Executive Licensing Panel - minutes

Centre 0325 (Bourn Hall (Norwich)) Progress Report

Friday, 15 January 2016

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

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

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

1. Background

1.1. Bourn Hall (Norwich), centre 0325, has a treatment and storage licence and provides a full range of fertility services. The centre has been licensed since 2013.

1.2. The Executive Licensing Panel considered the centre's renewal inspection report on 27 February 2015. The panel noted that at the time of the inspection on 9 and 10 December 2014, the inspectorate identified five major and three other areas of non-compliance. The panel noted that the Person Responsible (PR) had committed to fully implementing all of the recommendations within the prescribed timescales. However the panel was concerned that the PR's initial response to the report did not provide assurances that these recommendations would be fully implemented and endorsed the inspectorate's recommendation to continue to monitor the centre's performance.

2. Consideration of application

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

2.2. The panel noted that the inspectorate had confirmed that all of the recommendations have been fully implemented and no further action is required.

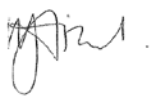
3. Decision

The panel thanked the inspectorate for the update and confirmation that all of the non-compliances have been addressed.

4. Chair's signature

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

Signature



Name

Juliet Tizzard

Date

25 January 2016

Executive Summary for Executive Licensing Panel
15 January 2016

Centre number	0325
Centre name	Bourn Hall (Norwich)
Person Responsible	Frances Rose-Smith

Progress report following up on recommended actions relating to non-compliances identified at renewal inspection, as requested by ELP

1. The ELP met on the 27 February 2015 to consider the centre's application to renew their treatment and storage licence. The minutes recorded the following:
    - *The panel noted the key dates for implementation of the recommendations and urged the centre to complete them within the prescribed timescales. The panel endorsed the Inspectorate's recommendation to continue to monitor the centre's performance. The Inspectorate is asked to provide the Executive Licensing Panel with an update report at the most appropriate time within the next 12 months.*

2. The ongoing monitoring of post inspection actions by the centre's inspector has enabled a progress update to be provided in the table below. The progress updates are noted in the Executive Review column.

3. The PR has provided evidence to confirm that actions have been taken in response to all non compliances identified within the prescribed timescales.

4. The Executive can confirm that all recommendations have been fully implemented and no further actions are required.

Karen Conyers
Inspector

Areas of practice requiring action

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 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
None identified at this inspection			

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
1. Eight out of 22 donor sperm samples used in treatment which had been supplied by their affiliate Bourn Hall Cambridge had not been screened for anti-hepatitis B virus core antibody. This has been categorised as a major (i.e. not critical) non-compliance as the donors had been screened for hepatitis B virus, but with only one of the two required tests. SLC T52b.	The PR should ensure that with immediate effect donor sperm samples to be used for treatments are from donors who have been fully screened in accordance with regulatory requirements. The PR should confirm to the centre's inspector that's this action has been implemented when responding to this report. The PR should investigate how donor sperm samples from gamete providers who had not been screened for anti-hepatitis B core antibody, which is non-compliant with SLC T52b, had been purchased and used. The	Our initial investigation was as follows: We have investigated this finding as requested and wish to reply that the finding is at odds with our understanding of the screeneing requirements, as clarified in Clinic Focus in January 2012. We acknolwledge that 8 out of 22 donor sperm samples received and used in treatment have not been screened for anti-hepatitis B virus core antibody. The 8 donors completed their quarrantine and screening process prior to January 2012. The Clinic Focus article of the same date gives clarification	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. Further action is required in relation to the completion of the audit due by 10 June 2015. **Progress update:** The PR provided the audit by 10 June. No further action is required.

