Licence Committee - minutes

Centre 0167 (University College London Hospitals)
Interim Inspection

Thursday, 7 November 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Jonathan Herring	
Members of the Executive	Dee Knoyle Bernice Ash (Observer)	Committee Secretary Committee Secretary
Legal Adviser	Eve Piffaretti	Blake Morgan LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

Papers enclosed:

- Cover sheet
- Inspection Report
- Previous licensing minutes for the last 3 years:

    - 15 January 2019 - Executive Licensing Panel Minutes - Change of Person Responsible
    - 30 June 2017 - Executive Licensing Panel Minutes - Renewal
    - 23 June 2017 - Licensing Officer Record of Consideration - Change of Centre Name

1. Background

1.1. University College London Hospitals is part of the University College London Hospitals NHS Foundation Trust. The centre has held a licence with the HFEA since 1997 and provides intrauterine insemination (IUI) with partner and donor sperm. The centre also offers a sperm storage service for patients who are having treatment that may impair their fertility.

1.2. The centre provides a satellite in vitro fertilisation (IVF) service to NHS patients in conjunction with The Centre for Reproductive and Genetic Health (HFEA Licensed centre 0044).

Licence

1.3. The centre changed its name from Reproductive Medicine Unit to University College London Hospitals in June 2017.

1.4. The centre's current licence was issued in November 2017 and was varied to change the Person Responsible (PR) in January 2019. The current licence was issued for a period of 4 years and is due to expire on 31 October 2021.

History of Non-Compliance

Consent to Storage

1.5. In 2013, over 3000 sperm samples were found to be in storage without effective consent. An action plan was submitted to the HFEA, however progress was slower than anticipated due to staff changes. An interim inspection was conducted in June 2015 and a large number of samples were in storage without valid consent. A full-time member of staff had been employed to address the matter and the recommendations were implemented within the revised timescale.

1.6. At the renewal inspection in May 2017, three sperm samples were in storage without effective consent, but action was taken by the centre following the inspection. The centre had made significant progress in resolving the storage issues.

2. Consideration of application

Interim Inspection

2.1. The committee noted that an unannounced interim inspection was conducted at centre 0167 on 8 May 2019. The inspection report covers the findings from this inspection, together with an assessment of the centre's performance based on information received, including the centre's self- assessment of its service and progress made implementing the recommendations identified at the last inspection.

The inspection covered:

- Quality of care
- Patient safety
- Patient experience

2.2. The committee noted that in 2018, the centre reported 149 cycles of partner insemination with 17 pregnancies. This represented a clinical pregnancy rate of 11% which was in line with the national average.

2.3. The committee noted that the centre provides insemination treatments only and is therefore not subject to the requirements of General Direction 0003 regarding multiple births. However, the centre has a multiple births minimisation strategy and conducts regular audits and evaluations of the progress and effectiveness of the strategy to ensure other HFEA requirements are met.

2.4. The committee noted that at the time of the renewal inspection, one critical, one major and two other areas of non-compliance were identified:

Critical areas of non-compliance:

- The PR must ensure that there is effective consent to storage for all cryopreserved gametes.

Major areas of non-compliance:

- The PR should ensure with immediate effect that patients and their partners are assessed for possible past or present Ebola virus exposure or infection and should ensure discussions and advice regarding patient travel history in relation to Zika and Ebola risks are clearly documented within the patient's records.

Other areas of non-compliance or poor practice:

- The PR should arrange for safety signage to be installed on the door of the cryostore room.
- The PR should ensure that audits are robust and corrective and preventative actions are effective in achieving improvements in practice.

2.5. The committee noted that since the inspection visit, the PR has fully implemented the major area of non-compliance relating to screening and one other area of non-compliance relating to safety signage for the cryostore room. The PR has committed to implementing the outstanding recommendations within the required timescales.

Consent to Storage

2.6. At the unannounced interim inspection on 8 May 2019, it was identified that there were approximately 100 samples in storage without effective consent.

Management Review Meeting – 28 May 2019

2.7. A management review meeting was held on 28 May 2019, in accordance with the HFEA's Compliance and Enforcement Policy, given the centre's history of storage consent issues. The Executive considered the extent of the critical non-compliance and whether any informal or formal regulatory action was required.

