HFEA Executive Licensing Panel Meeting

17 October 2014

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

Minutes – Item 1

Centre 0015 – (Sussex Downs Fertility Centre) – Interim Inspection Report

Members of the Panel:	**Panel Secretary:**
Rachel Hopkins – Head of HR (Chair) Nick Jones – Director of Compliance & Information Ian Peacock – Analyst Programmer	Dee Knoyle

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 Sussex Downs Fertility Centre has held an HFEA licence since 1992. The centre provides a full range of fertility services and also has a satellite treatment agreement with Goring Hall Hospital, Sussex.

2. The Panel noted that the centre's licence is due to expire on 30 June 2016.

3. The Panel noted that the inspection took place on 11 March 2014.

4. The Panel noted that in the 12 months to 31 January 2014, the centre provided 433 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

5. The Panel noted that for the year 2012 the centre reported 143 cycles of partner insemination with 17 pregnancies. This equates to an 11% pregnancy rate which is consistent with the national average.

6. The Panel noted that for the year 2013, the centre reported 121 cycles of partner insemination with nine pregnancies. This equates to a 7% pregnancy rate. The analysis of data provided nationally for this period was not available for comparison at the time this report was written.

7. The Panel noted that HFEA-held register data for the year ending 31 October 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exception;

    - Clinical pregnancy rates following IVF treatment with fresh embryos in patients aged 38 years and over are above average at a statistically significant level.

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 22%. 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 live birth rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represented performance that was not statistically different from the 15% maximum multiple live birth rate target for this period.

10. Between 1 January 2013 and 31 December 2013 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

11. The Panel noted that at the time of the interim inspection on 11 March 2014, one major and four other areas of non-compliance were identified. The Panel noted that since the inspection, the Person Responsible (PR) had provided evidence that all of the recommendations had been fully implemented.

12. The Panel acknowledged the positive comments made by patients in relation to their experience of the centre.

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

Decision

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

15. The Panel noted the centre's success rates following IVF in patients 38 years and over and the centre's pro-active approach in working towards the current 10% maximum multiple birth rate target. The Panel commended the centre on its achievements.

Signed: Date: 22 October 2014

Rachel Hopkins (Chair)

Interim Licensing Report

Centre name: Sussex Downs Fertility Centre
Centre number: 0015
Date licence issued: 01/07/2012
Licence expiry date: 30/06/2016
Additional conditions applied to this licence: None
Date of inspection: 11/03/2014
Inspectors: Mrs Gill Walsh (Lead), Dr Stephanie Gadd
Date of Executive Licensing Panel: 17/10/2014

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 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 with no additional conditions. In particular we note: the very positive comments made by patients in relation to their experiences; the centre's success rates following IVF in patients 38 years and over; and the centre's pro active approach in working towards the current no greater than 10% multiple birth rate target.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one major and four 'other' areas of non-compliance.

Since the inspection visit, the PR has provided evidence that following recommendations have been fully implemented:

'Major' area of non-compliance:

- The PR should risk assess the practice of not witnessing the movement of oocytes at the time of egg collection between a dish in the laboratory workstation to one in the holding area of the incubator and consider what actions may be required to minimise the risk of misidentification of oocytes during this process.

'Other' areas of practice that require improvement:

- The PR should review the processes for submitting consent to disclosure decisions made by patients and their partners, to ensure that the consent decision submitted to the HFEA register accurately reflects the decision documented by the person(s) providing consent.

- The PR should consider consolidating the centre's laboratory storage, consent and gamete / embryo use records to ensure that all records are updated contemporaneously and accurately reflect when gametes or embryos are used in treatment or allowed to perish.

- The PR should assess the confidentiality of the notes storage arrangements in the nursing office and provide a summary of the actions taken to mitigate the risk of patient / donor names inadvertently being disclosed to persons other than those permitted to have this information.
- The PR should ensure that eligible staff working in the embryology laboratory are registered, or are working towards registration, with the Health and Care Professions Council (HCPC).

Information about the centre

The Sussex Downs Fertility Centre is located at the BMI Esperance Hospital in Eastbourne and has held a licence with the HFEA since1992. The centre has a satellite treatment agreement with Goring Hall Hospital, Sussex.

The centre provides a full range of fertility services and provided 433 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2014. In relation to activity levels this is a small 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 31 October 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exception;

- Clinical pregnancy rates following IVF treatment with fresh embryos in patients aged 38 years over are above average at a statistically significant level. The centre is to be congratulated on this.

For the year 2012 the centre reported 143 cycles of partner insemination with 17 pregnancies. This equates to an 11% pregnancy rate which is consistent with the national average.