	findings of this investigation including corrective actions and the timescale for implementation should also be submitted to the centre's inspector when responding to this report. Within three months of the implementation of corrective actions identified in the review, the centre should perform an audit to ensure that changes have been effective. A summary report of the findings of the audit should be provided to the centre's inspector by 10 June 2015.	on the screening for HBv (i.e. gamete donors are screened for both Surface antigen and Core antibody). Since this clarification all donors have been screened as required. The article also indicates that "The HFEA will not usually expect centres to carry out screening for anti-HBc retrospectively" As the donors in question all had their post quarantine exit screening performed before January 2012 retrospective screening was not undertaken. However following receipt of the executive review and discussions with the inspectorate we accept that our interpretation of the guidance on this matter differed from how the Authority intended it to be read and we wish to advise that from hereon, we will only offer to new patients donor sperm from donors who have been fully screened. We envisage that there will be occasions where patients may wish for donor	

		sperm / embryos created using the donor sperm to be used in their treatment – examples of such occasions being a patient's wish to try for siblings or to use frozen embryos in storage. In these instances we aim to complete the screening via contact with the donor or through testing of samples held in storage. An audit of this change will be conducted and the summary of the findings will be presented to the centre's inspector by 10 June 2015.	
2. Blood samples from patients and partners are not obtained within a timeframe specified by the Authority, i.e. within three months before first use. SLC T51b. In two of six patient notes audited the anti-hepatitis B core antibody test result was not present in the records and the centre staff were not assured that the tests had been performed.	The PR should ensure that procedures for screening of patients, partners and donors are compliant with all relevant regulatory requirements and guidance. Due to the significant number of issues found relating to screening requirements it is recommended that the PR performs a full review of the centre's screening procedures. This review should include, but not be limited to, the issues	Blood samples for patients who do not have current* blood test results will be obtained within the timeframe specified by the authority. *Current blood tests means any required blood test related to ongoing infertility investigations that has been obtained from a blood sample obtained within the previous 24 months. Repeat blood tests will be taken to ensure that no result older than 24 months is used.	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed that the centre will ensure that screening tests for patients and partners will be undertaken within three months before their first use and every 24 months thereafter.

SLC T50a. The centre's processes for screening patient's, partners and donors do not include the requirement to consider when additional testing may be required depending on the patient/partner's/donor's travel and exposure history and the characteristics of the tissue or cells donated (e.g., Rh D, Malaria, CMV, T.cruzi). SLCs T50d and T52h. Diagnostic test results are communicated to the centre by the patient's referring clinician. The PR could therefore not be assured of the validity and accuracy of the results of the tests or that they had been performed in a suitably accredited laboratory. SLCs T51a.	identified during the inspection and described in the body of the report. The findings of the review including corrective actions and the timescale for implementation should be submitted to the centre's inspector by 10 March 2015. Within six months of the implementation of corrective actions identified in the review, the centre should perform an audit to ensure that changes have been effective. A summary report of the findings of the audit should be provided to the centre's inspector by 10 September 2015.	From January 2014 all patients starting treatment have been screened for HB core. A checklist process is in place on IDEAS to ensure that all required testing has been completed. The centres Standard Operating Procedures MN012 and associated Work Instruction MN012-WI04 detail the management of medical and non-routine issues and are included with this response. These documents will be reviewed to ensure they cover all the requirements detailed in the finding. Patient referrals from Consultants at level II facilities (NHS hospitals) detail the diagnostic test results current at the time of referral and these are checked by centre staff for completeness before the referral is accepted. We consider this as adequate assurance that the tests are valid.	The updated SOPs reflecting screening requirements and practices are awaited. The Executive acknowledges the PR's responses that the majority of testing will be performed in suitably accredited laboratories. The PR has provided assurance that she has reviewed the centre's processes and will put in place measures to ensure that evaluation of the accreditation status of all testing laboratories used will be undertaken e.g. if tests have been initiated by a GP. A summary of the findings of the review of screening processes due by 10 March 2015 is awaited. Further action is required in relation to the completion of the audit due by 10 September 2015. **Progress update:** The PR provided the review by 10 March and audit by 10

		NHS hospitals are required to use approriately accredited laboratories. Testing initiated by the centre is primarily conducted in the clinical science laboratory at Bourn Hall Clinic Cambridge (centre 0100) that has achieved ISO17025 accreditation or the Norfolk and Norwich Hospital that has Clinical Pathology Accreditation. Both facilities are included on the Quality Assurance department's supplier audit programme. In addition, for NHS funded patients, we have requested, via the CCGs, that copies of blood tests are provided with the referral forms. This will help us to confirm that the laboratories commissioned to undertake the tests are appropriately qualified and a review of this activity will be included in the audit to be conducted. For non NHS patients GP's will be requested to provide hard copies of diagnostic reports to	September 2015. No further action is required.

