Executive Licensing Panel - minutes

Centre 0007 (Hewitt Fertility Centre) Progress Report

Friday, 4 November 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) David Moysen Anjeli Kara	Director of Strategy & Corporate Affairs Head of IT Regulatory Policy Manager
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers		

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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. The Hewitt Fertility Centre, centre 0007 is located at Liverpool Women's Hospital in Liverpool. The centre provides a full range of fertility services including embryo testing and has been licensed by the HFEA since 1992. The centre has satellite agreements in place with five clinics and also has a transport IVF agreement with the Countess of Chester Hospital, centre 0280. In relation to activity levels this is a large centre.

1.2. The Executive Licensing Panel considered the centre's application to renew the treatment (including embryo testing) and storage licence at its meeting on 9 September 2016. The panel had noted that at the time of the renewal inspection on 14 and 15 June 2016, one critical, six major and two other areas of non-compliance were identified. The panel noted that the Person Responsible (PR) had committed to fully implementing all of the recommendations within the prescribed timescales and granted a licence for a period of four years without additional conditions, subject to the recommendations made in the inspection report being implemented within the prescribed timescales. The panel noted that there were recommendations with timescales for implementation set shortly after this Executive Licensing Panel meeting held on 9 September 2016 and therefore agreed that the inspectorate should provide the panel with an update, at the next available meeting, confirming whether the outstanding recommendations were implemented within the prescribed timescales.

2. Consideration of application

2.1. The panel considered the papers, which included an executive update, inspection report and licensing minutes for the last three years.

2.2. The panel noted that the Executive had confirmed that the actions due by 15 September 2016 had been implemented within the prescribed timescales. The panel was reassured by this.

2.3. The panel noted that the implementation of the recommendations with timescales set in November and December 2016 would be regularly monitored by the inspectorate.

3. Decision

3.1. The panel noted the executive update and was satisfied with the centres progress to date.

4. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

14 November 2016

Executive Licensing Panel
4 November 2016

Centre number	0007
Centre name	Hewitt Fertility Centre
Person Responsible	Karen Schnauffer

Update to renewal inspection report

1. Centre 0007's renewal application was considered by the Executive Licensing Panel (ELP) on 9 September 2016 and the centre's licence was renewed for a period of four years.

2. The panel noted that there were recommendations with timescales for implementation which expired shortly after the ELP meeting and requested the Executive provide the panel with an update, at the next available meeting, confirming whether the outstanding recommendations were implemented within the required timescales.

3. Annex 1 provides an update on the implementation of these recommendations.

4. The Executive can confirm that actions that were due by 15 September 2016 have been implemented within the timescales provided. Other recommendations have due dates in November and December 2016. Their implementation will be regularly reviewed by the centre's inspector using the on going monitoring system in Epicentre, as per the normal procedures used by the inspection team.

Janet Kirkland Machattie
Inspector

Annex 1: Recommendations that required further action

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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. 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	Executive Review
1. The records of two egg donors were reviewed on inspection. In both cases the donor's blood samples for screening were obtained at the time of donation, but this blood had not been screened for Hepatitis B surface antigen, Hepatitis B core antibody, Hepatitis C virus, or syphilis at this time. SLC T52(b) and SLC T53(b).	The PR should ensure that gamete donors are screened in accordance with regulatory requirements and professional body guidelines. The PR should provide the centre's inspector confirmation of revised screening practices, a copy of the updated donor screening SOP and evidence of relevant staff training when responding to this report. The PR should conduct an audit of the centre's screening practices and procedures for gamete donors (including sperm donors) to ensure that they are compliant with regulatory requirements and professional body guidelines.	The PR can confirm that all egg donors are now screened in accordance with regulatory requirements and professional body guidelines and the revised SOP to reflect the changes has been sent to the centre's inpsector (NURSE-SOP-60). The PR can confirm that all potential egg donors in the system (two) will be screened in accordance with the revised SOP. An audit will be performed within 3 months of the revised protocol being introduced and the PR will provide a summary of this audit to the centre's inspector by the 15th September 2016.	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The Executive has received the revised SOP and will continue to liaise with the PR to ensure it describes compliant practices. Upon completion of the SOP, the Executive will seek the requested evidence of staff training. The audit and root cause analysis is due to be provided by 15 September 2016. The Executive also requested a time line for obtaining advice

	The audit should also include a root cause analysis to identify why the centre's processes for screening egg donors were not compliant with regulatory requirements. The PR should provide the centre's inspector with a copy of this audit report, including corrective actions identified, by 15 September 2016. Within three months of the implementation of revised practices, the centre should carry out an audit of gamete donor screening to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 15 November 2016. The PR should seek the advice of an expert virologist to assess the risk to patients who have received treatment with eggs or embryos created with donated eggs, from donors where the screening	The PR is seeking expert advice from Ian Hart (Consulatnt Virologist) at the Royal Liverpool Hospital. The PR will provide the advice to the centre's inspector when it becomes available. The PR will review the centre's screening procedures for all gamete donors to ensure that they are compliant with regulatory and professional body guidelines and provide a RCA to identify why this was absent from the SOP - this will be sent to the centre's inspector by the 15th September 2016.	from the expert virologist. The timeline should be received no later than 15 September 2016. Further action required. **Progress update** The centre's screening policy has been reviewed and revised. The PR has confirmed that staff training has been provided and has submitted copies of the audit, root cause analysis and advice received from an expert virologist. Based on the advice, the centre has determined that there is a negligible infection risk to patients who have received treatment where donor screening has not been compliant with regulatory requirements. A further audit to ensure that corrective actions have been effective will be performed and the findings submitted to the centre's inspector on 15 November 2016.

