HFEA Executive Licensing Panel Meeting

2 May 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 4

Centre 0299 – (CREATE Centre for Reproduction and Advanced Technology) – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Dee Knoyle
David Moysen – Head of IT	**Also in attendance:**
Nick Jones – Director of Compliance & Information	Sam Hartley – Head of Governance & Licensing
	Sue Gallone – Director of Finance & Resources

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that CREATE Centre for Reproduction and Advanced Technology is located in West Wimbledon, London and has held a licence with the HFEA since August 2008. The centre provides a full range of fertility services.

2. The Panel noted that the centre is currently on a four-year licence, due to expire on 31 July 2016.

3. The Panel noted that the inspection took place on 25 February 2014.

4. The Panel noted that in the 12 months to 31 December 2013, the centre provided 780 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

5. The Panel noted that HFEA-held register data for the year ending December 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

6. The Panel noted that for the year 2012, the centre reported 47 cycles of partner insemination with one pregnancy. This is consistent with the national average.

7. The Panel noted that for the year 2013, the centre reported 32 cycles of partner insemination with no pregnancies. This is consistent with the national average.

8. Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 21%. This represented performance that was not statistically different from the 20% maximum multiple live birth rate target for this period.

9. Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. This represented performance that was not statistically different from the 15% maximum multiple live birth rate target for this period.

10. The Panel noted that at the time of inspection there were four major areas of non-compliance identified. The Panel noted the constructive response and commitment of the Person Responsible (PR) to fully implement the recommendations within the prescribed timescales.

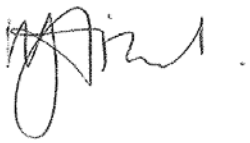
11. The Panel noted the progress made by the centre in meeting the HFEA multiple birth rate targets and congratulated the centre.

12. The Panel noted that the Inspectorate recommends the continuation of the centre's licence.

Decision

13. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its licence continued.

14. The Panel approved the Inspectorate's recommendation to continue the centre's Treatment and Storage Licence with no additional conditions.



Signed: Date: 19 May 2014

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: CREATE Centre for Reproduction and Advanced Technology
Centre number: 0299
Date licence issued: 01/08/2012
Licence expiry date: 31/07/2016
Additional conditions applied to this licence: None
Date of inspection: 25/02/2014
Inspectors: Mrs Susan Jolliffe (Lead), Dr Victoria Lamb
Date of Executive Licensing Panel: 02/05/2014

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence. In particular we note the progress made by the centre in meeting the HFEA multiple birth rate targets.

The Executive Licensing Panel is asked to note that there are four 'major' areas of non-compliance.

In providing feedback on this report the PR provided evidence that the following recommendations have been implemented;

- The PR should ensure gametes and embryos are stored within their consented storage period.
- The PR should ensure that all licensed treatment activity is reported to the HFEA within the timeframes required.

The PR has provided assurance that the following recommendations will be implemented.

- The PR should ensure that the witnessing steps to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process, are performed and recorded in the patient records.
- The PR should ensure that consent to disclosure of identifying information to researchers is submitted accurately to the HFEA.

Information about the centre

CREATE Centre for Reproduction and Advanced Technology is located in West Wimbledon and has held a licence with the HFEA since August 2008.

The centre provides a full range of fertility services and provided 780 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2013. In relation to activity levels this is a medium size centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Outcomes[1]

HFEA held register data for the year ending December 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2012 the centre reported 47 cycles of partner insemination with 1 singleton pregnancy. This is consistent with the national averages.

For the year 2013 the centre reported 32 cycles of partner insemination with no pregnancies. This is consistent with the national averages.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 21% : this represented performance that was not statistically different from the 20% multiple live birth rate target for this period.

Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 13% : this represented performance that was not statistically different from the 15% multiple live birth rate target for this period.

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[1] 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.

[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

Between 1 October 2012 and 30 September 2013, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 16%: this represented performance that was not statistically different from the 10% multiple live birth rate target for this period.

The progress in reducing the clinical multiple pregnancy rates from 2010/11 to 2012/13 suggests that the centre was proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target of 10% live birth rate, introduced in October 2012.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: egg collection; sperm preparation. All of the procedures observed were witnessed in accordance with HFEA requirements using a manual system.

The inspection team was able to review 10 sets of patient records and concluded that records of manual witnessing are maintained, with the exceptions noted below.

- In two records, the witnessing step of the disposal of gametes/embryos was not documented in the patients' record (Recommendation 2).
- In one record, the time of the witnessing step to cross check the embryo dishes against patient documentation and patient identification at embryo transfer was not recorded (Recommendation 2).

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 20 patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in only six of the records reviewed.

In five cases the documented consent decision indicated that consent to disclosure had been given by the patients, but the HFEA register indicated that consent had not been given.

In nine cases the patient had not been registered with the HFEA, by the centre. Therefore there was no record of their consent decision. (Recommendation 4).

Consent: To the storage of cryopreserved material

A review of the centre's database indicated that gametes and embryos currently in store are being stored within their consented storage period with the exception detailed below.