		support their referrals. If necessary we will repeat the test if considered clinically relevant. The clinic is implementing a new pathway which at the initial visit it will be determined if the virologies are within the required date range and can also be aligned to the anticipated treatment date. Repeat bloods tests will be taken by the clinic at this consultation if required to ensure compliance with the EU Directive 2012/39/EU. A review of the centres screening procedures will be undertaken and provided to the centres inspector by 10th March 2015. This will be followed by an audit of the screening processes and proecedures by 10th September.	
3. The following medical device used by the centre is not CE marked: supplement for LifeGlobal culture media.	The PR should conduct a review of all medical devices currently in use to identify where products are not CE marked and take action to source alternatives.	Following receipt of the executive review and discussions with the inspectorate we accept that assurances given to us by the manufacturer regarding the CE	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation.

The addition of a non-CE marked supplement to a CE marked culture media product was discussed with centre staff – it is noted that the addition of this product invalidates the CE mark status of the culture medium. Use of the medium is non-compliant with the requirements of SLC T30 which requires the use CE marked medical devices where possible. In a Clinic Focus article provided in April 2013 clinics were advised that in the absence of any prospect that non-CE marked products would meet the requirements of licence conditions, they should implement a plan of action to ensure compliance within the following year. The centre did not act on this guidance. SLC T30. Clinic Focus April 2013.	The PR should provide the centre's inspector with a list of all medical devices including disposables, equipment, and culture medium indicating the CE mark status of these products. Where devices are not CE marked then the PR should indicate what the timescale for sourcing alternatives is and inform the centre's inspector of this by 10 March 2015. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this it is expected that all medical devices should be CE marked by 10 December 2015.	marked status of their product is incorrect and we undertake to evaluate and introduce a fully CE marked alternative by 10th December 2015. A list of all medical devices will be provided by 10th March	Further action is required in relation to providing a list of medical devices in use by 10 March 2015, and confirming that all only CE marked medical devices will be used by 10 December 2015. **Progress update:** The PR provided a list of all consumables and reagents and their CE marked status by 10 March 2015 and confirmed that CE marked medical devices will be in use from 7 December 2015. No further action is required.

4. The inspection team found that there was uncertainty within the centre staff as to whose responsibility it was to provide patients using donated gametes with information regarding legal parenthood. In addition, written information provided to patients was potentially misleading. SLC T60 and Code of Practice 6.2. This puts the centre at risk of failing to provide proper information to patients giving consent, as required the HF&E Act 1990 (as amended). HF&E Act, Schedule 3 S.3 (1)(b).	The PR should ensure that the processes by which verbal and written information regarding legal parenthood is provided to patients using donated gametes are clear and well defined within the team. The PR should provide the centre's inspector with a summary report of the review of information and processes and copies of the updated patient information by 10 March 2015.	Review of associated processes and documentation is already being undertaken. Information will be provided by the 10th March 2015.	The Executive acknowledges the PR's responses and her commitment to fully implementing this recommendation. Further action is required in relation to a summary of the findings of the review and copies of updated patient information due by 10 March 2015. **Progress update:** The PR provided the review by 10 March and copies of the updated patient information shortly thereafter. No further action is required.
5. 20% (3/15) of the DI treatments reviewed in the course of the inspection had not been reported to the HFEA as required SLC T9e, T41 and General Direction 0005.	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 confirm that treatments identified as not reported at the time of the inspection have been reported	All activity has now been reported.	The Executive acknowledges the PR's findings of the review and her commitment to fully implementing this recommendation. Further action is required in relation to the findings of the

