HFEA Executive Licensing Panel Meeting

16 January 2015

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

Minutes – Item 2

Centre 0044 – (The Centre for Reproductive & Genetic Health) – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard (Chair) Director of Strategy & Corporate Affairs	Dee Knoyle
David Moysen – Head of IT	**Observing:**
Ian Peacock – Analyst Programmer	Sam Hartley – Head of Governance & Licensing

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

1. The Panel noted that the Centre for Reproductive and Genetic Health has held a licence with the HFEA since 1992. The centre is located in the Eastman Dental Hospital, London and provides a full range of fertility services including embryo testing.

2. The Panel noted that the centre's licence is due to expire on 31 March 2017.

3. The Panel noted that the inspection took place on 17 October 2014.

4. The Panel noted that in the 12 months to 31 August 2014, the centre provided 1421 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

5. The Panel noted that HFEA-held register data for the year ending 31 May 2014 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exceptions:

    - clinical pregnancy rates following ICSI in patients aged less than 38 years are above average at a statistically significant level;
    - clinical pregnancy rates following frozen embryo transfer in patients aged less than 40 years are above average at a statistically significant level;

6. The Panel noted that for the year 2013 the centre reported 253 cycles of partner insemination with 23 pregnancies which is in line with the national average.

7. Between 1 June 2013 and 31 May 2014, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%. This represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

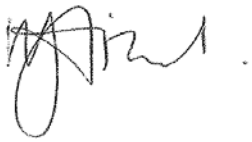
8. The Panel noted that at the time of the interim inspection on 17 October 2014, three major and one other area of non-compliance was identified. The Panel noted that since the inspection the Person Responsible (PR) had provided evidence that most of the recommendations made had been fully implemented. The Panel noted in particular, the PR's immediate response to the recommendations relating to consent and the progress made to date. The Panel noted that the non-compliance relating to consent was not classified as critical due to action already taken and the PR's approach and commitment to fully implement this recommendation within the prescribed timescales.

9. The Panel noted that the Inspectorate recommended the continuation of the centre's licence.

Decision

10. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment (including embryo testing) and storage licence continued.

11. The Panel was pleased with the progress made to date however concerned about the scale of the non-compliance relating to consent. The Panel endorsed the Inspectorate's recommendation that the PR must ensure that an effective system is in place to monitor all gametes and embryos in storage and associated storage consents, so that no samples are stored without consent.



Signed: Date: 30 January 2015

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: The Centre for Reproductive and Genetic Health
Centre number: 0044
Date licence issued: 01/04/2013
Licence expiry date: 31/03/2017
Additional conditions applied to this licence: None
Date of inspection: 17/10/2014
Inspectors: Andrew Leonard (Lead); Janet Kirkland MacHattie
Date of Executive Licensing Panel: 16 January 2015

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 on:

- **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.

The ELP is asked to note that recommendations for improvement were made in relation to three major areas and one 'other' area of non-compliance.

The PR has provided evidence that the following recommendations have already been fully implemented:

'Major' areas of non compliance:

- The PR should take immediate action to ensure that witnessing checks are performed at all critical points during the clinical and laboratory processes, including the discard of sperm.
- The PR must ensure that all necessary information about treatments at the centre is provided to the HFEA Register within the timeframes specified by the Authority.

'Other' areas of practice that require improvement:

- The PR should ensure that the times of witnessed identity checks and the signatures of the persons performing them, are always documented in each patient's/donor's medical record.

The PR has also provided information and evidence that actions have been, and will continue to be, taken to implement the following recommendations:

'Major' areas of non compliance:

- The PR must ensure that an effective system is in place to monitor all gametes and embryos in storage and associated storage consents, so that no samples are stored without consent.

Information about the centre

The Centre for Reproductive and Genetic Health centre is located in the Eastman Dental Hospital, London and has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services including embryo testing.

The centre provided 1421 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2014. In relation to activity levels this is a large centre.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

HFEA register data for the year ending 31 May 2014 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exceptions:

- clinical pregnancy rates following ICSI in patients aged less than 38 years are above average at a statistically significant level;
- clinical pregnancy rates following frozen embryo transfer in patients aged less than 40 years are above average at a statistically significant level;

For the year 2013 the centre reported 253 cycles of partner insemination with 23 pregnancies, performance which is in line with the national average.