2.8. The Executive was not assured that the centre had robust systems in place to effectively manage the issues related to the consent to storage of cryopreserved materials. The Executive met with the PR on 24 June 2019 to discuss the findings of the report and to seek assurances that the non-compliances identified in the report would be addressed as a priority.

2.9. The PR was invited to provide a response to the inspection report and provide a comprehensive report of all samples being stored beyond their consented storage period and the actions taken to address each case. The Executive received a response and considered it to be incomplete, with no accurate report of the number of patients affected and no clarification on the centre's position in seeking legal advice.

2.10. After further discussions with the PR and the centre's Laboratory Manager the Executive received a further response to the inspection report from the PR on 1 August 2019 and was satisfied with the response.

2.11. The committee noted that the PR has been in post since the beginning of 2019 and had the continued support from the previous PR and the centre's Laboratory Manager to deal with the areas identified as non-compliant on inspection.

2.12. The committee noted that significant improvement is required in order for the centre to reflect suitable practices.

2.13. The centre has a Quality Management System (QMS) and the PR is encouraged to continue to use it to monitor and improve the centre's success rates and the quality of the service offered to patients.

Recommendations

Licence

2.14. The committee noted that the Executive recommended the continuation of the centre's licence.

Inspection

2.15. The Executive also recommends a short notice focused inspection to be undertaken within the next twelve months to ensure that the recommendations made in the interim report have been effectively implemented. If further issues relating to storage are identified at the next inspection, the Executive will consider whether formal regulatory action is needed and submit a report to the Licence Committee for consideration.

3. Decision

3.1. The committee had regard to its decision tree and the HFEA Compliance and Enforcement Policy.

3.2. The committee deliberated on the centre's history of non-compliance, in particular the non-compliance relating to consent to storage. The committee noted that the centre has significantly improved in this area of practice since 2013, however, since 2017 compliance in this area has declined.

3.3. The committee noted that the PR has provided the Executive with the required action plans and assurances and that the inspectorate will continue to monitor the centre's performance and implementation of the recommendations made in the interim inspection report.

3.4. The committee acknowledged that the centre had a dedicated member of staff to resolve the issues relating to consent to storage. However, the committee expects the current PR to ensure that robust processes, as well as resources, are in place to prevent any further issues relating to consent to storage. Patients should be contacted within a reasonable time before their storage periods expire and the centre's bring-forward system should be maintained and not allowed to lapse in order to ensure sufficient advance notice of the end of the statutory storage period (or such shorter period as specified by a person who provided the gametes).

Licence

3.5. The committee was satisfied that the centre is fit to have its licence continued.

Inspection

3.6. The committee endorsed the Executive's recommendation to carry out a short notice focused inspection within the next twelve months. The committee agreed that if the Executive find any further issues relating to consent to storage at the next inspection, the matter should be referred to the Licence Committee for consideration with recommendations for formal regulatory action, if necessary.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

3 December 2019

Interim Licensing Report

Centre name: University College London Hospitals
Centre number: 0167
Date licence issued: 01 November 2017
Licence expiry date: 31 October 2021
Additional conditions applied to this licence: None
Date of inspection: 8 May 2019
Inspectors: Julie Katsaros and Louise Winstone.
Dafni Moschidou from the Department of Health and Social Care (observing).
Date of Licence Committee (LC): 7 November 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 (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. 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 LC with information on which to make a decision about the continuation of the licence.

Information about the centre

University College London Hospitals is part of the University College London Hospitals NHS Foundation Trust and has held a licence with the HFEA since 1997.

The centre provides intra uterine insemination (IUI) with partner and donor sperm. The centre also offers a sperm storage service for patients who are having treatment that may impair their fertility.

The centre provides a satellite in vitro fertilisation (IVF) service to NHS patients in conjunction with The Centre for Reproductive and Genetic Health (centre 0044).

The centre's licence was varied in June 2017 to reflect a change of centre name from Reproductive Medicine Unit to University College London Hospitals and in January 2019 to reflect a change of Person Responsible (PR).

