Executive Licensing Panel - minutes

Centre 0153 (Homerton Fertility Centre)

Executive Update

Tuesday, 2 June 2020

HFEA, Teleconference Meeting

Panel members	Richard Sydee (Chair) Howard Ryan Helen Crutcher	Director of Finance and Resources Data Analyst Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

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:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. The panel noted that Homerton Fertility Centre is located in London and has held a treatment and storage licence with the HFEA since 1995. The centre provides a full range of fertility services.

1.2. The panel noted that the renewal inspection report was initially presented to the Executive Licensing Panel (ELP) on 12 July 2018. Due to concerns regarding the number and extent of non-compliances identified at the renewal inspection, which impacted on the quality of care and safety of patients, the ELP adjourned consideration of the application and referred it to the Licence Committee (LC).

1.3. The panel noted that the renewal inspection was considered by the LC on 6 September 2018; a treatment and storage licence was granted for three years, rather than the standard four, due to the history and reoccurrences of non-compliances. There were concerns about the Person Responsible's (PR) lack of response to the request for information relating to the import and export of gametes and embryos, alongside concerns about the length of time taken by the PR to investigate the low success rates for IVF treatments involving fresh embryos in women under 38 years. An executive update was also requested.

1.4. The LC also considered the executive update, in relation to the implementation of outstanding actions relating to the non-compliances identified during the inspection. The LC requested that a further update be provided, as soon as the outstanding information, regarding imports and exports and success rates for IVF treatment involving fresh embryos in women under 38 years, was available. The LC agreed that an inspection should take place within the first year of the licence to ensure that the recommendations made in the report had been effectively implemented.

1.5. The panel noted that the LC considered an executive update on 2 May 2019, providing information on the non-compliances, found during the renewal inspection, in relation to imports and exports and success rates. The committee noted the progress made by the PR on the implementation of the recommendations to address the two major areas of non-compliance.

1.6. The panel noted that a short notice interim inspection took place on 6 and 7 August 2019 and three major and one 'other' area of non-compliances were identified. This report was presented to ELP on 28 January 2020, where concern was expressed that the non-compliances, identified at the previous renewal inspection, had not been fully addressed by the PR, within the prescribed timescales. The panel requested an executive update report be presented to ELP, within six months, to confirm whether non-compliances identified at the short notice inspection had been completed within the prescribed timescales.

1.7. The panel noted the actions taken by the PR, since the short notice interim inspection occurred.

1.8. The panel noted that, in view of the circumstances regarding Covid-19, the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing the recommendations.

2. Consideration of Progress Update

2.1. The panel considered the papers, which included an executive update, update on recommendations made in the short notice interim inspection report and licensing minutes for the last three years.

2.2. The panel noted the update on the implementation of the recommendations, made in the short notice interim inspection report. The non-compliances relating to the consent to storage of gametes and embryos and imports and exports had both been fully implemented. Audits remained outstanding, due to Covid-19, for the non-compliances surrounding pre-operative assessment and the surgical pathway and data submission.

3. Decision

3.1. The panel noted that the audits for pre-operative assessment and the surgical pathway and data submission remained outstanding, due to the suspension of activity at the centre in response to Covid-19, encouraging the inspector to follow-up on these outstanding actions with the PR, agreeing a suitable timescale for submission.

3.2 The panel agreed that, should all the audits be submitted within the newly agreed timescale, a further executive update would not be required. However, if sufficient progress is not made, a report should be submitted to ELP for consideration.

4. Chair's signature

4.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Richard Sydee

Date

8 June 2020

Executive update for Executive Licensing Panel

2 June 2020

Centre number	**0153**
Centre name	**Homerton Fertility Centre**
Person Responsible	**Mr Anil Gudi**

Background

12 July 2018:
The renewal inspection report was initially presented to ELP, but due to concerns regarding the number and extent of non-compliances identified at the renewal inspection, which impacted on the quality of care and safety of patients, the ELP adjourned consideration of the application and referred it to the Licence Committee. A progress update was also requested to be provided to the Licence Committee.

6 September 2018:
The Homerton Fertility Centre was granted a 'Treatment and Storage' licence by a Licence Committee (LC).