Multiple births[2]

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

For treatments performed between 1 June 2013 and 31 May 2014, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%; this represented performance that was not likely to be statistically different from the 10% multiple live birth rate target.

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; fertilisation checks; thawing of embryos; preparation for embryo transfer. All of the procedures observed were witnessed in accordance with HFEA requirements using a manual system.

[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. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

The inspection team was able to review records that were present in the laboratory and concluded that records of manual witnessing are maintained.

An audit of witnessing checks documented in six sets of laboratory records indicated that patient and sample identity checks are contemporaneously witnessed at all but one critical point during the clinical and laboratory processes: the discard of sperm is not witnessed (see recommendation 1). The audit also found that the times of the checks and the signatures of the persons performing the checks were not consistently recorded (see recommendation 4).

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 ten patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in all of the records reviewed.

Consent: To the storage of cryopreserved material

On the day of the inspection the centre did not have written effective consent from four patient couples for the storage of their cryopreserved embryos. Furthermore, it was not clear that effective records are maintained to ensure effective storage consent is present for all gametes and embryos in storage, and the inspection team were concerned that investigation would reveal further samples stored beyond the expiry of the storage consent (see recommendation 2).

The storage periods for three sets of embryos recorded on the centre's database were cross checked against the consent forms completed by the gamete providers. In all three cases, the dates on the database and consent forms concurred and the embryos were being stored in accordance with the gamete provider's consent.

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: patients were seen promptly on arrival; the atmosphere in the clinic appeared 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 no patients consented to speak to the inspectors however we were provided with the centre's analysis of feedback from patients attending for

consultations and procedures between 1 August 2013 and 31 July 2014. We also observed interactions between centre staff and patients and a further eight patients have provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive and four of the eight respondents to the HFEA commented that they had compliments about the care received. There was also however patient dissatisfaction regarding delays in appointments and rushed appointments in both the feedback to the centre and the HFEA. Feedback to the HFEA also highlighted problems with contacting the centre by telephone.

The centre has responded to this negative feedback by recently employing six more nurses, all experienced in the fertility sector, to enhance their capacity to provide consultations, support patients and respond to telephone calls. A system has also been put in place to monitor the waiting areas to ensure patients do not wait for excessive amounts of time before their appointments. The PR said the centre is committed to the patient feedback monitoring programme and will respond to complaints to improve the service provided. The corrective actions taken seem, to the inspection team, to be reasonable and proportionate responses and a further recommendation for improvement is not considered necessary,

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 further non-compliances than those discussed elsewhere on this report.

Compliance with recommendations made at the last inspection

Following the renewal inspection in October 2012, recommendations for improvement were made in relation to one critical, nine major and seven 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

In the last year, the centre has been issued with two alert emails from the HFEA risk tool related to success rates and was asked to review procedures for the provision of frozen embryo transfers and for minimisation of multiple pregnancies. The PR responded to the requests appropriately in both cases.

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.

In the time since the last inspection in October 2012, the centre has been sent seven risk tool alerts related to a delay or failure in the recording in the HFEA Register of the outcomes of treatments using donated gametes. Nine risk tool alerts have also been sent to the centre related to a delay or failure in the registering in the HFEA Register of donors whose gametes have been used in the provision of treatment services (see recommendation 3)

The partners of women treated with donated gametes or embryos, where the couple are neither married nor in a civil partnership, must give their consent in order to become the legal parent of any child born. If this consent is not properly taken, it can have serious consequences, such as the partner having to adopt any child born in order to become the legal parent. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. On this inspection we discussed the centre's audit and found that it had been performed according to the method specified by the HFEA and that actions had been taken in response to the audit findings.

