Executive Licensing Panel Minutes

Centre 0151 (Gloucestershire Hospitals NHS Trust)

Interim Inspection Report

Date:	29 June 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Richard Sydee (Chair) Yvonne Akinmodun Kathleen Sarsfield- Watson	Director of Finance and Resources Head of Human Resources Communications Manager
Executive:	Bernice Ash	Secretary
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 Gloucestershire Hospitals NHS Trust centre is located in the Microbiology Department of the Gloucestershire Royal Hospital and has held a licence with the HFEA since 1994. The centre holds a storage only licence, providing sperm storage facilities only for oncology patients in the Gloucestershire, Worcestershire, and Herefordshire areas. In relation to activity, this is a small sized centre.

1.2. The panel noted that, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA), was conducted for the centre's interim inspection, during which some potential areas of concern were identified, and were significant enough to merit an onsite inspection.

1.3. The panel noted that a videoconferencing meeting occurred on 21 April 2021, followed by an onsite inspection on 27 April 2021; this was a shorter than normal onsite visit, with one inspector, thereby reducing the risks of travel and close contact during the pandemic. The onsite inspection allowed for potential non-compliances to be appropriately reviewed.

1.4. The panel noted that at the time of the inspection, there was one critical area of non-compliance concerning consent to the storage of cryopreserved material. There was also one 'other' area of non-compliance surrounding patient support. Since the inspection, the Person Responsible (PR) has given a commitment to fully implementing both recommendations made in the report.

1.5. The panel noted the centre is well led and provides a good level of patient support.

1.6. The panel noted that the inspection team recommends the continuation of the centre's storage only licence, particularly noting the immediate actions taken by the PR in response to the critical non-compliance identified before and during the inspection.

2. Decision

2.1. The panel noted that, with regards to the critical non-compliance surrounding the consent to storage of cryopreserved material, the centre's database used for the 'bring forward' system would be updated, allowing sufficient time for consent and the medical practitioner statement (MPS) to be completed in a timely manner. The inspectorate was assured that changes to the centre's processes for samples in storage will ensure compliance with the relevant requirements; the robustness of the new processes will be reviewed at the next inspection.

2.2. 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

5 July 2021

Interim Licensing Report

Centre name: Gloucestershire Hospitals NHS Trust
Centre number: 0151
Date licence issued: 01 November 2019
Licence expiry date: 31 October 2023
Additional conditions applied to this licence: None
Date of inspection: 21 April (videoconferencing meeting); 27 April 2021 (onsite inspection)
Inspectors: Polly Todd (lead); Karen Conyers; Karen Campbell and Sarah Stedman (HFEA observers)
Date of Executive Licensing Panel: 29 June 2021

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, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law). 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 interim inspection, at the mid-point of the licence period.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk-based assessment (DBA) and the use of virtual technology where available and appropriate. A risk-based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

For this centre, the DBA/RBA process identified some potential areas of concern which the inspection team considered were associated with significant enough risk, to merit further review during an onsite inspection. Therefore, a shorter than normal on-site visit to the centre, with one inspector, together with videoconference meetings with key members of staff, was undertaken, thereby reducing the risks of travel and close contact during the pandemic. The on-site inspection allowed for potential non compliances to be appropriately reviewed.

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. In particular we note the immediate actions taken by the Person Responsible (PR) in response to the critical non-compliance identified before and during the inspection.

The centre is well led and provides a good level of patient support.

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

The PR has given a commitment to fully implementing the following recommendations:

Critical areas of non compliance:

- **The PR must ensure there is effective consent in place for all cryopreserved sperm in storage.**

'Other' areas of non compliance:

- The PR should ensure that there is a policy in place to support patients before, during and after their care at the centre.

Information about the centre

The Gloucestershire Hospitals NHS Trust centre is located in the Microbiology Department of the Gloucestershire Royal Hospital and has held a licence with the HFEA since 1994.

The centre provides sperm storage facilities only for oncology patients in the Gloucestershire, Worcestershire, and Herefordshire areas. 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

Treatment services leading to pregnancies are not provided by this clinic.

Multiple births

Treatment services leading to pregnancies are not provided by this clinic.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur.

This area of practice was assessed via DBA which indicated that 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 are stored in accordance with the consent of the gamete providers.

Samples in storage:
Prior to the inspection the PR had asked the HFEA for advice regarding samples stored for four patients for which he was not sure if there was effective consent in place. However, following a review by the HFEA in February 2021 it was established that these samples satisfied the criteria for extended storage under the Human Fertilisation and Embryology (HFEA) (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020.

In view of this, the HFEA was concerned that the PR and centre staff did not fully understand the regulations relating to storage and extension of storage. Therefore, on 19 February 2021 the PR was asked to implement a number of actions, including,

- conducting a full audit of all stored materials to ensure there were no further samples in storage where the validity of the consent is in question, due by 19 May 2021;
- undertake a refresher Person Responsible Entry Programme (PREP) test for modules relevant to the centre's licensed activities;

- obtain training for all relevant staff by a legal representative, conversant with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), and HFEA statutory storage regulations.

At the onsite inspection, the PR confirmed that the audit of stored sperm had been completed and results were discussed with the PR. As a result of the audit the PR has concluded that there are 15 patients with sperm in storage at the centre where there is some doubt as to the effectiveness of the consent. The main area of concern is whether these patients satisfy the criteria for extension of storage because the required written opinion of a medical practitioner (usually recorded by way of a 'medical practitioner statement' (MPS)) is either not present or has been completed outside the 'relevant period' as defined in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ('2009 regulations') or the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020.

The PR also confirmed that he had completed relevant parts of the PREP refresher on-line learning package and is in the process of purchasing further licenses for other members of the team to complete the training. Appropriate providers of legal training were also discussed.