	to the HFEA in responding to this report. The systems and processes used for licensed treatment data submission should be reviewed to enable the reasons for non-reporting of the DI treatments to be identified. The PR should inform the centre's inspector of the findings and corrective actions identified by 10 March 2015. The PR should conduct an audit six months after implementing any changes to confirm that any changes made to systems and processes are having the desired effect. A summary repor of the findings of the audit should be provided to the centre's inspector by 10 September 2015.	The processes required for reporting are already in place but had been overlooked in these instances. The staff have been reminded of these requirements. An audit will be conducted as requested.	review of systems and processes used for data submission due by 10 March 2015, and completion of the audit due by 10 September 2015. **Progress update:** The PR provided the review by 10 March and a copy of the audit by 10 July which indicated that further corrective actions were necessary. The centre's inspector requested a copy of the repeat audit by 10 December 2015. The PR provided a copy to the centre's inspector by 26 November 2015. 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	Executive Review
6. In two of five records reviewed the time of the witnessing check when gametes and/or embryos are placed into storage was not documented. Tubes used to collect follicular fluid during egg collections are not labelled and the centre's risk assessment requires a check of the working area (flow hood) to ensure that no unlabelled tubes remain between patients. In one of five records reviewed there was no documentation of the completion of the step confirming that the flow hood was clear of all unlabelled tubes. SLC T71, T101 and Code of Practice 18.8.	The PR should ensure that documentation of the time of witnessing and records pertinent to the egg collection are completed at the time the procedure takes place. The PR should review the relevant procedures and the documentation of witnessing. A summary report of the review findings including corrective actions and copy/copies of any amended documentation should be forwarded to the centre's inspector by 10 March 2015. Within three months of the implementation of any changes to the witnessing procedures, the centre should conduct an audit of witnessing and a summary report of the findings of the audit should be provided to the centre's inspector by 10 June 2015.	The two record reviewed at the time of inspection had the location recorded but the time of witnessing had been omitted. This information is added to our cryo sheet however the form does not accommodate this information in its current format. The document has been updated and is currently in our document control processes. The updated version will be provided to the inspectorate by 10th March 2015 The associated SOP is clear on the process of witnessing. The correct process has been reinforced with the embryology team. Audit to be actioned.	The Executive acknowledges the PR's findings of the review and her commitment to fully implementing this recommendation. A copy the updated document due by 10 March 2015 is awaited. Further action is required in relation to the completion of the audit due by 10 June 2015. **Progress update:** The PR provided a summary of the review by 10 March 2015 and audit by 10 June 2015 which indicated that further corrective actions were necessary. The centre's inspector requested a copy of the repeat audit by 10

			December 2015. The PR provided a copy to the centre's inspector by 26 November 2015. No further action is required.
7. The centre does not keep a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. General Direction 0003.	The PR should establish a summary log of cases where multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer with immediate effect and confirmation of establishment of the log should be provided to the centre's inspector when responding to this report. Within three months of the establishment of the log the PR should conduct an audit of the documentation of cases where multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer in the log. A summary report of the audit findings including corrective actions and the timescale for their implementation should be submitted to the centre's inspector by 10 June 2015.	A summary log has been implemented. Audit to be actioned.	The Executive acknowledges the PR's response that a summary log has already been implemented. Further action is required in relation to the completion of the audit due by 10 June 2015. **Progress update:** The PR provided a copy of the audit by 10 June 2015. No further action is required.
8. Patient feedback received at the HFEA included a concern from	The PR should review sedation practices to ensure that they are in line with current professional body	Action agreed. The recommended actions	The Executive acknowledges the PR's response and commitment

one patient regarding the sedation that they had received during their treatment at the centre. This was discussed with the PR during the inspection. The inspection team was informed that surgical procedures undertaken at the centre are performed under conscious sedation using protocols drawn up by the clinician at the centre. SLC T2.	guidelines: 'Safe Sedation Practice for Healthcare Procedures: Standards and Guidance issued by the Academy of Medical Royal Colleges in 2013' (http://www.rcoa.ac.uk/system/files/PUB-SafeSedPrac2013.pdf). The PR should inform the centre's inspector that this review has been completed by 10 March 2015.	were agreed in the PR's original response and a review of the sedation practices against current guidelines has been undertaken. An addition to the sedation medication has been implemented and a patient satisfaction questionnaire is being utilised to assess the effectiveness of the change. The outcome of this review will be provided to the centres inspector by 10th March 2015	to fully implementing this recommendation. Further action is required in relation to the outcome of the review of sedation practices against professional guidelines due by 10 March 2015. **Progress update:** The PR provided confirmation of completion of review and corrective actions completed by 10 March 2015. No further action is required.