

Executive Licensing Panel - minutes

Centre 0151 (Gloucestershire Hospitals NHS Trust)

Renewal Inspection Report

Tuesday, 23 July 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Howard Ryan	Director of Strategy and Corporate Affairs Communications Manager Data Analyst
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Moya Berry	Licensing Manager Committee Officer

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 considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.
- 1.2. The panel noted that the centre is part of Gloucestershire Hospitals NHS Foundation Trust, located in Gloucester, and has held a storage only licence since 1995. The centre offers a sperm storage service for the preservation of fertility to oncology patients in the Gloucestershire, Herefordshire and Worcestershire area. In relation to activity levels this is a very small centre.
- 1.3. An inspection was carried out at the centre on the 21 May 2019.
- 1.4. The panel noted that at the time of the inspection, there were no areas of practice that required improvement.
- 1.5. The panel noted that the inspection team recommended the renewal of the centre's storage only licence for a period of four years, without additional conditions.

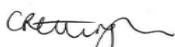
2. Decision

- 2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.
- 2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.
- 2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).
- 2.4. The panel endorsed the inspectorate's recommendation to renew the centre's storage only licence for a period of four years, without additional conditions. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

30 July 2019

Inspection Report



Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee (LC/ Executive Licensing Panel (ELP)) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 21 May 2019

Purpose of inspection: Renewal of a licence to carry out 'storage only'

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Nicola Lawrence, Mhairi West and Polly Todd

Date of Executive Licensing Panel: 23 July 2019

Centre name	Gloucestershire Hospitals NHS Trust
Centre number	0151
Licence number	L/0151/12/a
Centre address	Microbiology Department, Gloucestershire Royal Hospital, Great Western Road, Gloucester, GL1 3NN
Person Responsible	Dr Alan Lees
Licence Holder	Dr Sean Elyan
Date licence issued	1 November 2015
Licence expiry date	31 October 2019
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

The centre is part of Gloucestershire Hospitals NHS Foundation Trust, located in Gloucester, and has held a storage only licence since 1995. The centre offers a sperm storage service for the preservation of fertility to oncology patients in the Gloucestershire, Herefordshire and Worcestershire area. In relation to activity levels this is a very small centre.

Summary for licensing decision – pre review of draft by PR

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP) and standard licence conditions (SLCs), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were no areas of practice that required improvement.

Recommendation to the Executive Licensing Panel – pre-review by PR

The centre has no critical or major areas of non compliance.

The inspection team recommends the renewal of the centre's storage licence for a period of four years without additional conditions.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm) at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

▶ Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)

The centre's procedures for double checking the identification of gametes and the patient to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

What the centre could do better

Nothing identified at this inspection.

▶ Donor selection criteria and laboratory tests

Screening of donors prior to procuring and processing gametes

Payments for donors

Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)

The centre does not recruit donors therefore this area of practice is not relevant to this inspection.

Payments for donors (Guidance note 13; General Direction 0001)

The centre does not recruit donors therefore this area of practice is not relevant to this inspection.

Donor assisted conception (Guidance note 20)

The centre does not treat patients with donated gametes or embryos therefore this area of practice is not relevant to this inspection.

What the centre could do better

Nothing identified at this inspection.

► Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes
Transport and distribution of gametes
Receipt of gametes
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)

The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes in an environment of appropriate air quality.

The centre does not have any satellite or transport facilities.

Laboratory accreditation (Guidance note 25)

The centre's laboratories and third party laboratories which undertake the diagnosis and investigation of patients or their gametes are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)

The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management (Guidance Note 25)

The centre does not provide treatments requiring medicines therefore this area of practice is not relevant to this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)

The centre does not undertake procedures therefore this area of practice is not relevant

to this inspection.

Multiple births (Guidance note 7; General Direction 0003)

The centre does not provide treatment services and therefore this area of practice is not relevant to this inspection.