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. Patient and sample identity checks are contemporaneously witnessed at all but one critical point during the clinical and laboratory processes: checks at the discard of sperm are not witnessed (SLC T71).	The PR should take immediate action to ensure that witnessing checks are performed at all critical points during the clinical and laboratory processes, including the discard of sperm. The HFEA should be advised of the measures taken at the time the PR responds to this report. Within three months of the implementation of changes to witnessing procedures, the centre should conduct an audit of witnessing practice. A summary report of the	The sample discard checklist records the internal checks and the contemporaneous witnessing step at the time discarding of samples. The layout of the checklist is such that all internal checks have a side column for witnessing. Given that this is not a mandatory requirement this column has become redundant and not always completed. We confirm that the mandatory box for contemporaneous witnessing on the same sheet for the act of discarding has invariably been completed. In view of the above we have revised the layout of the discarding samples checklist to remove witnessing of internal checks and leave the contemporaneous witnessing box at the time of discard. A copy is provided with this response. In addition, an	11 December 2014: The inspection team conclude from the PR’s response and attached documents that appropriate actions have been taken to implement this recommendation when stored sperm is discarded. The PR has been advised that witnessing at the time of discard of fresh sperm samples also needs to be reviewed. 18 December 2014: The PR responded by email with evidence that corrective actions have been taken so that the discard of fresh sperm samples after treatment is now witnessed. No further actions are required.

	findings of the audit should be provided to the HFEA by 17 April 2015.	observational and retrospective audit of contemporaneous witnessing at the time of discard of semen samples was performed and is provided with this response. On all occasions the discard of semen samples was contemporaneously witnessed and signed for.	
2. On the day of the inspection the centre did not have written effective consent from four patient couples for the storage of their cryopreserved embryos. Furthermore, it was not clear that effective records were maintained to ensure all gamete and embryo samples are maintained in storage only if effective storage consent is present (HF&E Act 1990 (as amended), Schedule 3, 8.1).	The PR must ensure that gametes and embryos are not stored unless there is effective consent from the gamete providers to do so. The PR must ensure effective systems are in place to monitor all stored gametes and embryos and the associated storage consents. By the time this report is considered by a Licensing Committee, the PR should provide the HFEA with an update on the number of patients for whom gametes and embryos remain in store without	The non-compliance was mainly caused by the majority of patients consenting to 1 year of storage and the 1st letter being sent out 3 months prior to the expiry date; which in turn led to difficulties. We have used this opportunity to review the bring forward system and associated documentation. The review has led to a number of corrective actions / improvements, to prevent a reoccurrence of the non-compliance(s) noted. The corrective actions / improvements have been implemented and were shared with our HFEA Inspector on 6th November along with the progress made with contacting patients and disposing of samples. All corrective actions have been implemented. The relevant staff have been re-trained on the new bring forward system and	The centre was revisited on 6 November to discuss this matter. Evidence of significant progress in addressing this issue was provided, including a report of the full audit of electronic and paper records of stored samples. Samples from 520 patients had been found to be stored without effective consent. All such patients have been sent letters and new storage consent forms and 138 samples have been discarded with the gamete providers' consent. The report included the actions being taken to resolve the status of embryos and oocytes from 229 patient couples and sperm samples from 153 providers. The bring forward system has already been investigated and corrective actions to prevent recurrence are being implemented, as follows: • a new storage review/bring forward

	effective consent and a plan documenting the centre's intended actions, with timescales for implementation, to ensure gametes and embryos are lawfully stored. The PR should provide monthly updates to the HFEA on progress in implementing the proposed actions. The PR should review the bring-forward system and procedures for auditing cryopreserved material. Summary reports of the review findings, including corrective actions with implementation dates, should be submitted to the HFEA by 17 January 2014. Within three months of the implementation of corrective actions, the centre should conduct an audit of consent to	was completed on 04/12/2014. A copy of this documentation, along with all other documentation requested is provided with this response.	protocol has been written; • gamete providers will no longer be asked to consent to storage for only one year, as at present; • new template letters to send to gamete providers to extend or withdraw storage consent, have been developed and will be embedded in the electronic database to make the bring-forward system easier to administer; • the use of the electronic database is being revised to ensure easier monitoring of storage consent expiry in future. The Quality Manager reported that the 138 samples discarded so far were all seen to be in the correct locations in the dewars and their storage consent expiry dates were consistent throughout the records. This provides reassurance that samples have not been misplaced or storage consent expiry dates incorrectly recorded. The actions already taken and on-going, have reassured the inspection team of the centre's commitment to address this matter, hence it being graded as major rather than critical non-compliance.

