Executive Licensing Panel - minutes

Centre 0098 (Lanarkshire Acute Hospital NHS Trust)

Interim Inspection Report

Wednesday, 28 March 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Caylin Joski-Jethi (Chair) Helen Crutcher Niamh Marren	Head of Intelligence Risk & Business Planning Manager Regulatory Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Clare Ettinghausen Catherine Burwood Laura Riley Lisa Whiting	Director of Strategy and Corporate Affairs Senior Governance Manager Head of Regulatory Policy Data and Insights Analyst

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. Consideration of application

1.1. The panel noted that Lanarkshire Acute Hospital NHS Trust is in Airdrie and has held a licence with the HFEA since 1992.

1.2. The panel noted that the centre provides basic fertility services and long-term sperm storage facilities. The centre holds a treatment (insemination using partner/donor sperm) and storage licence. Currently, the centre does not provide treatments with donor sperm. However, this licence type is the most suitable for the centre's range of activities. The panel felt that because the centre had not undertaken donor treatment for a long period, the licence type should be reviewed at the next renewal inspection.

1.3. The panel noted that, in the 12 months to 31 December 2016, the centre reported 142 cycles of treatment (including partner intrauterine insemination), with 11 clinical pregnancies. This represents a clinical pregnancy rate of 7%, which is likely to be comparable to the national average. In relation to activity levels this is a small sized centre.

1.4. The panel noted that the inspection took place on 16 January 2018.

1.5. The panel noted that at the time of the inspection on 16 January 2018, one critical area of non-compliance was identified concerning consent to the storage of cryopreserved material. Three major areas of non-compliance or poor practice were identified, two concerning equipment and materials and another regarding the Quality Management System (QMS). There was also one 'other' area of non-compliance regarding screening.

1.6. The panel noted that since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations regarding two major non-compliances surrounding equipment and materials (CE marking) and the QMS and has committed, where required, to confirm actions and review the effectiveness of those actions within the required timescales.

1.7. The panel noted that the PR had given a commitment to implementing the outstanding recommendations concerning consent, equipment and materials (alarm systems) and screening within the prescribed timescales.

1.8. The panel noted that the inspectorate recommends the continuation of the centre's treatment (insemination using partner/donor sperm) and storage licence, particularly noting the positive feedback made by patients with regards to their experiences.

2. Decision

2.1. The panel was pleased to see the positive feedback from patients using the centre, but strongly encouraged the PR to ensure there is continued engagement with the inspectorate outside of inspections to ensure standards of care for patients do not decline between inspections.

2.2. The panel was satisfied the centre was fit to have its treatment (insemination using partner/donor sperm) and storage licence continued.

3. Chair's signature

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

Signature

Name

Caylin Joski-Jethi (Chair)

Date

3 April 2018

Interim Licensing Report

Centre name: Lanarkshire Acute Hospital NHS Trust
Centre number: 0098
Date licence issued: 1 July 2016
Licence expiry date: 30 June 2020
Additional conditions applied to this licence: None
Date of inspection: 16 January 2018
Inspectors: Polly Todd (lead), Andy Glew and Mhairi West (observer)
Date of Executive Licensing Panel: 28 March 2018

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 a short notice 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 2015-2018 the focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients in relation to their experiences

The ELP is asked to note that this report makes recommendations for improvement in relation to one critical, three major and one 'other' area of non-compliance or poor practice.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non-compliance:

- The PR should ensure that there is a robust process for disseminating and acting on information and guidance provided by the HFEA.
- The PR should ensure that there is a procedure in place for alerting staff of a potential malfunction of the dewars when the laboratory is unmanned or the clinic is closed.

The PR has given a commitment to implementing the following recommendations in the prescribed timescales:

Critical areas of non-compliance:

- **The PR must ensure that there is effective written consent for all stored gametes.**

Major areas of non-compliance:

- The PR should ensure appropriately CE marked medical devices are used where available.

'Other' areas of non-compliance:

- The PR should ensure that the risks of Ebola infection are considered prior to patients being treated.

Information about the centre

The Lanarkshire Acute Hospital NHS Trust is in Airdrie and has held a licence with the HFEA since 1992.

The centre provides basic fertility services and long-term sperm storage facilities. The centre holds a treatment (insemination using partner/donor sperm) and storage licence. The centre currently does not provide treatments with donor sperm, however, this licence type is the most suitable for the centre's range of activities.

The centre provided 142 cycles of treatment (including partner intrauterine insemination) in the 12 months to 31 December 2016. 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 important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes

For the year ending 31 December 2016, the centre reported 142 cycles of partner insemination with 11 clinical pregnancies. This represents a clinical pregnancy rate of 7%, which is likely to be comparable to the national average.

Multiple births

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

Between January and December 2016, the centre reported eleven pregnancies, two of which were multiples.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes and that identification errors do not occur. The following laboratory activities were observed during the inspection: sperm preparation. All the procedures observed were witnessed using a manual witnessing system in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes is an important service offered by fertility clinics. It enables patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes, and the 'bring-forward' system were discussed with staff, and two samples were described to the inspection team as being stored outside of their consented storage period.

