Executive Licensing Panel - minutes

Centre 0080 (Andrology Unit, Hammersmith Hospital)

Interim Inspection Report

Tuesday, 14 January 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dan Howard Anna Coundley	Director of Strategy and Corporate Affairs Chief Information Officer Policy 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 Andrology Unit, Hammersmith Hospital is located in London and has held a storage only licence with the HFEA since 1992. The centre is part of Imperial College NHS Trust and provides storage of sperm for patients who are undergoing treatment that may impair their fertility. The centre occasionally provides the same service to patients seeking short-term storage of sperm when undergoing fertility treatment.

1.2. The panel noted that an unannounced inspection took place on 29 October 2019.

1.3. The panel noted that, at the time of inspection, there was one critical non-compliance concerning the consent to the storage of cryopreserved material, alongside one major area of non-compliance regarding the Quality Management System (QMS). Since the inspection, the Person Responsible (PR) has provided a commitment to implementing both recommendations made in the report.

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

2. Decision

2.1. The panel noted that no patients had provided feedback on their experience of the centre, in the last 12 months, through the 'Choose a Fertility Clinic' facility available on the HFEA website; the panel suggested that the centre actively encourages patients to use this mechanism to provide feedback.

2.2. The panel expressed serious concern regarding the critical non-compliance on consent to the storage of cryopreserved material, particularly considering the activities of the centre. The panel also noted this non-compliance had also been identified at the centre's renewal inspection conducted on 31 October 2017.

2.3. The panel was satisfied the centre was fit to have its storage only licence continued at this time, requesting an update report from the inspectorate, regarding the implementation of the recommendations surrounding the consent to the storage of cryopreserved material. Noting that a summary of findings of the files in storage, corrective actions and timescales, is due for submission to the inspector by 29 October 2020, the panel expected to receive the update by the end of 2020, at the latest. Upon receipt of the update report, the panel would make a further decision on the continuation of the centre's licence.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

20 January 2020

Interim Licensing Report

Centre name: Andrology Unit, Hammersmith Hospital
Centre number: 0080
Date licence issued: 31 October 2018
Licence expiry date: 28 February 2022
Additional conditions applied to this licence: None
Date of inspection: 29 October 2019
Inspectors: Nicola Lawrence (lead), Victoria Brown and Lesley Brown
Date of Executive Licensing Panel: 14 January 2020

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 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. 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 – pre review of draft by PR

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 critical and one major area of non compliance, as follows:

Critical areas of non compliance:

- **The PR should ensure that the process used to monitor consent to storage expiry dates is robust and accurate.**

Major areas of non compliance:

- The PR should ensure that the centre's quality management system processes are effective.

Information about the centre

The Andrology Unit, Hammersmith Hospital is located in London and has held a storage only licence with the HFEA since 1992. The centre is part of Imperial College NHS Trust and provides storage of sperm for patients who are undergoing treatment that may impair their fertility. The centre occasionally provides the same service to patients seeking short-term storage of sperm when undergoing fertility treatment.

Since the last renewal inspection an application to vary the centre's licence to reflect a change of Person Responsible (PR) was agreed by Executive Licensing Panel (ELP) on 24 October 2018, the new PR is Mrs Monica Flipia de Brito Figueiredo.

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]

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

Multiple births[2]

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

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 with staff and review the centre's own witnessing audit. These activities 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 and embryos are stored in accordance with the consent of the gamete providers.

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[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%.

On inspection, the 'bring-forward' system was discussed with staff and reports of audits of stored gametes and of the accuracy of storage logs along with storage records were reviewed. These activities indicate that the centre's processes for storing gametes in line with the consent of the gamete providers are not effective because:

- The centre does not have a robust 'bring-forward' system in place. The current system used at the centre to monitor storage consent expiry dates is held on several spreadsheets managed by different centre staff and involves an audit of all samples stored 10 years prior to the audit, undertaken once a year. This system does not capture any patient who has consented to store sperm for less than 10 years;

- Additionally, out of five patient records reviewed, the details of three patients who had stored sperm had not been entered into the spreadsheet for audit. The other two records had been entered into the spreadsheet;

- As part of the previous post inspection actions the centre completed an audit of every file in storage to check for gaps in the LGS form (Your consent to extending the storage of your eggs or sperm beyond 10 years). The audit report states that Medical Practitioner's Statements (MPS) form dates were reviewed as part of this, however, the member of staff who completed the audit stated they did not look at the dates of expiry of the MPS forms, or if there were gaps between dates of signing of these forms, when completing the report;

- When this was discussed with centre staff, they could not provide a list of patients whose consent forms are due to expire or explain why the MPS expiry date was not being recorded;

- Centre staff were not aware that gaps in cover for samples subject to the extended storage period regulations are likely to be irreconcilable with legal storage. MPS forms have a 10 year life span if signed after October 2009. New MPS forms have to be signed within 10 years of the last one;

- The inspection team is concerned that some samples may have been in storage for longer than the statutory storage period of 10 years, without evidence of compliance with the 2009 storage regulations being recorded in the patient records.

See recommendation 1.

Schedule 3, 8(1) HF&E Act 1990 (as amended).

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009

Code of Practice Guidance 17.21

SLCs T36, T79

Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; laboratory staff reported being able to carry out their activities without distraction, with staff available to carry out witnessing activities when required.

Quality Management System (QMS)

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

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: infection control; witnessing; consent to storage; traceability.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements. The centre's recent audit of storage consent checked only for gaps in the LGS form for samples that had been stored for more than 10 years and therefore the audit methodology was inadequate.
Additionally, the centre did not have a Standard Operating Procedure (SOP) for the 'bring forward' system.