For the year 2013 the centre reported 121 cycles of partner insemination with 9 pregnancies. This equate to a 7% pregnancy rate. The analysis of data provided nationally for this period is not yet available for comparison.

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 22%; this represented performance that was not statistically different from the no greater than 20% multiple live birth rate target for this period.

Between 1 April 2011 and 30 September 2012, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 14% this represented performance that was not statistically different from the no greater than 15% multiple live birth rate target for this period.

[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 2012/13 MLBR target of 10% is calculated as equivalent to a 13% MCPR.

Between 1 January 2013 and 31 December 2013 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%: this represents performance that is not likely to be statistically different from the no greater than 10% multiple live birth rate target for this period.

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 and sperm preparation. All of the procedures observed with the exception documented below, were witnessed in accordance with CoP requirements using a manual system.

The inspection team was able to review five patient records and concluded that records of manual witnessing are maintained.

It was noted when observing egg collection that the movement of oocytes between a dish in the laboratory workstation to a dish in a holding incubator is not witnessed by a second person. See recommendation 1.

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 five patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in two instances. In one instance there was no record of the patient and partner's consent decisions submitted to the HFEA register in two other instances the patient and partner recorded consent to generic disclosure to researchers but the decisions submitted by the centre to the HFEA register recorded that the patient and partner withheld consent to disclosure. Although this does not risk inadvertent disclosure of information provided to researchers, it does not accurately reflect the consent provider's wishes. See recommendation 2.

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 periods. The storage periods for three sets of embryo as recorded on the centre's database were cross checked against the consent given by the gamete providers. In the three sets of records checked, the embryos were being stored in accordance with those consenting decisions.

On reviewing the centre's storage 'bring forward' system against patient and laboratory records it was noted that, not all records had been contemporaneously updated to consistently reflect when embryos had been used in treatment or thawed. See recommendations 3.

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

No patients in treatment were available on the day of inspection to provide feedback to the inspection team regarding their experience at the centre. However 25 patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive with 21 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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;
- maintains an effective system for responding to patient phone calls.

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 the following non-compliances:

- Not all laboratory staff eligible to do so are registered with HCPC. See recommendation 4.
- It was noted on patient / donor records seen that the folders in which the record are held are boldly labelled with the patient's name. It was also noted that records stored in a 'case cart' in the nurses office and admin area were stored with the patient names uppermost such that they could possibly be identified from some distance away. See recommendation 5.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in February 2012 recommendations for improvement were made in relation to three areas of major non-compliance and six 'other' area(s) of non-compliance.

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

The following recommendation has now been fully implemented but was not completed within the required timescale:

- The PR should ensure that success rate data published on the centre's website meets the requirements of Chair's Letter CH (11) (02) Responsible use of websites: the duty of centres.

On-going monitoring of centre success rates

The centre has not received any HFEA alerts regarding their success rates. It is noted that the centre's clinical pregnancy rate following IVF treatment with fresh embryos in patients aged 38 years and over is above average at a statistically significant level; the centre is to be congratulated for this.

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 register team of the HFEA report that the centre is compliant with requirements to provide data to the HFEA register.

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			

‘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. Observation of witnessing practice on the day of inspection showed that at egg collection, the movement of eggs between a dish in the laboratory workstation to one in the holding incubator is not witnessed by a second person. It was noted that this area is a confined space and the centre considers that to have a second person in this area at the time oocytes are moved represents a greater risk than that of not having a second person witness this step. SLC T71	The PR should further risk assess the practice of not witnessing the movement of oocytes at egg collection from a dish in the laboratory work station to a dish in the incubator and consider what actions are required to minimise the risk of misidentification of oocytes during this process. In the event that the centre considers it impractical for a second person to witness this step, the centre should consider how the risk of misidentification can be further reduced. The centre should consider whether having a designated 'spot' in this incubator, only available for oocyte collection, or the use of a separate holding incubator for	A designated chamber within the existing upright incubator has already been created for egg collection patients only so as to minimise the risk of misidentification of oocytes during this process. This chamber is used soley for egg collection and is labelled as such. Once all the oocytes have been collected, the patients dishes are then moved to another designated incubator space A quote has been received for a mini bench top incubator that will be located inside the air flow hood and used soley for egg collection. Once approval has been issued for the purchase of	The Executive is satisfied with the PR’s response and actions taken regarding the implementation of this recommendation. The risk assessment was provided by the centre in April 2014. Subsequent to providing a response to the report it has been confirmed that a bench top incubator is awaited and that this incubator be used to hold the dish(es) containing the eggs of the patient undergoing egg collection. This will further mitigated any risk of the eggs of one patient being transferred to the dish of another patient in the absence of a witnessing step. It is recommended that

	this step should be used. The PR is to provide to HFEA a summary of the risk assessment and steps taken to mitigate any risks identified by 11 June 2014.	this item, it will be ordered immediately. A risk assessment of the egg collection procedure will be submitted by 11.06.14 Once all the eggs have been collected the patients dishes are then moved to another incubator chamber.	consideration is given to including an additional step in the egg collection procedure to confirm and document that this "holding" incubator is cleared at the end of every egg collection procedure. No further action is required.