The centre has a previous history of storage consent issues first identified in 2013, when over 3000 sperm samples were found to be in storage without effective consent. Following advice from both a legal specialist and an external advisor, an action plan was submitted to the HFEA with the expectation that it would be fully implemented by August 2013. When responding to the report immediately after the inspection, the PR agreed to implement the recommendations, but later reported that staff changes had made progress slower than anticipated.

At the subsequent interim inspection in June 2015, it was noted that whilst significant progress had been made, there were still 1305 samples in storage without valid consent and a critical non-compliance was cited. The PR assured the inspection team that a full-time member of staff had been employed to address the matter and the PR provided a plan for resolution by March 2016 and monthly updates on progress were sent to the centre's inspector and implemented within the revised timescale.

At the renewal inspection in May 2017, three sperm samples were in storage without effective consent but given the centre's progress in resolving the storage issues the non-compliance was down-graded to a major non-compliance and actions were taken by the centre to fully comply with the recommendations following the inspection and prior to ELP meeting.

At this unannounced interim inspection, it was identified that there are approximately 100 samples in storage without effective consent.

Given the centre's history of storage consent issues and in accordance with the HFEA's Compliance and Enforcement Policy, a management review meeting was held on 28 May 2019 to consider the extent of the critical non-compliance and to determine whether any informal or formal regulatory action was required. Whilst it was considered that there were no immediate risks to patients, staff, gametes or embryos, the critical non-compliance regarding consent to storage of cryopreserved materials was deemed significant. Those attending the management review meeting were not assured that the centre had robust systems in place to effectively manage the issues related to the consent to storage of cryopreserved materials. It was agreed that the PR should meet with the HFEA to discuss the seriousness of the inspection findings prior to providing a response to this report and

seek assurances from the PR that the non-compliances identified in the report will be addressed as a priority.

On 24 June 2019 the Executive met with the PR to discuss the findings of the report and to seek assurances that the non-compliances identified in the report would be addressed as a priority. Following the meeting the PR was invited to provide a response to the inspection report and provide a comprehensive report of all samples being stored beyond their consented storage period and the actions taken to address each case. The Executive extended the PR's timeframe for providing a response to the report from the usual 10 working days to 25. Just prior to the deadline for the response to the report to be submitted the PR requested a further six working days extension to further consider her response, this was agreed by the Executive. The PR's response was received on 15 July 2019 and was considered by the Executive to be unsatisfactory because the PR had not:

- Provided an accurate report of the number of patients for whom gametes remain in storage beyond their consented storage period as requested both in the report and at the meeting with the Executive on 24 June 2019
- Provided a detailed action plan to include the specific detail that was requested and the proposed actions to be taken by the PR to ensure compliance with the HF&E Act and the relevant HFEA Statutory Storage Regulations.
- Clarified the centre's position in seeking legal advice for the gametes identified as in storage beyond their consented storage period.

The Executive held a further tele-conference meeting with both the PR and the centre's laboratory Manager to discuss the PR's responses to the report and the PR was again, invited to send a further response to the report. This was received on 1 August 2019 to the satisfaction of the Executive and the PR's amended responses are documented in the compliance table at the end of this report.

The PR reminded the Executive on several occasions that despite in her own words ' having only been the PR since the beginning of the year ' that she had the continued support of the previous PR and the centre's Laboratory Manager to be able to effectively deal with the areas identified as non-compliant on inspection.

Summary for the Executive Licensing Panel

Summary for licensing decision

An initial recommendation to continue the centre's licence was conditional on the PR developing and implementing effective action plans to address the non-compliances in this report and providing suitable assurances to the satisfaction of the Executive. Taking everything into account the Executive concluded that the centre's licence should continue.

The PR has provided the required actions plans and assurances and therefore the Executive recommends continuation of the centre's licence with a short notice focused inspection to be undertaken within the next twelve months to ensure that the recommendations made in this report have been effectively implemented. If further issues with effective storage are identified at the next inspection, the Executive will consider whether formal regulatory action is needed and submit a report to LC for consideration.

The centre's inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.
The LC is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one critical, one major and two 'other' areas of non-compliance or poor practice.