The licence was issued for a period of three years (rather than the standard four) due to:

- the history and recurrence of non-compliances;
- concerns about the Person Responsible's (PR) lack of response to a request for information relating to the import and export of gametes and embryos;
- concerns about the length of time taken by the PR to investigate the low success rates for IVF treatments involving fresh embryos in women under 38 years.

The committee also considered the update provided by the executive in relation to the implementation of outstanding actions regarding the non-compliances found during the inspection and requested that they be provided with a further update as soon as the outstanding information regarding imports and exports and success rates for IVF treatment involving fresh embryos in women under 38 years was available.

The committee agreed that an inspection should take place within the first year of the licence to ensure that the recommendations made in the report had been effectively implemented.

2 May 2019:
As requested by LC, a further executive update on the non-compliances found during the renewal inspection in relation to imports and exports and success rates was provided. The committee noted the progress made by the PR on the implementation of the recommendations to address the two major areas of non-compliance.

6 and 7 August 2019:
A short notice interim inspection took place. At the time of the inspection, three major and one 'other' area of non-compliance were identified.

28 January 2020:
The report was presented to Executive Licensing Panel (ELP).
The panel expressed concern that non-compliances identified at the previous renewal inspection had not been fully addressed by the PR within the prescribed timescale and requested an executive update report to be presented to ELP, within six months, to confirm whether non-compliances identified at the short notice inspection had been completed within the prescribed timescales.

The following table in Annex A provides the requested update. It outlines the non-compliances that were identified at the short notice inspection and the actions the PR has subsequently taken to achieve compliance.

Annex A:

'Other' areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non-compliance, but which indicate a departure from statutory requirements or good practice.

An 'other' area of non-compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1.Consent to storage of gametes and embryos A review of patient records undertaken at the inspection in March 2018 identified one case in which there was a period of lapsed storage consent between the expiry of the original storage consent and the signing of storage extension consent, with completion of the MPS form outside the relevant period. Despite the PR having sought specialist legal advice and further guidance from the HFEA, this case is still unresolved.	The PR should ensure there is effective consent in place for all cryopreserved samples**.** The PR should seek further legal advice from a representative that is conversant with the HFEA Act 1990 (as amended) and the HFEA statutory storage regulations to discuss this case in particular and to determine what actions he should take to resolve the issues identified. The PR should consider a thorough review of the patient's records. This could	Our protocols ensure that consents are effective for all patients The sample in question was from UCL where sperm was frozen prior to Chemotherapy in 2002 . The Samples were extended at UCL in 2012 with a lapse of consent for 4 months . The MPS was signed in 12/2012 2 ampoules were brought in 2015 and the consents at time from UCL were valid . The majority of the samples continue to be at UCL . We had contacted the legal team after the HFEA	**Update following ELP consideration 28 January 2020:** The PR confirmed when responding to the report, that the sample in question was discarded on 16 December 2019. No further action required.

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 and SLC T79.	include a review of other healthcare records (such as oncology records) that may contain information pertaining to the patient's fertility status. On receipt of the legal advice the PR should inform the centre's inspector of the actions that he is going to take to ensure compliance with the statutory and regulatory requirements. It is expected that this information will be provided to the centre's inspector by 9 February 2020.	inspection and the legal advice was ------. Since the HFEA meeting, wehere additional advice was given , we have enquired from UCL to send us a copy of medical document adving the freezing of samples due to Chemotherapy. The patients has requested us to discard the sample at Homerton .We have discarded the sample on 16/12/2019.Our protocols have been changed to Check for all consents from date of freezing . We have obtained the letter from the oncology department at UCL recomending freezing of sperm for Cancer from 16th April 2004 and sperm test recommendation in 2002	
2. Pre-operative assessment and the surgical pathway The inspection team were concerned that swab counts were not being undertaken in such a manner as to protect	The PR should ensure that swab counts performed during surgical procedures are compliant with best practice guidance and the centre's own SOP.	Following the inspection we have changed our protocol .Having spoken to the clinician who carried out the egg collection , she confirmed the swab count was done by 2 people but did not vocalise it so all could	**Update following ELP consideration 28 January 2020:** The PR subsequently provided a response as to why the recommendations following the investigation of an incident