	storage and a summary report of the findings of the audit should be provided to the HFEA. 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 there be a possibility of legal challenge to the disposal of cryopreserved material.		The PR provided a further update and documents on 11 December 2014 that indicate that the corrective actions resulting from the audit of the bring-forward system have been implemented and appropriate training provided to staff. The PR also provided a report which detailed that, as of 4 December 2014, embryos from 69 patient couples and sperm from 54 providers, were in storage without effective consent. The inspection team note the rapid improvement in the numbers of samples held without storage consent between 6 November 2014 (382 samples) and 4 December 2014 (123 samples) and improvements in the centre's processes in this area, which should prevent a recurrence of this non-compliance. The PR should continue to provide monthly updates regarding these samples, as he has committed to do.
3. In the time since the last inspection in October 2012, the centre has been sent seven risk tool alerts	The PR must ensure that all necessary information about treatments at the centre is provided to the HFEA Register within the	Each alert has been addressed in a timely fashion. It would appear in a number of instances due to the lag between the submission of the register data and the sending of alerts (as stated in the HFEA alert email(s)), the issue(s),	The inspection team conclude from the PR's response and review of the documents provided (training records and SOP updates) that appropriate actions have been taken to implement this recommendation.

related to a delay or failure in the recording in the HFEA register of the outcomes of treatments using donated gametes. Nine risk tool alerts have also been sent to the centre related to a delay or failure in the registering in the HFEA Register of donors whose gametes have been used in the provision of treatment services (General Direction 0005).	timeframes required by General Direction 0005. The PR should review the centre's EDI data submission processes and should take corrective actions to prevent late or absent data reporting. A summary of the review and corrective actions required should be provided to the HFEA by 17 January 2015. The PR should also review information on the clinic portal related to the centre's HFEA Register data errors and should ensure that data submission errors are cleared by 17 January 2015.	may had already been resolved. Measures have been put in place to avoid reoccurrence (refresher training of the relevant staff, SOP reviewed, updated and recirculated to relevant staff). On occasion there are difficulties obtaining the outcome of treatment(s) from the patient(s). The alert(s) are not related to the obtaining outcome process(es) but the patients being un-contactable and/or not contacting CRGH. The current processes do not need to change as they have not contributed or caused the non-compliance. The opportunity was taken to discuss the above at the staff meeting to ensure that all members of the team are clear as to these requirements. The SOP(s) which detail the specific tasks and responsibilities for EDI data submission of staff have been implemented and are supplied with this response. EDI responsibilities are clearly defined and assigned to individual members of the team. All managers and staff involved in EDI data submission are known to each other.	No further actions are required.

		The EDI errors are identified and resolved whenever they occur or from our monthly EDI data audits. These audits also identify individuals who require additional training which is provided as required and appropriate. A corrective action has been to retrain staff that perform certain EDI functions (completed).	

‘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
4. An audit of witnessed identity checks documented in patient records indicated that the times of the checks were not consistently recorded, nor were the signatures of the persons performing the checks (SLC T71).	The PR should take immediate action to ensure that the times of witnessed identity checks and the signatures of the persons performing them, are always documented in each patient/donor medical record. The HFEA should be advised of the measures taken by 17 January 2015. Within three months of the implementation of changes to witnessing procedures, the centre should conduct an audit of witnessing documentation. A summary report of the findings of the audit should be provided to the HFEA by 17 April 2015.	At the time of the inspection it was noted that act of witnessing on some records was only via a stamp of the operator without a signature. Protocols have been amended to ensure the time and the signature is recorded. An audit will be provided in due course	The inspection team conclude from the PR’s response and attached documents that appropriate actions have been taken to implement this recommendation. The PR has committed to provide the report of the recommended audit to the HFEA by 17 April 2015.

Additional information from the Person Responsible