Executive Licensing Panel - minutes

Centre 0031 (Assisted Reproduction Unit (ARU), University Hospital of Hartlepool)

Interim Inspection Report

Tuesday, 10 December 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

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

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

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

1. Consideration of application

1.1. The panel noted that the Assisted Reproduction Unit (ARU), University Hospital of Hartlepool has held a licence with the HFEA since 1992. The centre has held a storage only licence since March 2018.

1.2. The panel noted that the centre was previously licenced to provide a full range of fertility services. As a result of a decision by North Tees and Hartlepool NHS Foundation Trust, the centre ceased licensed treatments in December 2016. In June 2017, the Person Responsible (PR) applied to renew its licence as a storage only, which was agreed by Executive Licensing Panel (ELP) on 1 December 2017. This allowed the storage of gametes and embryos to continue until the Trust could arrange transfer of the stored material to other licensed centres. The centre continues to store gametes and embryos and the PR is working with the Trust to determine the future of the storage arrangements.

1.3. The panel noted that a short notice inspection took place on 15 October 2019.

1.4. The panel noted that at the time of inspection there was one major area of non-compliance concerning equipment and materials. Two 'other' areas of non-compliance were also identified regarding consent to the storage of cryopreserved material and confidentiality. Since the inspection, the PR has provided evidence that all of the recommendations made in the report have been implemented. The PR will provide a summary report of the audit conducted, in relation to consent to the storage of cryopreserved material, to ensure that all requirements have been met and/or legal advice has been sought.

1.5. The panel noted that the inspectorate recommended the continuation of the centre's storage only licence.

2. Decision

2.1. The panel was satisfied the centre was fit to have its storage only licence continued.

3. Chair's signature

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

Signature

Name

Richard Sydee

Date

17 December 2019

Interim Licensing Report

Centre name: Assisted Reproduction Unit (ARU), University Hospital of Hartlepool
Centre number: 0031
Date licence issued: 1 March 2018
Licence expiry date: 28 February 2022
Date of inspection: 15 October 2019
Inspectors: Sandrine Oakes (lead) and Karen Conyers
Date of Executive Licensing Panel: 10 December 2019

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 (SLCs).

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. The current foci for an interim inspection are:

- **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.

The ELP is asked to note that this report makes recommendations for improvement in relation to one major and two 'other' areas of non compliance or poor practice.

Since the inspection, the Person Responsible (PR) has provided evidence that the following recommendations have been implemented. The PR will provide a summary report of the audit conducted to ensure that all requirements for effective consent to storage have been met and/or legal advice has been sought.

Major area of non compliance:

- The PR should ensure that the validation of the dry shipper includes an assessment of temperature.

'Other' areas of practice that require improvement:

- The PR should ensure that the centre's processes for ensuring that there is effective consent in place for all stored gametes and embryos are robust.
- The PR should ensure that access to the centre's electronic systems is secure.

Information about the centre

The Assisted Reproduction Unit (ARU), University Hospital of Hartlepool has held a licence with the HFEA since 1992. The centre has held a 'Storage only' licence since March 2018.

The centre was previously licenced to provide a full range of fertility services. As a result of a decision by North Tees and Hartlepool NHS Foundation Trust, the centre ceased licensed treatments in December 2016. In June 2017, the PR applied to renew its licence as a 'Storage only', which was agreed by ELP on 1 December 2017. This allowed the storage of gametes and embryos to continue until the Trust could arrange transfer of the stored material to other licensed centres. The centre continues to store gametes and embryos and the PR is working with the Trust to determine the future of the storage arrangements.

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

This inspection theme is not relevant as the centre does not offer treatment services.

Multiple births

This inspection theme is not relevant as the centre does not offer treatment services.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing practices with staff and to review witnessing checks in patient records. Witnessing procedures are compliant with HFEA requirements.

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, the team reviewed the audit of all stored gametes and embryos, the accuracy of storage logs and consent records, and the 'bring-forward' system was discussed with staff. The following were noted.

- the centre's bring forward system does not include consideration of the date on which the most recent medical practitioner statement has been completed;
- the centre's audit of stored material included a review of consent forms, but it was not clear if this also included consideration of the medical practitioner statements necessary to ensure that extension of storage beyond the statutory storage period is effective.

See recommendation 2.

Staffing

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

Staffing levels observed during the inspection appeared suitable for the activities being undertaken.

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: quality management system; infection control; consent to storage; witnessing.

The inspection team noted that the PR has ensured that the QMS and quality manager (QM) continue to be supported despite the recent uncertainties of the centre's future. The inspection team was assured that the centre's procedures for auditing and acting on the findings of audits was compliant with requirements. Whilst the PR and QM assured the inspection team that they regularly review the centre's ongoing QMS activities, a formal

review of the QMS has not been completed since the last licensed treatments were performed in December 2016. Given the limited activities being undertaken at the centre and that the PR has provided evidence that such a review has been completed immediately after the inspection on 21 October 2019, the inspection team makes no further recommendation at this time.