Since the inspection visit the Person Responsible (PR) has confirmed that the following recommendations have been fully implemented:

Major areas of non-compliance:

- The PR should ensure with immediate effect that patients and their partners are assessed for possible past or present Ebola virus exposure or infection and should ensure discussions and advice regarding patient travel history in relation to Zika and Ebola risks are clearly documented within the patient's records.

'Other' areas of practice that require improvement:

- The PR should arrange for safety signage to be installed on the door of the cryostore room.

Since the inspection visit the PR has given a commitment to implementing the following recommendations within the prescribed timescales:

Critical areas of non-compliance:

- **The PR must ensure that there is effective consent to storage for all cryopreserved gametes.**

'Other' areas of practice that require improvement:

- The PR should ensure that audits are robust and corrective and preventative actions are effective in achieving improvements in practice.

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

In 2018, the centre reported 149 cycles of partner insemination with 17 pregnancies. This represents a clinical pregnancy rate of 11% which is in line with the national average.

Multiple births

The centre provides insemination treatments only and is therefore not subject to the requirements of General Direction 0003 regarding multiple births. However, insemination

treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. Thus, it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a multiple births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activity was observed in the course of the inspection: sperm preparation for IUI. The procedure observed was witnessed using manual double witnessing in accordance 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, records of audits of all stored gametes and of the accuracy of storage logs were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes in line with the consent of the gamete providers are not compliant because approximately 100 sperm samples are being stored without effective storage consent in place (see recommendation 1).

Staffing

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

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

The centre's procedures for auditing and acting on the findings of audits are broadly compliant with requirements because:

- The centre's audits reviewed on inspection did not systematically document corrective actions or the timeframe for the completion of corrective actions (see recommendation 3).

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:

- patient support
- extension of storage consent
- consent
- screening
- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions

The centre is effective in implementing learning from their audits and guidance from the HFEA, with the exception noted above, (see recommendation 3).

Medicines management

The centre does not keep, dispense or administer medicines therefore this area of practice is not applicable to this inspection.

Prescription of intralipid 'off label'

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at 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 all medical devices in use in the laboratory was reviewed in the course of the inspection. 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. Only 15 patients have provided

feedback in the last 12 months, giving an average 4 star rating to the centre on the HFEA website. This suggests that the clinic does not actively seek patient feedback for comparison purposes. The centre has a large number of 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, as well as the needs of patients undergoing IUI treatments. For a system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

The centres' audit of patient feedback, for January 2019, was also reviewed, 8 patients had provided feedback which was positive and patients complimented the care received.

During the inspection the inspectors spoke to two patients who also provided positive feedback on their experiences.

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 with the following exceptions:

- Zika and Ebola assessment is not recorded in the patients records. The inspection team were assured by staff that travel history is discussed with patients undergoing treatment cycles in relation to Zika, however, the inspection team were not assured that the centre's staff consider possible past or present Ebola virus exposure or infection when assessing patients and their partners for treatment. The inspection team could not be assured that staff were aware of the latest guidance on Ebola screening (see recommendation 2).
- There is no safety signage present on the door of the cryostore room (see recommendation 4).

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 major and one 'other' area of non-compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales, however the non-compliance relating to storage consents has reoccurred.

On-going monitoring of centre success rates

The HFEA risk tool is used to monitor the success rates of centres providing IVF and ICSI treatments. This centre is not subject to ongoing monitoring through the HFEA risk tool and has not therefore been issued with any performance alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The centre provided its annual IUI treatment return for 2018 within the required timescale.

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

The centre commenced treating patients with donor sperm at the beginning of 2018 and was therefore not in operation in February 2014 when the HFEA asked all centre's to audit their practices in this area.

To provide assurance of compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff. The centre has only treated one couple in the last year where treatment with donor sperm had been provided in circumstances where consent to legal parenthood was required and these records were audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements. Due to the few numbers of patients having been treated with donor sperm, this activity has not yet been formally audited by the centre.