The embryos for one couple are currently being stored beyond their consented storage period. The consent expired on 11 February 2014.

A storage review has recently been performed and the centre's intended actions with respect to these embryos have been identified. The actions being taken by the centre were discussed and considered by the inspection team to be sufficient to ensure that these embryos can continue in storage with appropriate consents in place

The centre has a bring forward system in place to manage stored material at the end of the consented period. However, in this case, the centre experienced delays in being able to obtain a response from the couple within the planned timescale (Recommendation 1).

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: the atmosphere in the clinic appeared busy but calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit we spoke to five patients who provided feedback on their experiences, and we observed interactions between centre staff and patients. A further 17 patients also provided feedback directly to the HFEA in the time since the last inspection. Twelve of the individuals providing written feedback to the HFEA commented that they had compliments about the care that they received commenting on the caring and professional approach that they experienced.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- is a busy centre, which can impact on waiting times, but this does not detract from the patient experience.
- maintains an effective system for responding to patient phone calls.

The centre conducts patient satisfaction surveys on a regular basis and the most recent survey results from February 2014 were provided on inspection. No trends or themes were noted. Positive feedback was seen, and any constructive or negative comments are taken to the monthly clinical meetings for discussion and action.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self-assessment questionnaire and from observations during the visit to the centre, the inspection team identified no additional non-compliances.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2012 recommendations were made in relation to four major and two 'other' non-compliances.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

The centre has received one HFEA alert in the last six months regarding their success rates, which has been addressed.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

The HFEA information team consider that the centre is partially compliant with register submissions because the centre has had four alerts in the last six months for providing 'treatments with unregistered donors.. (Recommendation 3)

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

‘Critical’ area of non compliance

A ‘critical’ area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A ‘critical’ area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None noted			

‘Major’ area of non compliance

A ‘major’ area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Consent for storage On the day of the inspection the centre did not have written effective consent for the storage of one set of cryopreserved embryos. (Schedule 3, 8(2) HF&E Act).	The PR should update the lead inspector with the consent decision, for the one set of embryos seen at inspection without written consent, by 25 March 2014. The PR is reminded of guidance issued by the HFEA in CH(03)03 http://www.hfea.gov.uk/2687.html in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should	This couple had given a verbal consent to continue with storage of their embryos at the time of the inspection. We were waiting for written consent forms. The couple came in for a follow up consultation following our contact with them and we have received the signed ES forms from her and her partner. We have a robust SOP to ensure that timely contact is made and correspondence is sent out in advance of the expiry date for storage of	The PR has informed the inspector that the centre now has effective consent for the set of embryos. No further action is required.

	there be a possibility of legal challenge to the disposal of cryopreserved material.	cryopreserved material. The staff are fully aware of this SOP .	
2. Witnessing The centre does not double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. On inspection, the patient record audit showed that; • the time of one witnessing step was omitted. • the disposing of gametes/embryos was not recorded in two records. (SLC T71) (CoP 18.8(b) and 18.4(j)).	The PR should take immediate action, to ensure that no treatments are provided without witnessing procedures being implemented to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. The lead inspector should be advised of the measures taken to ensure that this happens by the time this report is considered by the ELP on 02 May 2014. Within three months of the inspection, the centre should conduct an audit of witnessing and a summary report of the findings of the audit should be provided to the lead inspector. By 25 May 2014	The centre always double-checks the identification of samples and the patients or donors to whom they relate to at all critical steps. In fact the inspector has observed egg collections and sperm preparations during the inspection and has observed that all relevant steps are witnessed both in theatre and in the laboratory. The inspector has also had the witnessing form explained and has been shown that all steps are being covered for the procedures that the inspector was not able to observe during the inspection. During the inspection, one patient record showed that the time of one witnessing step was not recorded. Only the time of witnessing was missing in the records. The witnessing had been done and recorded but it	The PR has been proactive in addressing the issues raised, and following a review at the laboratory meeting, the witnessing SOP has been reviewed. A prospective audit has been started regarding witnessing and is expected to be completed 17 April, and a retrospective audit will be completed in May. The lead inspector will follow this up through the post inspection monitoring.

		was only the time that was not recorded. The disposing of gametes/embryos was not recorded in two records. We are aiming to go paperless in the near future and we are encouraging staff to record on IDEAS as much as possible. We found that the disposing step was recorded on IDEAS in these two cases. Since the implementation of IDEAS that particular step has been recorded on IDEAS only. The SOP has been changed after the inspection so that this step is recorded on paper in the witnessing sheet. The updated SOP has been reviewed in a laboratory meeting and a prospective audit has been started regarding witnessing which will last 1 month (17.3.2014-17.4.2014) to ensure that this step is included in the paper-witnessing sheet. A retrospective audit will be started in the first week of May,	

