observed by the inspectors, these must be adhered to *(CoP S.6.3.2)*

Areas for consideration

Cryo-store:
The cryo-store room currently houses 19 dewars including those not currently in use and top up vessels as well as centre's clinical stores.
The storage room is small, cramped and may have health and safety issues for staff working in this environment and/or in the case of emergency. In light of the fact that the centre has plans to increase sperm storage activity consideration should be given to reallocation of space or/and relocation of some of the stores within the centre to provide a larger space for cryo storage.

External Security:
There are two double magnetic door/access system is in place leading into two locations in the main hospital. One of which is kept permanently closed it was suggested by the PR that the other one would stay open during working hours. The inspection team suggested this may be inappropriate as members of the public could access the unit unobserved by the staff, compromising security. A risk assessment of possible security/access through this door should be carried out to promote secure access.

Executive recommendations for Licence Committee

None

Areas not covered on this inspection

Risk Assessments: other than those done as part of the facilities refurbishment

Evaluation

Some improvements required

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

1. General Information
2. Meetings and communication
3. HFEA Alerts
4. Welfare of child
5. Confidentiality and access to health records
6. Traceability and coding
7. Coding/ identification of samples
8. Information for service users/consents
9. Donor information
10. Donor registration
11. Surrogacy
12. Procurement and distribution of receipt of gametes and embryos
13. Home procurement report documentation
14. Packaging &distribution
15. Labelling of packages containing procured gametes
16. Transportation, labelling of shipping container and recall
17. Receipt of gametes

Areas of firm compliance
General information: Display boards in the access corridor and main reception area have posters showing the Centres in-date HFEA Licence, ISO 9000 certification and an NHS Quality & Service Award. Also displayed are photographs of staff working in the Centre, various information leaflets including about PALS and how to make a complaint, including how to make a complaint directly to the HFEA. **Meetings and communication:** Weekly general meetings and monthly administration meetings where all appropriate staff are required to attend: The agenda was seen to include: day to day clinical updates: changes in buildings and facilities: pregnancy rates and HFEA Alerts. Dated minutes were observed by the inspection team. The centre appears to have an effective means to communicating information to staff. *(CoP S.6.2.13)* **Confidentiality and access to health records:** The centre is part of a larger organisation University Hospitals Leicester NHS Trust and follows the policies and procedures in order to ensure information provided in confidence by service users is kept confidential. *(CoP S.7.2.1)* Health records were seen to be stored securely in the lockable cupboards in the main administrative area. Archived health records were also seen to be appropriately securely stored in a locked room in locked cupboards in another part of the hospital *(CoP G.10.2.1)* During interview the member of staff responsible for maintaining the records library demonstrated a practical knowledge of records management, storage and confidentiality.

Information for service users/consents:
Service user information has recently been reviewed in accordance with the QMS and ISO 2000 Registration. Information received prior to inspection, during inspection and during interviews with staff appears to show that the centre ensures that before individuals give consent to treatment are given appropriate and sufficient information on which to make their decision on treatment. *(CoP S.7.4.1)*

A comprehensive Quality Manual has been established using the Centres electronic system; protocols etc are readily available in paper format located in the central corridor of the centre. The inspection team saw evidence of version control and review. The Centre has successfully achieved ISO 9000 certification. *(CoP: S.4.2.1)*

Service user information provide by the centre and observed during the inspection by the inspection team appeared to contain sufficient information on which services users could make decisions on treatment. *(CoP S.7.4.1)*

Consent audit:
Five sets of health records were audited. All were found to be in good order. All audited consent forms were relevant to treatment, complete taken by the appropriate person and stored appropriately. *(CoP S.7.5.1).* The centre carries out a weekly audit on records.