‘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
2. The records of consent to disclosure to researchers given by five patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in two instances. In one instance there was no record of the patient and partner consent decision, in two other instances the patient and partner recorded consent to generic disclosure to researchers but the decision submitted to the register withholds consent to disclosure. Direction 0007	The PR should review the processes for submitting consent to disclosure decisions made by patients and their partners to ensure that the consent decision submitted to the HFEA register accurately reflects the consent wishes of the person(s) providing consent. The PR should provide the HFEA with a summary of this review. Three months after the implementation of any corrective actions, the PR should conduct an audit of consent decisions to determine the effectiveness of the corrective actions and provide a report of the audit findings to the HFEA by 11 June 2014.	Hard copies of the completed consent to disclosure forms for both patient and partner are checked at the time of initial consultation by either the Consultant or one of the Clinical team. Effective 01.05.14, when the information contain therein is uploaded onto the EDI system, this will be crossed checked by a second person to ensure the information uploaded accurately represents the wishes of the person (s) providing consent. An audit will be conducted towards the end of July to determine the effectiveness of these corrective actions and a report will be submitted to the HFEA by 8.8.14	The Executive is satisfied with the PR’s response and implementation of this recommendation. A consent to disclosure audit has been provided by the centre which showed that of 66 patient and partner consent to disclosure decisions audited one non conformance was noted. Corrective action has been implemented and commitment to re audit in December 2014 provided. No further action required.
3. A review of the centre's	The centre should consider		The Executive is satisfied with

	storage 'bring forward' system showed that records of storage consent and stored gamete or embryo usage appeared fragmented such that there was a risk that all records would not be updated contemporaneously with gamete or embryo usage, allowing errors in the records to occur. CoP Guidance 17.7.	consolidating their laboratory storage, consent and gamete / embryo use records to ensure that all records are updated contemporaneously to that the records accurately reflect when gametes or embryos are used in treatment or allowed to perish. This should be competed by 11 June 2014.	Effective 01.05.14 the embryo record sheet that records the details of frozen embryos will no longer be copied and filed in the patients notes. The original document will remain in the folder located in the laboratory and an index created at the front of this folder. Records will be stored in numeric order. This means there will only be one copy, and as such when embryos are used in treatment or allowed to perish only one document requires amending.	the PR's response and implementation of this recommendation. No further action is required.
4.	Not all eligible staff working in the clinical embryology laboratory are registered with the Health Care Professions Council (HCPC). SLC T14.	The PR should review the skills and experience of relevant laboratory staff and provide the HFEA with a report documenting how they are acquiring skills equivalent to those conferred by working towards HCPC registration or, alternatively, provide an action plan documenting how the centre will ensure that eligible staff in the clinical embryology laboratory will work towards HCPC registration. This information should be provided by 11 June 2014.	An action plan will be submitted by 11.06.14 that will document how the only eligible member of the embryology team will work towards state registration and following this, monthly reports will be submitted on the progress of this action plan.	The Executive is satisfied with the PR's response. A detailed action plan had been provided and progress updates have been forthcoming. HCPC registration is anticipated by spring 2015. The PR should continue to provide periodic updates regarding progress towards achieving this.

	The PR should thereafter provide monthly updates to the HFEA on progress in implementing any actions identified as necessary.		
5. It was noted on patient / donor records seen that the 'case sheets' in which the record are held are boldly labelled with the patient's name. It was also noted that records stored in a 'case cart' in the nurses office and admin area were stored with the patient names uppermost and could possibly be identified from some distance away. SLC T43.	The PR should assess the confidentiality of the notes storage arrangements immediately and provide a summary of the actions taken to mitigate the risk of patient / donor names inadvertently being disclosed to persons other than those permitted to have this information. The PR should inform the HFEA of actions taken when responding to this report.	Effective immediately, all notes held in the case cart are covered by a lid to mitigate the risk of patient/donor names inadvertently being disclosed to persons other then those permitted to have this information. This is a temporary measure. Trolleys with lids have been ordered that will hold all patient/donor records that are 'active' and need to remain in the office for the attention of one of the clinical team. The lid will remain closed at all times.	The Executive is satisfied with the PR's response and implementation of this recommendation. No further action is required.

Additional information from the Person Responsible