		the results of the audit will be sent to the HFEA.	
3. Treatment with unregistered donors The PR has not provided the information required by the Authority within the timescales required; The centre has had four risk tool alerts in the last six months for 'treatments with unregistered donors'. (SLC T9(e) / T41) (General Directions 0005).	The PR should review the process for inputting data, and identify if this is a training issue for staff, and address any identified training needs. The outcome should be shared with the lead inspector by 25 May 2014. The standard operating procedure (SOP) for submission of data to the HFEA should be reviewed and shared with the lead inspector to ensure it is compliant, by 25 March 2014. An action plan to correct outstanding errors should be submitted to the lead inspector by 25 March 2014.	There were several different types of errors regarding donor registration. One was missing donor information, which has been completed and sent to the HFEA. This error involved 1 patient. The second type of error was that the donor was registered with his own registration number from the donor bank to EDI but since that number already existed on IDEAS as a patient number the donor was assigned a new number in the clinic records on IDEAS. On the EDI treatment form the donor number appeared as it is on IDEAS but HFEA had the register with the initial donor bank number. A correction to the donor information form has been submitted. This error involved 3 patients.	The PR has reviewed the process for inputting data and has identified a number of key issues. 1. Staffing - A full time EDI co-ordinator is now in post. 2. The SOP- ' EDI protocol' has been reviewed. 3. Training needs - The HFEA register team worked with staff at the centre on 28 February, to provide support and training for key staff at the centre. Any future outstanding errors will be monitored by the inspector, who will liaise with the HFEA register team.

		The third error occurred with a donor imported from centre 0119. Since this donor was already registered by centre 0119, the donor registration from has not been done at Create. The initial gamete movement in the form did not have a record of the DI number from centre 0119. A correction to the gamete movement in the form has been created where this number has been included. In the initial the treatment form, the origin of the donor was put as Create by mistake, which has been changed in a correction form to centre 0119. This error involved 1 patient. We experienced some problems with the linkage between IDEAS and EDI. We have appointed a full time EDI co-ordinator who will deal with EDI and data registration. This should facilitate regular reviews to identify any errors and avoid delays. This is an important	No further action required.

		positive step we have taken. The problems with EDI have been addressed on the 14th of March 2014 with the HFEA Register Information Team Leader Cathy Hodgson at a meeting at Create Fertility where all staff involved in EDI has been present. All errors, problems and questions were identified and addressed. Following this meeting all staff involved in EDI registration including the new EDI coordinator have gone over the SOP and have updated it. The new SOP was sent to Susan Joliffe on the 14th of March. Any further errors that arise will be corrected immediately and for any problems the HFEA Register Information Team will be contacted. All current errors have been corrected. There is one donor information number missing which needs to be sent from centre 088 to us.	

4. Consent to disclosure to researchers The decisions regarding consent to disclosure to researchers held by the HFEA register either do not match or are missing when compared to those recorded on CD consent forms contained in 14 patient files at the centre. (General Directions 0005)	The PR should liaise with the HFEA Register team to ensure that action is taken to correct any errors identified. The PR should correct the submissions that have been identified as being incorrect by 25 May 2014. The PR should audit procedures for submitting patients' consent to disclosure to researchers to the HFEA. A summary report of the findings of the audit including corrective actions and the timescale for implementation of the corrective actions should be submitted to the centre's inspector by 25 May 2014. Six months after the inspection, the centre should audit a minimum of 10 sets of records chosen at random. The audit should be submitted	All missing registration forms and incorrect submissions have been corrected. The PR will start an audit regarding procedures for submission of patient consents to the HFEA where the EDI coordinator will be audited. This issue has been discussed at the management meeting after the inspection. The PR has also addressed the discrepancy in patient's consents regarding consent to research. A consent audit will be performed looking into this. The results of the two audits will be sent to the HFEA with corrective action plan by 25 May 2014. In August 2014 a retrospective audit of minimum 10 patient notes will be conducted and the results will be sent to the HFEA by 25 August 2014.	The PR has taken immediate action and corrected the 14 forms. The first audit is planned before May 2014. A second audit is planned before August 2014.

	to the lead inspector by 25 August 2014.		

‘Other’ areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a ‘critical’ or ‘major’ area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None identified			

Additional information from the Person Responsible

On behalf of all the staff at CREATE, I would like to thank Mrs Susan Joliffe and Dr. Victoria Lamb for facilitating a smooth inspection and their cooperative and positive attitude. An unannounced inspection can be a difficult day, as we need to manage t patient care and the inspection effectively. I thank all our staff who helped to make the day successful. I would like to thank our patients who agreed to speak to the inspection team.

At CREATE, we are very proud that we provide a safe, cost-effective, accessible and successful fertility care to couples and women. We have a highly trained and skilled medical, scientific and administrative and management team who deeply care about our patients and ethos.

We are particularly proud of our safety record, as no woman has been admitted to hospital with severe OHSS for many years. We run an “OHSS Free” service with modern and mild stimulation protocols. Our patient satisfaction is very high and we are very happy about this. As the demand for our service as grown over the years, we are expanding and setting up another centre in Central London, which would relieve any pressure on the current service.