Executive Licensing Panel - minutes

Centre 0031 (Assisted Reproduction Unit, University Hospital of Hartlepool) – Interim Inspection Report

Friday, 27 November 2015

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

Panel members	Juliet Tizzard (Chair) Joanne Anton Jessica Watkin	Director of Strategy & Corporate Affairs Policy Manager Policy Manager
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers	Trisram Dawahoo	Digital Communications 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. Consideration of application

1.1. The panel noted that Assisted Reproduction Unit, University Hospital of Hartlepool, centre 0031, has held a licence with the HFEA since 1992 and provides a full range of fertility services.

1.2. The panel noted that the centre's licence is due to expire on 28 February 2018.

1.3. The panel noted that the inspection took place on 15 September 2015.

1.4. The panel noted that in the 12 months to 31 July 2015, the centre provided 275 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the year ending 30 April 2015 showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2014, the centre reported 19 cycles of partner insemination with one pregnancy, which was in line with the national average.

1.7. The panel noted that HFEA-held register data for the year ending 30 April 2015 showed the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 19%. This means that the centre's multiple live birth rate is not likely to be statistically different from the 10% maximum multiple live birth rate target.

1.8. The panel noted that at the time of the interim inspection on 15 September 2015, one critical, one major and one other area of non-compliance was identified. The panel noted that the Person Responsible (PR) has committed to fully implementing all of the inspectorate's recommendations within the prescribed timescales.

1.9. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence.

2. Decision

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

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

7 December 2015

Interim Licensing Report

Centre name: Assisted Reproduction Unit (ARU),
University Hospital of Hartlepool
Centre number: 0031
Date licence issued: 01 March 2014
Licence expiry date: 28 February 2018
Additional conditions applied to this licence: None
Date of inspection: 15 September 2015
Inspectors: Mrs Lesley Brown (Lead), Dr Vicki Lamb, Mrs Kathryn Mangold
Date of Executive Licensing Panel: 27 November 2015

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 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

The inspection team recommends the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that following the inspection, there were recommendations for improvement in relation to one critical, one major and one 'other' area of non compliance or poor practice.

Since the inspection the PR has given a commitment to fully implement all the following recommendations within the prescribed timescales.

'Critical' areas of non compliance

- The PR should ensure that there is consent in place for all gametes and embryos that are in storage. The PR should also ensure suitable system is in place to identify stored material within a suitable timeframe of the expiry of the consented storage period.

'Major' areas of non compliance:

- The PR should ensure that CE marked medical devices are used whenever possible.

'Other' areas of practice that require improvement:

- The PR should ensure documented procedures accurately reflect centre practice.

Information about the centre

The Assisted Reproduction Unit (ARU), University Hospital of Hartlepool has held a licence with the HFEA since 15 July 1992.

The centre provides a full range of fertility services.

The centre provided 275 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2015. 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[1]

For IVF and ICSI, HFEA held register data for the year ending 30 April 2015 show the centre's success rates are in line with national averages.

In 2014, the centre reported 19 cycles of partner insemination with 1 pregnancy, which is in line with the national average.

Multiple births[2]

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

HFEA held register data for the year ending 30 April 2015 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 19%: This means that the centre's multiple live birth rate is not likely to be statistically different to the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The inspection team were not able to observe any laboratory activities during the inspection but were able to discuss witnessing with staff and review the centres own witnessing audit. These activities indicated that witnessing procedures are compliant with HFEA requirements. However, the documented procedure for labelling egg collection tubes did not accurately reflect the practice described by staff. Staff described how the centre practice is to label the lid of the egg collection tube during egg collection, however the written procedure does not direct staff to label tubes (see recommendation 3).

[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2] The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and 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 and embryos are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs were reviewed and the 'bring-forward' system was discussed with staff. These activities indicated that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are not effective. The centre's own storage audit showed that all gametes and embryos were stored with appropriate consent at the time the audit was completed in 2014. It was not possible to determine from the centre's record of storage whether gametes were being stored in line with the gamete provider's consent, because the freeze date was recorded, but the consented storage period was not always recorded. On the day of inspection the PR informed the inspection team of several patients with sperm samples currently in store at the end of their statutory storage period. The PR later confirmed by email that the gametes of ten patients were being stored beyond their consented storage period. The centre's storage audit had been completed before the end of the consented storage period for nine of the patients described (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. The centre is not currently fully staffed, however staffing levels are reviewed regularly and consultation sessions and treatment cycles are adjusted to take staffing levels into account. The inspection team were satisfied that the PR is taking appropriate action to ensure patient safety by limiting activity to take account of staffing levels. .

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 prescribed 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 and consent to treatment and storage.

The witnessing audit reviewed on inspection had been carried out in accordance with requirements. However, information regarding the storage of gametes outside of consent provided by the PR post inspection suggests that the centre's own audit of consent to storage had failed to identify a sample stored beyond the consented storage period since 29 December 2013.

As a result of this observation the centre's procedures for auditing and acting on the findings of audits were considered only partially compliant with requirements however the

inspection team were assured that changes to staff personnel and audit practices implemented after the completion of the last storage audit mean that audit procedures are likely to be compliant and as a result no further recommendation has been made.

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 centre's audits of clinical success rates
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding equipment failures
- guidance issued in 2012 related to the use of non CE marked medical devices

The centre is broadly effective in implementing learning from their audits and from guidance from the HFEA. However, they had not fully implemented guidance issued in 2013 in relation to the use of CE marked medical device (see below 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.