Annex 1

Areas of practice that require the attention of the Person Responsible

This 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 storage of cryopreserved materials On the day of the inspection the centre did not have written effective consent for the storage of approximately 100 cryopreserved sperm samples. HF&E Act (1990) as amended, Schedule 3, 8(1)	The PR must ensure that there is effective consent to storage for all cryopreserved gametes. The PR must; • Provide an accurate report of the number of patients for whom gametes remain in store beyond their consented storage period.	There is a written standard operating procedure for management of sperm samples in storage for fertility preservation. This was shown to the interviewers on 24.06.19. Point 1. Please see attached report of current status of	The PR did not provide the accurate report initially requested by the Executive, but following a meeting with the Executive the PR subsequently provided the information requested. The Executive acknowledge receipt of the report of the

Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009.	• In all cases where there has been a failure to comply with the storage regulations the PR must seek independent legal advice, with a legal representative who is conversant with the HF&E Act 1990 (as amended) and the HFEA statutory storage regulations 1991, and 2009, on how to proceed, including whether affected patients should be informed. • Provide an action plan with an anticipated timescale for implementation by the time this report is considered by a licensing committee. The action plan should include detail of the date the sample was first placed into storage; the period of consent initially given by the patient and the actions the PR proposes to take to ensure compliance with the Act and the relevant HFEA	sperm samples (Table1). Please note that significant clearance of backlog was achieved in June 2019. The number of discards exceed number of expiration of consents as patients whose repeat semen analysis revealed normal fertility potential consent to discards after appropriate clinical advice and counselling. Point 2. Number of samples in storage awaiting legal advice prior to discard: 24 (Table1). The independent legal representative (Hempson's) is conversant with HF&E Act, 1990 and HFEA statutory storage regulations. Hempson's report dated 2.March 2011, point 4.4 states that 'sperm stored between 1 August 1991 and before 2009 can be kept until the providers 55th birthday if extension critera are met, i.e her was under 45yrs at the time of providing consent and	number of patients for whom gametes remain in storage beyond their consented storage period. As a consequence of the PR not providing the report as described above, it was not clear as to the extent of the centre's failure to comply with the storage regulations and whether legal advice had been sought for those cases. Following a meeting with the Executive the PR subsequently provided a detailed update to the satisfaction of the Executive. The PR did not provide the action plan initially requested by the Executive, but following a meeting with the Executive this was subsequently provided by the PR.

	Statutory Storage Regulations. A copy of this action plan should be provided to the centre's inspector when responding to this report. The PR must review procedures for storage consent and ensure they are robust and effective in ensuring written effective consent is in place for all cryopreserved gametes. The PR must provide a summary report of this review including any corrective actions taken, to the centre's inspector by 8 August 2019. Three months after the review, the PR must audit storage consent procedures to ensure that corrective actions implemented have been effective in achieving compliance. A summary report of this review should be provided to the centre's inspector by 8 November 2019.	there is a written medical opinion indicating likely reduced fertility. This is the case even in the absence of written specific consent to prolonged storage-as long as individual has indicated that they consent to the maximum possible storage'. We are asking clarification whether stating that they wish to extend in the 'keeping in touch ' form satisfies this clause.Please see revised SOP with timescales (Document 1) and action plan regarding upcoming expriration of consent (Table1) Point 3. The action plan is per the revised SOP with timelines. Table 1 and document 1 provide the action plans. A database (Meditex) is used to monitor storage, paperwork, sending out keeping in storage letters and outcomes.This is	The PR provided a summary report of the review including corrective actions by the date requested to the satisfaction of the Executive. **Further action is required.**

		maintained by a dedicated member of staff. An review of the augmented process will be carried out before 08 August 2019 as per instruction. An audit of the storage consent procedures and outcome will be carried out prior to 8 November, 2019 and a summary report submitted to the HFEA. Updated response dated 01.08.2019 At the time of the inspection, inspectors picked up about 100 samples in storage without effective consent. These were a mix of back log of discard and those requiring independent legal advice. As consents expire every day, the numbers to discard also change every day. At the time of the interview on 24.06.2019, I presented 52 patient samples (up to date as of 21.06.2019) without possible effective consent	