The consented storage period for the first sample had expired in July 2017. On the day of inspection, further investigation by centre staff revealed that the gamete provider had also stored gametes at another licenced centre and had provided consent there to extend the period of storage of his gametes. However, centre 0098 was not aware of this extension

and did not hold a record of this consent. The inspection team was concerned that, until the inspection visit, the centre had not taken any steps to investigate if the consented storage period had been extended.

This situation indicates that the 'bring-forward' system is not sufficiently robust and, as centre 0098 indicated that the practice of patients storing additional gametes at another centre was relatively common, there was reason to believe that there may be other gamete providers who have or will provide consent to extended storage in another licenced centre, but centre 0098 be unaware of this.

The consented storage period for the second sample had expired in October 2017, and the patient was deceased. Staff reported that they were waiting for authorisation from the PR before allowing this sample to perish. The PR reported that she was awaiting the HFEA visit to ask advice of the inspection team.

These activities indicate that the centre's 'bring-forward' system, and processes for storing gametes in line with the consent of the gamete providers are partially effective. There is not a clear procedure to follow when the end of the consented storage period is reached (see recommendation 1).

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations 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.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing, infection control, drug prescribing and QMS review.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions

- HFEA Clinic Focus articles regarding screening requirements and CE marking of medical devices

The centre is partially effective in implementing learning from guidance from the HFEA. The inspection team does not consider that there is a robust system for disseminating information and learning from guidance issued by the HFEA (see recommendation **Error! Reference source not found.**). The centre has not ensured compliance with guidance regarding screening for Ebola issued in February 2017 and April 2017 (see recommendation 5) and guidance regarding CE marking of medical devices (see section Equipment and Materials, and recommendation 2).

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance.

Prescription of intralipid 'off label'

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed during the inspection: culture media, plastic ware, and equipment. We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices wherever possible. Tubes (six and 14 ml), 60ml specimen container, Pastettes, 5ml pipettes, and the laboratory centrifuge were not CE marked (see recommendation 2).

The alarm systems that alert laboratory staff to low liquid nitrogen levels in the storage dewars or low atmospheric oxygen, only operate within the clinic; the liquid nitrogen alarm calls the laboratory via an auto dialler, and the low oxygen alarm activates an audible siren in the clinic. The laboratory will not always be manned to answer the telephone, and when the clinic is closed, there is no process in place for alerting staff of a potential malfunction of the dewars (see recommendation 3).

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Twelve patients provided feedback directly to the clinic in the time since the last inspection. Feedback was positive with all the individuals providing written feedback giving compliments about the care received.

Based on 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;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions;

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

Information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is fully compliant with HFEA requirements with the exceptions noted in this report.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2016, recommendations for improvement were made in relation to one critical, five major and three 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

As this centre only provides partner IUI treatment, their success rates are not subject to on-going monitoring through the HFEA risk tool and the centre has not therefore been issued with any performance alerts.

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 clinic provided its annual IUI treatment return for 2016 within the required timescale.

Legal parenthood

The centre has not performed any donor treatments since 2008, therefore this section does not apply.

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 made.

Critical areas 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 non-compliance requires immediate action to be taken by the Person Responsible.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. **Consent: To the storage of cryopreserved material** On the day of the inspection staff reported that the consented storage period for two sperm samples had expired in July 2017 and October 2017 respectively. On further investigation,	The PR must ensure that there is effective written consent for all stored gametes. The PR should ensure that the 'bring forward system' protocol incorporates the actions required coming up to and at the expiry of effective written consent to ensure compliance with Statutory Storage Regulations.	The revised protocol for the 'bring forward' system is attached.All laboratory staff will take part in a rota and have a dedicated session every month to inspect and monitor effective written consent for all stored gametes.The protocol for split samples stored at two different centres is also being	The executive acknowledges the PRs response and commitment to implementing this recommendation. The executive acknowledges receipt of a revised protocol. However, the PR has not assured the executive that there is a robust process in place regarding when samples

one sample had been divided between centre 0098 and another licenced centre in the locality and actually did have valid storage consent, but this was not known to centre 0098. The consented storage period for the second sample belonged to a patient who was deceased, and whose storage consent expired in October 2017. Staff reported that they were waiting for authorisation from the PR before allowing this sample to perish. The PR reported that she was awaiting the HFEA inspection to seek clarification on the matter. Subsequent to the inspection visit, the PR has confirmed that the sample for which consent to store had expired, has now been allowed to perish. Schedule 3 of HF& E Act 1990 (as amended). CoP 17.21. The Human Fertilisation and Embryology (Statutory Storage	The PR should provide a copy of the revised 'bring forward system' protocol when responding to this report. The PR should ensure that she and all clinic staff are fully conversant with the requirements of the HF&E Act (1990) and the Statutory Storage Regulations (2009). The PR must ensure there are procedures in place to manage the effective written consent of patients who have samples stored at two licensed centres and develop a mechanism to ensure that both centres are aware of, and are in possession of a copy of, that consent. This should include details of the centre responsible for acquiring consent from the patient, ensuring that the relevant storage regulations are complied with and mechanisms for ensuring copies of the patient's consent is held at both centres. It is expected that this procedure will be fully implemented and a	revised ensuring that both centres are in possession of a copy of a written valid consent.	are split between two centres, which is due by 16th April 2018. Further action is required.