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:

- leadership
- patient support
- counselling
- consent

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

Medicines management

This inspection theme is not relevant as the centre does not offer treatment services.

Prescription of intralipid 'off label'

This inspection theme is not relevant as the centre does not offer treatment services.

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'.

This CE mark status inspection theme is not relevant as the centre does not offer treatment services and does not use products.

The inspection team noted that the shipper that the centre uses to transport stored gametes and embryos to other centres has been recently validated, but this did not include an assessment of temperature of the shipper over a period of time.

See recommendation 1.

Patient experience

This inspection theme is not relevant as the centre does not offer treatment services.

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 following exception:

- on inspection, it was observed that a computer in a consultation room did not log off automatically. The inspection team was concerned that if a member of staff was called away from their computer there is a risk that someone else may be able to access the systems that they are logged into.

See recommendation 3.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to three major and two '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

This inspection theme is not relevant as the centre does not offer treatment services.

Provision of information to the HFEA

This inspection theme is not relevant as the centre does not offer treatment services.

Legal parenthood

This inspection theme is not relevant as the centre does not offer treatment services.

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	Executive review
None identified.			

‘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	Executive review
1. Equipment and materials The shipper that the centre uses to transport stored gametes and embryos to other centres has been recently validated but this did not include an assessment of temperature of the shipper over a period of time. SLC T24.	The PR should ensure that the validation of the dry shipper includes an assessment of temperature. The PR should provide evidence of an updated validation to the centre’s inspector when responding to this report.	The dry shipper temperature has been validated over a period of 7 days and a report is enclosed.	The executive acknowledges the PR’s response. The PR has provided evidence of an updated validation for the shipper that the centre uses to transport stored gametes and embryos to other centres. No further action.

‘Other’ areas of practice that requires improvement

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
2. Consent to the storage of cryopreserved material On inspection, the following were noted: • The centre’s bring forward system does not include consideration of the date on which the most recent medical practitioner statement has been completed. • The centre’s audit of stored material included a review of consent forms, but it was not clear if this also included consideration of the medical practitioner statements necessary to ensure that extension of storage beyond the statutory storage period is effective.	The PR should ensure that the centre’s processes for ensuring that there is effective consent in place for all stored gametes and embryos are robust. The PR should review the database used in the centre’s bring forward system to ensure that it includes the date on which the most recent medical practitioner statement has been completed. The PR should audit the records of samples in storage at the centre beyond the statutory storage period to ensure that all requirements for effective consent to storage have been met.	Date of the MPS forms has been added to the data base. This includes a traffic system reminder (green , amber and red). A full audit for the long term stored oncology sperm samples was completed and the report enclosed. The PR is satsified about the available documents for all the sperm samples in storage. However, For one sample there are more documents required from a nearby trust. The PR shall forward this information to the inspection team once revieved.	The executive acknowledges the PR’s response and commitment to implement this recommendation. The executive has reviewed the information provided by the PR and has sought further clarification on the methodology used before being able to determine if it is a robust audit. The executive has reiterated to the PR the complexity of these regulatory requirements and he has been asked to review and audit further with the aim to complete by 15 January 2020. The executive will continue to liaise with the PR to ensure he can provide confirmation that all requirements for effective

The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. SLC T36.	When responding to this report the PR should provide the centre's inspector with a plan, with timelines, by which this audit and review will be completed. The PR should confirm that this recommendation has been implemented by 15 January 2020.		consent to storage have been met, and where there is any doubt, he will seek advice from lawyers who are specialist in this area of practice. Further action required.
3. Confidentiality On inspection, it was observed that a computer in a consultation room did not log off automatically. The inspection team was concerned that if a member of staff was called away from their computer there is a risk that someone else may be able to access the systems that they are logged into. SLC T44.	The PR should ensure that access to the centre's electronic systems is secure. The PR should ensure that immediate actions are taken to address the issue noted on inspection, and also consider if any staff training should be provided. Confirmation of the actions taken should be provided to the centre's inspector when responding to this report.	The trust IT department was consulted about the issue raised by the inspectors and the following actions were taken with immediate effect: 1) The automatic log off of the screens of two computers were changed to personal log in which allows the screen to log off (lock) if the computer is not used. 2) All the staff members in the ARU were advised to manually log off the computer screens if they leave the consultation	The executive acknowledges the PR's response. The PR has confirmed that all corrective actions have been implemented and staff training provided. No further action.

		rooms so that patients will have no access to identifying information on the computers screens.	

Additional information from the Person Responsible
Following the advice of the inspection team, live graphs have been created to monitor the liquid nitrogen top ups to ensure safety of the stored samples and to early diagnose any potential leakage or tank failure. The trust risk assessment for the storgae tanks has been updated with the actions taken so far. A digital safe lock was installed in the cryo lab for the padlocks keys as recommended by the inspection team. The dewar alarm and triggering of the on-call process has been added to the routine dewars inspection. A record is created and the alarms would be tested and result recorded on quarterly basis (SOP enclosed). On behalf of the ARU, the PR would like to thank the inspection team for their profesionalism and support.l