		and discussed the legal complexity about those who were young and those who at some point in the last 10 years had written with intension to extend storage but did not sign the HFEA consent forms despite repeated communication. This means that most of the backlog was cleared as samples were discarded on a weekly basis. At the time of submitting the response on 15/07/2019, legal advice was sought for 24 samples of sperm which remained beyond the 10 year period patients had consented to. On this day (01.08.2019), 22 patient samples remain in storage beyond their effective consent, representing less than 0.05% of our storage inventory. Since our telephone conversation on 25.07.2019, we have identified that the consent of one of the previously-stated 24 patients has not yet	

		expired and we have been able to discard a sample following a repeat semen analysis. A further sample was removed from legal advice and put in queue for discarding. A full summary of the 24 patient samples that we have discussed is attached. In each case, we have provided information about when the gametes were stored, the period of consent initially given by the patient, the date of completion of MPS and our course of action and timescales. Although we pursued legal advice via the trust legal team, I as PR have communicated directly with the lawyer dealing with our queries and date is included in the spreadsheet. Independent legal advice was sought from Hempson's via our Trust's legal team over long periods in 2011, 2014, 2016, 2017, and for further	

		clarifications on 15/07/2019. The nature of the query and advice received from Hempson's has been included in the list. We will write to all patients to where we have advice from Hempson's about the outcome. This will be concluded by 03/09/2019. However we appreciate that as all of these patients have not responded to our recent communications. The affected patients all stored prior to the change in laboratory management in 2010 when significant improvements were made to the consenting and follow-up processes. Since taking on the role of PR in January I have spent considerable time with the laboratory team to understand the complexities of a cryopreservation service of this magnitude. I will provide a summary report of the consent and renewal processes by 08/08/2019,	

		and will submit an audit by 08/11/2019.	

‘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 partially 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. Screening of patients Zika and Ebola assessment is not recorded in the patients records. The inspection team were assured by staff that travel history discussions are being discussed with patients undergoing treatment cycles in relation to Zika, however, the inspection team were not	The PR should ensure with immediate effect that patients and their partners are assessed for possible past or present Ebola virus exposure or infection and should ensure discussions and advice regarding patient travel history in relation to Zika and Ebola	The patient questionnaire asking details of travel in the last 2 months was shown to the HFEA interviewers (document 2). The check list undertaken prior to IUI treatment was also shown. Check list completed	The PR provided evidence that the centre are now assessing the travel history of patients and documenting this in patient records, however, the PR did not respond to the Executive request for consideration with expert advice if necessary, if there is were any risk to patients

assured that the centre's staff consider possible past or present Ebola virus exposure or infection when assessing patients and their partners for treatment. The inspection team could not be assured that staff were aware of the latest guidance on Ebola screening. SLC T52; EUTCD 2006, professional body guidelines 2008.	risks are clearly documented within the patient's records. The PR should consider, with expert advice if necessary, if there is any risk to patients resulting from the past failure to perform Ebola assessment. If risk is present, appropriate risk control measures should be implemented. The PR should review patient screening processes, including any staff training requirements and inform the centre's inspector of the actions taken to implement this recommendation when responding to this report. Three months after implementing corrective actions, the PR should audit their effectiveness. A summary report of this audit should be provided to the centre's inspector by 8 August 2019.	prior to IUI is attached (Table2). An audit carried out showed 100% compliance with regards to zika virus exclusion in the checklist (Document 3). Ebola virus has been included in the checklist (table 2) and will be re-audited prior to 08 November 2019 and included in the summary report. Recommendations have been made for quality management and improvement courses. A refresher of patient screening processes have been carried out though the clinical multidisciplinary team meeting and quality management meeting. Outcome will be included in summary report. Updated response 01.08.2019 I can confirm that looking through the health records of	resulting from the past failure to perform Ebola assessment. If risk was present, appropriate risk control measures should be implemented. Following a meeting with the Executive the PR subsequently provided the assessment to the satisfaction of the Executive. The PR has provided the audit requested. **No further action is required**

		all patients who had IUI treatment, no patients reported temperature, joint and muscle pain, severe muscle weakness or sore throat or any symptoms suggestive of Ebola during their fertility assessment or during treatment. The clinic performed an assessment by contacting 20 patients so far who concluded treatment to ask about travel to Ebola risk areas within the last 2 years (West Africa including DRC). All 20 patients denied travel in the last 2 years. This assessment is ongoing and will include all patients treated before the update of the questionnaire. I contacted the consultant virologist of UCLH about any reported or suspected cases of Ebola since 2016. I was informed that there were none. I put the following questions to the expert:	