See recommendation 1.

'Bring-forward' system:
The inspection team reviewed the centre's 'bring-forward' system during the DBA and videoconference meeting. The centre acknowledges that the system was not robust as it did not allow sufficient time to ensure that consent and an MPS were completed in a timely manner, and in accordance with the regulations. As a result, these processes were changed immediately and the centre will now contact colleagues in the oncology team 12 months prior to the expiry date of the consented storage period, to ensure that if needed, a written MPS is obtained in the relevant period required by the 2009 regulations.

Staff at the centre also confirmed that the database used for the 'bring-forward' system will detail the dates that the MPS was signed, and this will also be updated when, and if a new MPS is completed. The period of consent to storage and date on which the MPS is signed will be used by the centre to ensure that the date of expiry of consent to storage is correctly calculated and any extensions of storage can be completed within the required timeframes. The inspection team is assured that these changes to the centre's processes for managing samples in storage will ensure compliance with relevant requirements therefore no further action is needed in relation to the centre's 'bring-forward' system. The robustness of the new processes will be reviewed at the next inspection.

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 and the atmosphere in the clinic appeared calm at all times.

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: infection control; witnessing; consent to storage and traceability.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements with the exceptions noted in relation to consent to storage.

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:

- counselling
- consent
- screening
- data protection and confidentiality
- the use of CE marked medical devices.

The centre has been effective in ensuring compliance with guidance issued by the HFEA with the exception noted in relation to consent to storage and the patient support section of this report.

Medicines management

This centre does not provide treatment services, therefore this area of practice is not applicable to this inspection.

Prescription of intralipid 'off label'

This centre does not provide treatment services therefore this area of practice is not applicable to 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 DBA, we reviewed infection control practices. The centre had arranged for a member of the hospital infection prevention and control team to audit the centre. Recommendations were made for improvements following this audit and discussions with centre staff during the on-site inspection confirm that those recommendations are being actioned therefore no further recommendation is made in this report.

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 all medical devices used by the centre was reviewed during the DBA and videoconference meeting. The centre is compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors, and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information, and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are broadly compliant with HFEA guidance because the centre does not have a patient support policy in use at the clinic. The PR was able to provide a draft copy of a proposed policy which has not been approved or implemented into practice.

See recommendation 2.

Patient feedback

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic however, because of the nature of the activities undertaken by patients at this clinic, it is not relevant for this group of patients. The centre obtains their own patient feedback and the most recent patient survey responses were reviewed; 10 out of 26 surveys sent to patients were returned to the clinic for the period January 2019 to March 2021. Patients commented that they were treated with dignity and respect. There were some negative comments which were discussed at the inspection with the PR who made a commitment to address the issues raised by patients. This will be reviewed at the next inspection and therefore no recommendation has been made at this time.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible, and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

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.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2019 there were no recommendations for improvement made.

On-going monitoring of centre success rates

Treatment services that result in success rates monitored by the HFEA are not provided at this centre.

Provision of information to the HFEA

This centre is not required to provide information to the HFEA.

Legal parenthood

Treatment services that may require a person to consider providing consent to legal parenthood are not provided at this centre.

Leadership

The inspection team notes the critical non-compliance identified but considers that overall, the PR provides a good level of leadership and therefore makes no formal recommendation in this regard at this time.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles, and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

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
1. Consent to the storage of cryopreserved material The centre has identified 15 samples where there is some doubt as to the effectiveness of the consent (see main body of the report for further detail). Human Fertilisation and Embryology (Statutory Storage	The PR must ensure there is effective consent in place for all cryopreserved sperm in storage. In addition to the actions required of the PR prior to the inspection and detailed in this report, the PR must seek legal opinion for the 15 further samples identified, to ascertain	I agree with the actions required. I will discuss with our legal services department in order to progress the legal opinion and staff training by a legal representative conversant with the HF&E Act 1990 (as amended) and the relevant HF&E Statutory Storage regulations. I will ensure that a summary report	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

Period) Regulations 1991. Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020. SLCs T12, SLC T79, SLC T80, and SLC T82.	if there is lawful consent in place for continued storage of these samples. This opinion must be sought from a legal representative conversant with the HF&E Act 1990 (as amended) and the relevant HF&E Statutory Storage regulations. The PR must provide a detailed summary report of the findings of the legal opinion demonstrating why (where applicable) the samples may continue to be lawfully stored. The PR should also provide confirmation that staff training has been provided by a legal representative conversant with the HF&E Act 1990 (as amended) and the relevant HF&E Statutory Storage regulations. This, and the summary report of the findings of the legal opinion should be provided to the centre's inspector by 27 October 2021.	of the findings of the legal opinion and confirmation of staff training is provided to the centre's inspector by 27 October 2021.	

	Where, following legal review, there are any patient samples which cannot lawfully remain in storage at the clinic, the PR must notify the HFEA of this to discuss further options that may be available for these patients.		

‘Major’ areas 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
None identified			

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement are any areas 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. Patient Support: The centre does not have a patient support policy in place. The centre was able to provide a draft copy of a proposed policy which has not been approved, ratified, or implemented into practice. Chair’s letter CH (18)04; HFEA Code of Practice (9th edition) 2019, guidance notes 3.14; 3.15 and 3.16.	The PR should ensure that there is a policy in place to support patients before, during and after their care at the centre. It is expected that a ratified policy is in place and has been implemented across relevant staff groups by 27 July 2021. The PR should provide confirmation of this to the clinic inspector by this date.	I agree with the action required and will confirm ratification and implementation of our patient supprt policy to our clinic inspector by 27 July 2021.	The executive acknowledges the PR’s response and commitment to implementing this recommendation. Further action required.

Additional information from the Person Responsible
I would like to thank the inspection team for their work and this report.