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 medical devices in use at the centre was reviewed in the course of the inspection. We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices. The following medical devices are not currently CE marked: 14 ml round-bottomed tubes, 1ml pipette (see recommendation 2).

Patient experience

During the inspection, we spoke to one patient about their experiences at the centre and 43 patients provided feedback directly to the HFEA in the time since the last inspection.

Feedback was positive, with 81% of the individuals providing written feedback giving compliments about the care received.

On the basis of this feedback and observations made in the course of the inspection, it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

Patient feedback also included several negative responses regarding cancelled and delayed appointments. 65% of patients who provided feedback directly to the HFEA reported appointments had been cancelled or delayed by the centre. These were discussed with the PR. He was aware of these issues from patient feedback collected by the centre, and advised the inspectors that actions are ongoing to address this matter. It is acknowledged however that this feedback may be a reflection of the actions taken by the PR to ensure that treatment activity is limited when there are fluctuations in staffing levels (see above). The inspection team urge the PR to continue to monitor patient feedback and to ensure that there is effective communication of the reasons for delayed or cancelled treatments.

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 compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2013, recommendations for improvement were made in relation to, three major and five 'other' areas of non compliance.

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

On-going monitoring of centre success rates

Since the last renewal inspection in 2013 the centre has not received any performance related risk tool 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. This information is held in the HFEA Register.

The clinic is complaint with requirements to submit information to the HFEA. This conclusion is based on a review of the clinic's register submissions conducted on 9 September 2015.

The partners of women treated with donated gametes or embryos, where the couple are not married or in a civil partnership, must give written consent in order to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe.

Prior to inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and that no actions were necessary in response to the audit findings.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical 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 area of non compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. On the day of the inspection the centre was storing the gametes or embryos of ten patients for whom gametes or embryos were in store beyond the consented period (Schedule 3, 8(1) HF&E Act). (T79) The centre's records of storage were not considered adequate to support a robust bring forward system. Concerns about the	The centre should conduct an audit of consent to storage for all material currently in store. The PR should review the bring-forward systems and procedures for auditing storage of cryopreserved material. A summary report of the findings of the audit including corrective actions and the timescale for their implementation should be submitted to the HFEA by 15	A new electroic data base for the storage of sperms and embryos was created. This will alert the admin team and embryology team with the date of expiry date. It will help them to generate letters to patients, one year, 6 months and two month before the destruction of the stored gametes. Standard letters have been generated. A new protocol for gamete and embryo storage has been	The Executive acknowledges the PR's response and his commitment to fully implementing the recommendation. Further action required.

adequacy of this system prompted classification of this non-compliance as critical.	November 2015. The PR should provide monthly updates to the HFEA on progress in implementing the proposed corrective actions. Within three months of the implementation of corrective actions, the centre should conduct an audit of consent to storage and a summary report of the findings of the audit should be provided to the HFEA. The PR is reminded of guidance issued by the HFEA in CH(03)02 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.	created to reflect the changes in the data base. The centre will carry out an audit of consent to storage for all material currently in store once the embvryologist (L T) is back from her annual leave towards the end of November. I will send copy of the summery report and the corrective actions to the HFEA once completed.	

‘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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
2. The following medical devices used by the centre are not CE marked: 1ml pipette and 14ml round-bottomed tube. SLC T30 The PR failed to take action following guidance provided in 2013 on expectations with respect to the use of CE marked medical devices.	The PR should conduct a review of all medical devices currently in use with respect of the CE marked status of the devices. The PR should provide the centre’s inspector with a list of all medical devices including disposable plastic ware, equipment, and culture medium indicating the CE mark status of these products. Where devices are not CE marked then the PR should indicate the proposed timescale for sourcing alternatives by 15 December 2015. The PR should review whether there are barriers to the implementation of learning from	The 1 ml pipette and 14 mls round bottom tubes that are CE marked were requested and ordered through the CARDIA system following the inspection and the centre is currently awaiting the supply of these equibments in the near future. By December 2015 all the equibments used in the lab will be CE marked.	The Executive acknowledges the PR’s response and his commitment to fully implementing the recommendation. Further action required, in particular to review the barriers to implementation of learning from guidance issued by the HFEA.

	guidance provided by the HFEA and/or other sources. The PR should provide feedback on this review to the centre's inspector by 15 December 2015.		

‘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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
3. When describing the witnessing process, the description of practice did not accurately reflect the documented procedure. Staff described how the centre practice is to label the lid of the egg collection tube during egg collection, however the written procedure does not direct staff to label tubes. (T70)	The PR should update the documented procedure to ensure it accurately reflects practice. A copy of the revised standard operating procedure should be provided to the centre’s inspector by the time this report is considered by the Executive Licencing Panel. Within three months of the implementation the recommendation, the centre should conduct an audit of witnessing practice that must include adherence to the documented procedure. A summary report of the findings of the audit should be provided to the HFEA by 16 December 2015.	The Protocol for witnessing was reviewed and updated to reflect the current practice a copy of the protocol is attached. The protocol was reviewed and discussed with theatre nurses and the embryology team and agreed. A practice versus protocol audit will be carried out in three months as requested by the HFEA.	The Executive has reviewed the updated protocol and notes the current practice differs from the practice described on the day of inspection. The SOP supplied by the PR directs staff to label a heating block with a patient addressograph, prior to egg collection tubes being placed in the block. This step is double witnessed and recorded in the witnessing record. A “Bench clear and clean” step is also double witnessed and recorded in the witnessing record. The Executive is assured this procedure satisfies the requirements of SLC T70 Further action required.

Additional information from the Person Responsible