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
- implications of treatment and consent
- extension of storage consent
- screening
- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions
- HFEA Clinic Focus articles regarding: EU exit and screening requirements.

The centre is only partially effective in implementing learning from their audits and or guidance from the HFEA because the PR does not share relevant clinic focus articles with centre staff and the centre has not ensured compliance with guidance regarding storage consent.

See recommendation 2.

SLCs T32, T33.

Medicines management

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

Prescription of intralipid 'off label'
The centre does not provide treatments requiring medicines therefore this area of practice is not relevant 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 inspection, we reviewed infection control practices and found them to be compliant with guidance.

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

The CE mark status of the following medical devices was reviewed in the course of the inspection: plasticware and media. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience
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. For a system to work well, it's important that every patient knows about the rating system. 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 sought to ensure that there is consideration of their needs.
The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.
The centre's own most recent patient survey responses were reviewed. A total of 33 responses were reviewed, most of which provided feedback that was extremely positive. 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.

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 with the exception noted in this report.

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 one critical, and five 'other' areas of non-compliances or poor practice. The PR provided information and evidence that the recommendations have been fully implemented. However, the inspection team could not be assured that the following critical non compliance has been fully resolved:

- The PR must ensure that gametes are stored only when valid consent for storage is in place.

On-going monitoring of centre success rates

Since the last renewal inspection in October 2017 the centre has not received any performance related risk tool alerts.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. Consent to the storage of cryopreserved material The centre's processes for storing gametes in line with the consent of the gamete providers are not effective, for reasons detailed in the main body of the report.	The PR should ensure that the process used to monitor consent to storage expiry dates is robust and accurate. The PR should review the electronic storage database for completeness, including the presence of an accurate expiry date for all stored samples,	The PR will review the storage databases and ensure its completeness including presence of an accurate expiry date for all stored samples. A review of training will be completed by the PR. The revision will include more training provided to all staff,	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action is required.

The centre also received critical non compliances for consent to storage at their previous two inspections. Schedule 3, 8(1) HF&E Act 1990 (as amended). The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 Code of Practice Guidance 17.21 SLCs T36, T79	and the process for ensuring the accuracy of the database when there is a change in the status of the patient, their partner, or their consented storage period. The executive acknowledge that this will take some time. A summary of the findings of the review, including any corrective actions with timescales for implementation, should be provided to the centre's inspector by 29 October 2020. The PR should ensure that staff receive appropriate training, in the conditions that must be met to allow the lawful extension of statutory storage of gametes. Details of the proposed training should be provided to the centre's inspector when responding to this report. The PR must ensure that gametes are stored only when valid consent for storage is in place.	encompassing, basic user competency in consents. Advanced user competency training in consents, will be given to relevant members of staff. Extension of storage consent training seminar was provided to staff on 29/11/2019. Bring forward system: Master Gamete excel spreadsheet has been created to record all storage consents expiry dates. The spreadsheet will alert members of staff 1 year before the consents expiry date (colour change alert). This spreadsheet will enable the centre to have all information about all patients' storage consent forms in one place. A business case for recruitment of an extra member of staff was sent to the management team to support the full audit. Additionally whilst business case is being considered, overtime was also requested to	

	The PR should ensure storage is only extended beyond the statutory storage period when there is compliance with the 2009 storage regulations, both in relation to patient consent and evidence of either premature infertility or of likely premature infertility in the future. The PR should review all long term stored samples to ensure that all appropriate consents and written medical opinions, completed within the relevant timeframe, are in place. The executive acknowledge that this will take some time. A summary of the findings of the review, including any corrective actions with timescales for implementation, should be provided to the centre's inspector by 29 October 2020. Monthly progress updates should be submitted to the centre's inspector.	advance the audit in the meantime. Andrology will audit all patients' files in storage with a completion scheduled for 29/10/2020. The PR will review all long term stored samples, to ensure all appropriate consents are present on files including written medical opinions. A summary of the findings of the review, including corrective actions and timescales for its completion will be provided to the inspector by 29/10/2020. The PR will seek legal advice on how to proceed whenever consents in place do not comply with 2009 storage Regulations. In this case, proposed actions will be forwarded to HFEA before actions being taken. The PR will provide monthly updates to the HFEA inspector	

	In any cases where there has been a failure to comply with the 2009 storage regulations, the PR should seek independent legal advice on how to proceed. Proposed actions in response to this advice should be forwarded to the HFEA for review prior to any action being taken.	on progress including number of files audited.	

‘Major’ area of non compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
2. **Quality Management System (QMS)** The centre’s quality management system processes are not consistently effective, for reasons detailed in the main body of the report. SLCs T32 and T33.	The PR should ensure that the centre’s quality management system processes are effective. The PR should provide a summary report of this review, and an action plan with timescales for implementation, to the centre’s inspector by 29 January 2020. The PR should provide the centre’s inspector with a copy of the ‘bring forward’ system SOP by 29 January 2020.	The PR has drafted the “bring forward SOP” and this is now up for revision. Once reviewed and submitted onto Q-Pulse Quality management System, a copy of the SOP will be submitted to the inspector on the 29/01/2020. A summary report with review and action plan will be provided to the inspector on the 29/01/2020.	The Executive acknowledges the PR’s response and commitment to implementing this recommendation. Further action is required.

‘Other’ areas of practice that requires improvement

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

Additional information from the Person Responsible