Procurement of gametes (Guidance note 15)

The centre's procedures are compliant with HFEA requirements to:

- document the justification for the storage of the patient's gametes;
- where sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes (Guidance note 15; General Direction 0009)

The centre does not store embryos. The centre's procedures for the transport, distribution and recall of gametes are compliant with HFEA requirements. This is important to ensure that all gametes sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes (Guidance note 15)

The centre's procedures for the receipt of gametes are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)

The centre's procedures for import and export of gametes are compliant with HFEA requirements.

Traceability (Guidance note 19)

The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes;
- to identify any person who has carried out any activity in relation to particular gametes; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)

The centre has a QMS that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)

The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)

The centre does not have any transport or satellite agreements therefore this area of practice is not relevant to this inspection.

Equipment and materials (Guidance note 26)

The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff. The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)

The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)

The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Nothing identified at this inspection.

 **Staff engaged in licensed activity**

Person Responsible (PR)

Staff

What the centre does well**Person Responsible (Guidance note 1)**

The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

Staff (Guidance note 2)

The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.
What the centre could do better Nothing identified at this inspection.

► Welfare of the child and safeguarding
What the centre does well
Welfare of the child (Guidance note 8) The centre provides gamete storage services only therefore this area of practice is not relevant to this inspection.
Safeguarding (Guidance Note 25) The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.
What the centre could do better Nothing identified at this inspection.

► Embryo testing Preimplantation genetic screening Embryo testing and sex selection
What the centre does well
Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10) The centre does not provide preimplantation genetic screening or embryo testing and sex selection, therefore this area of practice is not relevant to this inspection.
What the centre could do better Nothing identified at this inspection.

2. The experience of patients

▶ Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their centre. No patients have provided feedback in the last 12 months. This suggests that the clinic does not actively seek patient feedback for comparison purposes.

The centre has patients with underlying medical conditions using their services, including those storing sperm prior to commencing cancer therapies. It is important that the feedback of this group of patients is also sought to ensure that there is consideration of their needs.

The centre's own patient survey responses were reviewed. Several patients had provided positive comments about the service they had received.

On the basis of this feedback it was possible to assess that the centre:

- treats patients with privacy and dignity;
- 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.

What the centre could do better

Nothing identified at this inspection.

▶ Treating patients fairly

Counselling

Egg [and sperm] sharing arrangements

Surrogacy

Complaints

Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)

The centre does not undertake egg and sperm sharing, therefore this area of practice is not relevant to this inspection.

Surrogacy (Guidance note 14)

The centre does not undertake surrogacy therefore this area of practice is not relevant to this inspection.

Complaints (Guidance note 28)

The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)

The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Nothing identified at this inspection.

 **Information****What the centre does well****Information (Guidance note 4; Chair's Letter CH(11)02)**

The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Nothing identified at this inspection.

 **Consent and disclosure of information, held on the HFEA Register, for use in research****What the centre does well****Consent (Guidance note 5;6)**

The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)

The centre provides gamete storage services only and does not ask patients to consider consent to disclosure to researchers; therefore, this area of practice is not relevant to this inspection.

What the centre could do better

Nothing identified at this inspection.

3. The protection of gametes

▶ Respect for the special status of the embryo

What the centre does well

The centre does not create or store embryos therefore this area of practice is not relevant to this inspection.

What the centre could do better

Nothing identified at this inspection.

▶ Screening of patients and Storage of gametes

What the centre does well

Screening of patients (Guidance note 15)

The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes.

Storage of gametes (Guidance note 17)

The centre's procedures for storing gametes are compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes in accordance with the consent of the gamete providers. The storage of gametes is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy.

What the centre could do better

Nothing identified at this inspection.

▶ Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)

The centre does not create or store embryos therefore this area of practice is not relevant to this inspection.

What the centre could do better

Nothing identified at this inspection.

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)

The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)

The centre does not undertake patient treatments therefore this area of practice is not relevant to this inspection.

What the centre could do better

Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, recommendations for improvement were made in relation to one major and two 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

The monitoring of success rates is not applicable to this inspection because the centre does not provide treatment services.

Areas of practice requiring action

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

▶ Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

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			



Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several 'other' areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

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			



Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

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
None			

Reponses from the Person Responsible to this inspection report

I would like to thank the inspection team for their report.