	has not been compliant with regulatory requirements. The PR should inform the centre's inspector of the timeline for obtaining this expert advice when responding to this report.		Further action is required.

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 to a 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	Executive Review
2. Several non-compliances were noted in the QMS: • an audit of counselling did not include a summary of findings or documentation of corrective actions; • an audit of donor recruitment, selection and screening has not been conducted within the last two years; • the SOP to direct the process for egg and embryo donation, and egg donor recruitment had not been audited against compliance with regulatory requirements as it does not include all	The PR should review the SOP directing the process of donor selection and screening to ensure that it is compliant with regulatory requirements. The PR should review the centre's audit process to ensure that they include an audit against regulatory requirements and centre's activities and that audits are documented in a consistent manner. Audit reports should also include a summary of findings and corrective actions where applicable. The PR should provide the centre's inspector with a copy of the review and an action plan for	The PR can confirm that the screening protocol for donors has been revised to include the regulatory requirements - a copy of the revised SOP has been past to the centre's inspector (NURSE-SOP-60). The PR can confirm that the centre's audit process is being reviewed to ensure that all audits are appropriately documented to include a summary and corrective actions where applicable. This review will then be sent to the centre's inspector with an action plan for implementation of recommendations.	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. A copy of the review of the centre's audit process and resulting action plan should have been submitted with the response to the inspection report however the Executive acknowledges the actions taken to date and will accept this being submitted in addition to copies of the incomplete and missing audits by 15 September 2016. Further action required.

screening tests required at the time of donation. SLC T36.	implementation of this recommendation when responding to this report. The PR should provide copies of the incomplete and missing audits identified in this report to the centre's inspector by 15 September 2016.	The PR can confirm that the missing/incomplete audits identified during the inspection are will be provided to the cnetre's inspector by the 15th September 2016.	**Progress update** Requested review and audits provided. No further action required.
3. The centre undertakes procurement by way of surgical sperm retrievals at unlicensed premises and has not established written agreements to cover these activities SLC T111.	The PR should ensure that third party agreements are in place with third party premises where surgical sperm retrievals are performed. The PR should provide the centre's inspector with copies of these agreements by 15 September 2016.	The PR can confirm that the centre's Business Manager and Quality Manager are sending the third party agreements for surgical sperm retrievals to the external sites. The PR will then provide copies for the centre's inspector by the 15th September 2016.	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. Copies of third party agreements to be received by 15 September 2016. Further action required. **Progress update** Third party agreements provided. No further action required.
4. The following medical devices used by the centre are not CE marked:	The PR should ensure that CE marked medical devices are used wherever possible.	The PR can confirm that the protocols are being revised and CE marked products are being sourced to ensure	The Executive acknowledges the PR's response and her commitment to fully

containers used for semen sample collection; serological pipettes. SLC T30.	The PR should ensure the implementation of this recommendation by 15 December 2016.	compliance by the 15th December 2016.	implementing this recommendation. Confirmation of compliance with this recommendation to be received by 15 December 2016. Further action required. **Progress update** Final implementation due by 15 December 2016. Further action required.
5. A review of the centre's incident log on inspection identified two adverse incidents which had not been reported to the HFEA. SLC T120.	The PR should ensure that all relevant adverse incidents are reported to the HFEA. The PR should review the incidents identified on inspection to consider why they had not been reported to the HFEA. The PR should ensure that all staff are aware of their responsibility to report serious adverse events and serious adverse reactions to the HFEA.	The PR can confirm that there is a system in place where every incident report is passed to her and she forwards these onto the HFEA. There are deputies in her absence. All staff understand that PR (or deputies in her absence) must be made aware of all incidents immediately, however on the two occasions identified in the inspection it was the PR that failed to send the completed reports to the HFEA due to confusion with incidents that had been reported. An	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. A summary of the review of the reporting system to be received by 15 September 2016. Further action required. **Progress update** A review of the adverse incident reporting process has