Period for Embryos and Gametes) (Amendment) Regulations 2009 This was a non-compliance at the interim inspection in 2014.	copy provided to the centre's inspector by 16 April 2018.		

‘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;
- which can comprise 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.

A major area of non-compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
2. Equipment and Materials The following medical devices were not appropriately CE marked: centrifuge; 6 ml tubes; 14ml tubes; 60 ml specimen container; pastettes and 5ml pipettes. SLC T30.	The PR should ensure appropriately CE marked medical devices are used where available. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment. However, the PR should ensure that a plan is developed and implemented so that appropriately CE marked medical devices are used for licensed activities, where available.	The clinic is looking at sourcing CE marked devices where available.We have contacted other local clinics and obtained a list of CE marked devices and are in contact with the manufacturers to procure them.	The executive acknowledges the PR’s response and commitment to this recommendation. No further action is required beyond confirmation of implementation of the plan, due by 16 January 2019.

	This plan should be provided to the centre's inspector on responding to this report. It is expected that this plan will be fully implemented and confirmation of this provided to the centre's inspector by 16 January 2019.		
3. Equipment and Materials The alarm systems that alert laboratory staff to low liquid nitrogen levels in the storage dewars or low atmospheric oxygen, only operate within the clinic. There is no process in place for alerting staff of a potential malfunction of the dewars outside of clinic opening hours, or when the laboratory is unmanned. CoP GN 26.6.	The PR should ensure that there is a procedure in place for alerting staff of a potential malfunction of the dewars when the laboratory is unmanned or the clinic is closed. In the interim, the PR should provide evidence of any risk mitigation measures that are currently in place to the centre's inspector on responding to this report. A copy of the procedure implemented, should be provided to the centre's inspector by 16 April 2018	Arrangements are being made to connect the alarm system in the laboratory to the hospital switch-board when the laboratory is un-manned or outside of clinic hours. The switch-board will contact the laboratory staff for appropriate action. Response to Point 4 below-A designated senior member of staff will review all information and guidance provided by HFEA and Clinic Focus articles.The updates will form	The executive acknowledges the PR's response and confirms receipt of the risk mitigation measures implemented. No further action required.

		an agenda item for our unit meeting held every 8-12 weeks.	
4. Quality Management System The clinic's processes for learning are not effective in relation to implementing HFEA Clinic Focus guidance regarding screening for patients with relevant travel history and the use of CE marked devices. SLC T32.	The PR should review the process in place for disseminating and acting on information and guidance provided by the HFEA to ensure robustness and allow learning. The PR should provide a summary report of the review, with corrective actions, to the centre's inspector by 16 April 2018. Three months after the implementation of corrective actions the PR should review the process for disseminating information to the team to ensure that actions implemented have been effective. The PR should provide a summary report of this review to the centre's inspector by 16 July 2018.		The executive acknowledges the PRs response and commitment to implementing this recommendation, which she has documented in recommendation three. No further actions required beyond submission of a review of the processes implemented, due by 16 July 2018.

‘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	Inspection team’s response to the PR’s statement
5. Screening The centre does not consider the need for additional screening tests which may be required because of patients travel and/or exposure history, with regards to Ebola SLC 50(d).	The PR should ensure that the risks of Ebola infection are considered prior to patients being treated. The PR should ensure that the centre’s procedures for screening patients, clearly document the requirement for consideration of additional screening, including (but not exclusively) Ebola. The PR should provide a copy of the revised procedure to the centre’s inspector by 16 April 2018. Three months after implementing the revised procedure, the PR	The questionnaire used for history taking for all couples has been revised .Specific question regarding foreign travel and country of travel has been incorporated. If any of the high risk countries have been visited advise as per the HFEA will be followed and we would also contact our local infectious department if required.	The executive acknowledges the PRs response and commitment to implementing this recommendation. The executive awaits a copy of the revised procedure for screening patients, due by 16 April 2018. Further action required.

	should audit patient history and screening procedures to ensure that corrective actions implemented have been effective. A summary report of the audit should be provided to the centre's inspector by 16 July 2018.		

Additional information from the Person Responsible
The SOP for the "bring forward system" and the new patient history questionnaire is attached. The Laboratory staff has now more dedicated sessions specifically to ensure that all gametes including split-samples stored have valid consents and that the system is being effective. The PR will oversee this and any issue highlighted will be discussed at regular unit meetings.CE marked devices will be procured as soon as feasible and the centre will aim to implement these changes by Jan2019.The alarm system in the laboratory is being connected to the switch-board who in turn will alert the relevant staff. We will also perform an audit following introduction of revised screening protocol for diseases such as Ebola and robust measures have been put in place to ensure effective learning from advise disseminated by HFEA and Clinic Focus articles.