		Q: Is it possible for the infection to surface a year or 2 later? A: Small possibility of recurrence e.g. from the eye, but I've not heard of this happening after as long an interval as 2 years. Q: What would be your advice for those with unknown risk i.e. where we don't know if they have travelled to the DRC in the last 2 years and we have treated them already. A: The period of concern for DRC would begin in May 2018. DRC has had 2 Ebola outbreaks in the last 2 years. It had a small outbreak in May-July 2018 & a much larger outbreak from August 2018 to present date (North Kivu). There are few links between UK & DRC so it's relatively unlikely we have many patients from DRC, travelling to DRC etc. If any patient who has been to DRC since May 2018, we may need to think	

		about these specific cases & we'd need very detailed travel history with exact dates & places. If we do not know a patient has travelled to DRC, I would not be concerned about Ebola EVD. I (PR) contacted Public Health England with query about any case of Ebola reported recently in the UK. They have confirmed that there have been none. These enquiries lead me to believe that no patients were at risk. I will submit another report by 08.08.2019 of my audit questioning all patients treated for IUI last year and up to 08.05.2019. I would also like to point out that we do not recruit gamete donors in our centre.	

‘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
3. QMS The centre does not systematically document corrective actions or the timeframe for the completion of corrective actions. SLC T32.	The PR should ensure that audits are robust and corrective and preventative actions are effective in achieving improvements in practice. The PR should conduct a review of all audits undertaken in the last two years to ensure that corrective actions have been documented and timeframes for their implementation are recorded, together with confirmation that the required action has been completed. A summary report of this review, including any further actions implemented, should	The standard audit form used by the centre was shown to the HFEA interviewers. An audit will be carried out of the documentation to be provided prior to 08.08.2019 A review of all audits is ongoing. I have started reviewing all the audits in the laboratory. Any non-compliance to agreed standard is documented and recommendation for corrective action is recorded. A target date for implementation and reaudit is recorded. A summary report will be provided by 08 August 2019.	The Executive acknowledges the PR’s response and her summary report and corrective actions received by the date requested. **No further action is required**.

	be provided to the centre's inspector by 8 August 2019.	Updated response 01.08.2019 We have undertaken a review of all audits carried out in the last two years, and a summary report is attached. The majority of audits did include documentation of corrective actions. Where this detail is missing on the audit report, we are satisfied that there have been no instances of poor practice caused as a result of our audit processes, however, we recognise that the documentation of audits has not been consistent. We have improved our audit templates to ensure that details of corrective actions identified, implemented and completed are always recorded	
4. Safety and Suitability of Premises There is no safety signage present on the door of the cryostore room.	The PR should arrange for safety signage to be installed on the door of the cryostore room. Confirmation that the signage has been installed should be	Confirmation will be provided by 08.08.2019. Updated response 01.08.2019: I can confirm that the signages are in place.	The Executive acknowledges the PR's response and for confirming that this recommendation has been fully implemented **No further action is required**.

DH Health Technical Memorandum 02-01: Medical gas pipeline systems; part B operational management.	provided to the centre's inspector by 8 August 2019.		