	The PR should provide a summary report of the actions taken to meet these regulatory requirements to the centre's inspector by 15 September 2016.	identification system for reports send to the HFEA has now been agreed with the HFEA Governance Lead to help to avoid this occurring again. The PR can confirm that the reporting system will be reviewed and a summary report will be sent to the centre's inspector by the 15th September.	been provided. No further action required.
6. At the time of the inspection discrepancies were found between four completed patient/partner disclosure consents on patient files (15 checked in total) and the related consent data submitted for inclusion on the register. CH(10)05 and General Direction 0005. It is noted that this was also identified as a non-compliance at the interim inspection in 2014 and has therefore been classified	The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms. The PR should also correct the submissions that have been identified as being incorrect and confirm this has been completed when responding to this report. The PR should conduct an audit six months after the implementation of corrective	The PR can confirm that a review of the CD consent form information submission to the HFEA is underway and a six month audit will be performed and submitted to the centre's inspector by 15th December. The four discrepancies that were identified during the audit will be identified and corrected.	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. Audit summary to be received by 15 December 2016. Further action required. **Progress update** Audit due by 15 December 2016. Further action required.

as a major non-compliance.	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 15 December 2016.		
7. The following issues were identified relating to the accuracy and timeliness of the centre's submission of data to the HFEA Register. • One egg donor, whose donated eggs were used to create embryos which have been imported into to the centre, has not been registered with the HFEA. • The centre reported four treatments with the gametes of unregistered donors. • At the time of the inspection 5% (6/133) of the IVF treatments reviewed had been reported to the HFEA outside the time period required by General Direction 0005.	The PR should ensure the accuracy and timeliness of the centre's submission of data to the HFEA. The PR should register the egg provider identified on inspection as a donor with the HFEA and confirm that this has been completed when responding to this report. The PR should review the centre's processes for registering donors and completion of donor details in patent's treatment forms and review all donors in use at the centre to confirm that they have been registered as a donor with the HFEA. The PR should provide the centre's inspector with a copy of this review including corrective actions identified and	The PR has confirmed that this donor has now been registered. The PR has met with the embryology team and reminded them to select 'partner' from the drop down box in the IDEAS database when preparing the semen sample as the four occasions identified on the inspection as use in treatment of unregistered donors were data input errors. Further details of this will be provided by 15 September 2016. The PR can confirm that the process for data submission is being reviewed and training will be provided where necessary. The details of the review and an action plan will	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR is advised to discuss the specific cases identified on inspection with the HFEA registry team. The Executive should receive clarification that this has been addressed in the summary of the review of the centre's processes for registering donors and completion of donor details in patient's treatment forms which is to be received by 15 September 2016. The Executive awaits a copy of the review of procedures used to submit licensed treatment data to the HFEA which should have been

General Direction 0005, SLC T41, SLCT9e. It is noted that delays in data submission to the HFEA was identified as a critical non-compliance at the renewal inspection performed in 2013. The centre improved their processes and there were no related issues identified at the interim inspection in 2014. This has therefore been classified as a major non-compliance in accordance with the HFEA's assessment framework.	evidence of staff training by 15 September 2016. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for poor quality submissions. The PR should provide the centre's inspector with a copy of the review and an action plan for improving the time frame for reporting treatments when responding to this report. The PR should conduct an audit six months after implementing any corrective actions, to confirm that they have been effective. A summary of the audit should be provided to the centre's inspector by 15 December 2016.	be sent to the inspector once completed. The PR can confirm that an audit and action plan of corrective actions will be provided to the centre's inspector by 15 December 2016.	submitted with the response to the report. The Executive accepts that the review may not have been completed and therefore extends the date for receipt of the review to 15 September 2016. A summary of the audit to be received by 15 December 2016. Further action required. **Progress update:** The centre has put measures in place to improve the accuracy and timeliness of data submission and are running EDI reports every other day to ensure continued improvement. A further audit to confirm that corrective actions have been effective will be performed and the findings submitted to the centre's inspector on 15 December 2016. Further action 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	Executive Review
8. An audit of patient records performed on inspection identified an instance where the time of administration of a controlled drug was not documented in the patient's record. SLC T2.	The PR should with immediate effect ensure that the details of controlled drugs including the time of administration are clearly documented in the patient record. The PR should perform an audit of patient records to ensure that the details and time of administration of any controlled drugs administered to the patients are clearly documented. The PR should provide the centre's inspector with a summary of the audit findings including corrective actions identified by 15 September 2016.	The PR can confirm that the anaesthetic department has been contacted and made aware that the full details including date and time of drug administration must be clearly documented in the patient's notes (copies of emails available on request). An audit of patient records will be completed and a summary report will be sent to the centre's inspector by 15th September.	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. Summary of audit to be received by 15 September 2016. Further action required. **Progress update** Requested audit provided. No further action required.
9. The centre has not documented the validation of the suction pumps used for egg collection.	The PR should ensure that the validation of all critical equipment is completed and documented.	The PR can confirm that the process of validation of all critical equipment is being reviewed and the validation documentation will be sent to	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation.

It is noted that the HFEA's assessment framework recommends classification as a major non compliance but in consideration that the centre had undertaken the relevant testing prior to installation, and that regular servicing had been performed this has been classified as an 'other' non compliance. SLC T24.	The PR should ensure the validation of the egg collection suction pumps are documented and a copy provided to the centre's inspector by 15 September 2016.	the centre's inspector by the 15th Septmenber.	Copy of validation document to be received by 15 September 2016. Further action required. **Progress update** Validation documents provided. No further action required.