patients from a swab being retained within the body. SLC T2. The Association for perioperative practice (AFPP) 2018.	When responding to this report the PR should provide an explanation as to why recommended actions following the investigation of the incident were not immediately implemented, along with an update on the actions he has taken since the inspection to minimise the risks to patients from a swab being retained within the body. Within three months of actions being taken the centre should conduct an audit of swab count practices and the documentation of swab counts in patient records to determine the effectiveness of actions taken. A summary report of the findings of the audit should be provided to the centre's inspector by 9 May 2020.	hear .Staff now ensure that all theatre staff can hear the count and we immedicately changed the check list to ensure the count is confirmed by 2 signatures We will conduct a complaince audit of Swab practices in February and March and send the Audit findings before the 9th of May 2020	relating to swab counts were not immediately implemented. The PR has further updated the centre's check list for egg collection procedures, to ensure robust checking systems are in place. The PR had planned to undertake an audit of swab count practices in April, but due to the current pandemic, the PR has suspended fertility treatments in the clinic in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing the recommendations. .

3.Import and export The centre has imported donor sperm from a sperm bank within the EEA, with which it has a service level agreement which describes a fixed rate payment scheme of 45 Euros per donation visit, provided to donors 'irrespective of any actual expenses, loss of earnings and other costs or inconveniences incurred in connection with the donation.' This compensation scheme is non-compliant with General Direction 0001. These donor sperm samples have been imported into the UK under General Direction 0006, which requires that compensation to providers of gametes to be imported, should be compliant with General Direction 0001.	When importing sperm, the PR should ensure that money or other benefits provided to donors are compliant with General Direction 0001, if the import is to be undertaken under the authorisation provided by General Direction 0006. The PR should review all imports of donated gametes since the last inspection and should determine, with the overseas centre if necessary, the level of compensation provided to donors and whether it has been compliant with General Direction 0001. A report of this review should be provided to the centre's inspector by 9 February 2020. The PR should review all the centre's EEA service level agreements to ensure that they are in line with General Direction 0001, if the import is to be undertaken under the authorisation provided by	We can confirm that for imported donor sperm , the 3rd party agreement reflects concurrrence with General direction 0001. The TPA was changed in August 2019 to reflect the adherence to Direction 0001 and 0006 . The donor bank has confirmed and sent a statement stating the payments/compensation to donors between March 2018 to August 2019 which complies with general direction 0001 and 0006 . The review will be included . The other Donor banks are compliant with the general directions The Laboratory director has reviewed the directions along with retraining has been carried out in the Laboratory meeting . Another training has been planned in January 2020	**Update following ELP consideration 28 January 2020:** The PR has provided the reviews within the timescale requested. All relevant staff received specific training in import and export activities and a nominated member of the laboratory team oversees the centre's import and export activities. The PR reports that this system is working well. No further action required.

	General Direction 0006 and provide confirmation of the review. Where the agreements are not compliant, he should inform the centre's inspector of the actions he has taken to become compliant by 9 February 2020.		

'Other' areas of practice that requires improvement

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An 'other' area of non-compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. **Data submission** There are number of minor data submission issues related to treatments with unregistered donors,	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should review the procedures used by the centre to submit licenced treatment data to the HFEA to identify and address	At the Homerton , when donor sperm is received from the abroad , we register the donor with HFEA . In a few cases we reistered UK donor samples as new donor . This was realised and corrected after the inspection. We will audit with the annual gamete audit and sumit it in February 2020	**Update following ELP consideration 28 January 2020:** The PR has committed to ensuring that the centre's data is submitted within the required timescales. The PR was due to submit an audit summary report to the executive in May, but due to the current pandemic, the PR has suspended

outstanding validation errors and missing forms and the centre is working with the HFEA register team to resolve the issues identified. General direction 0005 and SLC T41.	the reasons for delayed submissions, poor quality submissions and treatment involving donor gametes by 9 February 2020. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centre's inspector by 9 May 2020.		fertility treatments in the clinic in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing the recommendations.