Additional information from the Person Responsible
A meeting was held on 08.07.2017 with the lead of the andrology laboratory, the administrator for the sperm storage and the previous PR to inform them of the outcome of the interview on 24.06.2019 and appraise the team of both the feedback from the meeting and the items in the report. The pregnancy rate is quoted in the report as 17 pregnancies out of 149 cycles. This leads to a measure of 11.4%, not 6 %. The evidence of the centre's policy and implementation of systems in dealing with stored sperm samples comes from the improvement it had made from thousands to 3 samples as mentioned in the report. Our system and processes will be further augmented by the helpful advice from the HFEA. We would like to highlight we demonstrated a patient centred approach in our care. Updated response, 01.08.2019 UCLH has provided a large and necessary fertility preservation service since the 1970s and currently stores samples for nearly 5000 patients who may have no other option for biological parenthood. We have always worked closely and transparently with our inspectors to resolve the sometimes unique and frequently complex challenges that arise from providing this service. Each month, around 50 new patients preserve their fertility with us, and around 50 samples are marked for disposal, and we aim for a patient-centred approach to managing such a high turnover of patient samples and meticulous review of each patient file. The number of outstanding samples represents a very small proportion of our storage service, but we do recognise that we should be complaint with regulation at all times. I presented the number of samples that have already been discarded to address the backlog that was in existence at the time of the inspection. Improvements must be made to our timescales for resolving these difficult cases. Towards this end, I am extremely grateful for the advice from the interview panel on 24.06.2019 to pursue legal advice proactively much before the date of expiry of consent. As a clinician, it is an ethical dilemma to discard a sample of a young man who most likely to need to use his stored gametes. It was our organisation's practice to gather as many instances as possible before approaching the legal team for independent legal advice to optimise time and legal costs. However, I will henceforth follow the advice of the inspector to perform this exercise well ahead of time. The clinic felt ethically compromised to allow the samples to perish without first seeking advice as to what we could do in the best interests of the patients, given the consents had expired or were soon to expire. I would also like to highlight that as a recently appointed PR, I recognised this significant issue and took the advice of my senior colleagues, both of whom have been previous

persons responsible as soon as I took handover. They were in agreement that discards were not in the patients' best interest and independent legal advice should be sought. We have done this and we have received independent legal advice on which we are taking action and have provided the timescales for completion. We are confident that the changes we have made to consenting and follow-up procedures for those who have stored after 2010 and that the HFEA will be familiar with, will ensure that a similar situation will not reoccur. I will also provide an update of our storage compliance by 08.11.2019

I apologise that there were errors in my self-assessment questionnaire. It appeared my questionnaire revealed that I had checked not compliant where we were complaint and vice versa (our inspector had kindly pointed this out to me during our discussions after the inspection). I did experience an IT issue during filling the SAQ for which I had requested assistance from the HFEA (email to Victoria Askew dated 15/03/2019). This may have led to inadvertent errors. However, I take full responsibility.

We are grateful for our inspector's support and understanding of the constraints of running a clinic within a larger organisation and within the time frames and resources available within the NHS. With regards to non-compliance about documentation about Ebola risk, I would like to highlight that it had always been a mandatory question in the checklist for patients who have IVF treatment. We acknowledged that this question was missed from the IUI checklist which was added after the inspection on 08.05.2019 and therefore has been a part of mandatory questioning since then.

I would like to emphasise that we recognise that we need to improve our audit process and a summary of audits of the last 2 years and corrective actions and timelines is attached. A key feature is to repeat an audit of audits annually.

Executive response.

Pregnancy rate

The Executive thanks the PR for highlighting this inaccuracy and the figure has been amended in the report to reflect an accurate pregnancy rate for 2018.

Consent to storage of cryopreserved material

The Executive is aware that the centre stores gametes for a large number of patients who have underlying medical conditions, some of which are life limiting and the Executive understands that these patients need to be approached with sensitivity and that on occasions the centre may face ethical dilemmas, which is why it is so important to ensure that effective consents are in place to enable patient's wishes to be carried out should the situation arise and that patients and their families do not end up facing very upsetting legal cases in the courts.
The centre is not unique in having a large number of gametes in storage and the Executive would expect that robust processes are in place to avoid these situations in the future.
The Executive cannot reconcile the PR's claim that she was advised by the inspector to seek legal advice 'well ahead of time'. At the meeting with the Executive, the PR's processes for contacting patients whose consent to continued storage was required was discussed. The PR's current system was to attempt contact with the patient two years before the consent expiry, but then take no further action (if they had not had a response from the patient) until three months before the consent expires. It appears the PR may have misunderstood the inspector who advised that the centre's process for trying to contact patients who have not responded to previous attempts should start well before three months prior to the date of expiry of storage consent.

Self-assessment questionnaire

The Executive acknowledges that this was an oversight and the comment has been removed from the main body of the report.