Areas for improvement
One of the protocols observed by the inspection team noted that "payment" was offered for sperm donation. This was brought to the attention of the PR who agreed to withdraw the document from circulation and amend the word "payment" to "reimbursement" as is their practice. *(CoP S.7.6.6 (b))*
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None

Evaluation
Some improvement required

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

1. Laboratory processes
2. Selection and Validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing

Full time equivalent staff

GMC registered doctors	5
NMC registered nurses	5
HPC registered scientists	1+1 Andrologist
Scientists working towards registration	5
Support staff (receptionists, record managers, quality and risk managers etc)	8 staff: 1x senior administrator: 1 x administrative officer: 2 x clerical officers: 3 x team support workers: 1 x unit domestic
Counsellors	2

Summary of laboratory audit / Audit of records

Summary of spot check of stored material
Four embryos were tracked from the records to the tank and visa versa: no discrepancies noted. Four sperm sample was tracked from the records to the tank and vice versa: no discrepancies were noted. *(S.7.3.1)* Evidence of splitting patient embryos between dewars was also observed for oncology patients.

Areas of firm compliance
Laboratory documented procedures: Laboratory documented policies and procedures have been reviewed and modified following refurbishment of laboratory facilities and relocation of equipment. The documents were seen to be fit for purpose. The PR provided evidence to the inspection team that there is sufficient, suitably qualified laboratory staff working within the Centre (S.6.2.1). **Counselling:** Counselling is promoted within the centre and the centre ensures that service users are given suitable opportunity to participate in counselling about the implications of their proposed actions. The counselling service was seen to be provided independently of the clinical service

by two appropriately qualified counsellors. *(S.7.6.1 & G.1.4.2)*
The Head of Nursing/Counsellor sees all patients under the age of 18 to explain treatment and consent.

Witnessing:
Protocols and procedures are in place to ensure the safe handling of samples within the laboratory which were considered fit for purpose by the inspection team. All witnessing steps, in the records observed by the inspection team were seen to be being performed according to Directions D2004/4

Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
As the laboratory and clinical areas have been out of use for four weeks it was not possible to see the laboratory staff at work Nor to the see the “patient flows” through the department

Evaluation
No improvements required

Report compiled by:

Name Mrs Ellie Suthers

Designation Inspector HFEA

Date April 25th 2008

Appendix A: Centre Staff interviewed

Jane Blower, PR plus 5 members of clinic staff
1 patient

Appendix B: Licence history for previous 3 years

2007
Licence Committee 7th June 2007
Renewal Inspection – Licence continued

2007
Licence Committee 21st March 2007
Application to vary the centres licence presented to include egg freezing: This was approved

2006
Licence Committee 18th December 2006
Application taken to Licence Committee to change the PR. This was approved

2005
Licence Committee 31st October 2005
Conditions removed from the centres licence

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0068

Name of PR Dr Jane Blower

Date of Inspection March 4th 2008

Date of Response April 17th 2008

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

Signed……

Name…….

Date……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

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

Recommendation 1
I have completed the risk assessments regarding the cryostore arrangements and the breaches of confidentiality from counselling/treatment sessions, and have forwarded these to the UHL Trust for appropriate action.

Breach 5
I can confirm that the paperwork for sperm donors is now version controlled and the references to payment have been removed,

Recommendation 4

I am investigating the OHSS rate given in the inspection report. I have emailed our QA officer in the registry department for more information and this was her response:

"The number of OHSS has come from 1/4/2003 – 31/03/2006 time period and is for 66 cases from a total of 739 fresh stimulated treatments (1227 treatments overall for this period). The parts of the (old IVF) form the information comes from is section 8 if OHSS is ticked or Hyper-stimulation is indicated in the 'other' field and section 10 again if OHSS is ticked or Hyper-stimulation is written in the 'other' field."

It would appear that this high rate is related to the coding that we have used when sending treatment forms to the HFEA.

Section 8 referred to on the forms asks: If egg collection was abandoned or 0 eggs were collected.
One of the response options is: Risk of OHSS. We have used this response to indicate the cycle was cancelled in order to avoid OHSS, not that the patient had OHSS.
The same relates to section 10 of the IVF treatment forms, when viable embryos were available but not replaced. One of the response options is:
Risk of OHSS, again we have used this option to indicate embryos were not transferred to avoid OHSS, rather than the patient having OHSS.

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

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF