Executive Licensing Panel - minutes

Centre 0153 (Homerton Fertility Centre)

Targeted Interim Inspection Report

Tuesday, 28 January 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dina Halai Laura Riley	Director of Strategy and Corporate Affairs Scientific Policy Manager Head of Regulatory Policy
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Bernadette O'Leary	Licensing Manager Clinical Inspector (Induction)

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 Homerton Fertility Centre is located in London, has held a treatment and storage licence with the HFEA since 1995, and provides a full range of fertility services.

1.2. The panel noted that the report of the renewal inspection, which occurred in March 2018, reported eight major and eight 'other' areas of non-compliance or poor practice. Two management review meetings were held, in accordance with the HFEA Compliance and Enforcement Policy, to evaluate the centre's performance. The first meeting, in May 2018, considered whether there were any serious or urgent risks to patients and the safety of gametes and embryos. A subsequent meeting, in June 2018, considered the Person Responsible's (PR) responses to addressing the non-compliances and implementation of the recommendations made in the report. After careful consideration, the executive deemed that any potential risks, to the safety of patients, gametes and embryos, were not urgent or serious risks, and it was evident that the PR had shown commitment to implementing the recommendations made by the inspection team.

1.3. The panel noted that the renewal report was initially presented to the Executive Licensing Panel (ELP) on 12 July 2018, but due to concerns expressed by the panel, regarding the number and extent of non-compliances identified at the renewal inspection, the meeting was adjourned and referred to the Licence Committee (LC), with a request for an executive update on numerous areas.

1.4. The report of the renewal inspection, along with an executive update, was presented to the LC on 6 September 2018. The committee expressed disappointment regarding the history and recurrence of non-compliances at the centre and was concerned by the PR's lack of response regarding a request from the executive for information relating to imports and exports. They were also particularly concerned about the length of time taken to investigate the low success rates for IVF treatments involving fresh embryos in women under 38 years at the centre, and the lack of data about the reasons for this.

1.5. The panel noted that the LC carefully considered the duration of licence and agreed that a three-year licence was appropriate, with no additional conditions, subject to the implementation of the recommendations set out in the renewal inspection report, including the provision of the results of the pregnancy success rates review and that they be provided with an update as soon as the outstanding information regarding imports and exports and success rates for IVF treatments involving fresh embryos in women under 38 years was available. The committee also agreed that an inspection should take place within the first year of the licence to ensure that the recommendations made in the report had been effectively implemented.

1.6. The LC was provided with an Executive Update on 2 May 2019 regarding the outstanding information in relation to imports and exports and success rates for IVF treatments involving fresh embryos in women under 38 years. The PR had provided the outstanding information regarding imports and exports and the executive was assured that the centre's processes in this area were now compliant with requirements. Following an independent review of all clinical and laboratory practices and procedures that could have an impact on pregnancy success rates, the executive received a summary report which included recommendations, along with an action plan for the implementation of the recommendations, some of which the PR had already implemented at the time of the executive writing their update. The PR committed to keeping the success rates for these patients under close review.

1.7. The panel noted that the PR has regularly updated the centre's inspector with his actions and the progress that he has made in achieving compliance.

1.8. The panel noted that, in the 12 months to 30 April 2019, the centre had provided 1158 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre.

1.9. The panel noted that, for IVF and ICSI, HFEA register data, for the period 1 August 2018 to 31 July 2019, show the centre's success rates are in line with the national averages.

1.10. The panel noted that, in 2018, the centre reported 88 cycles of partner insemination, with ten pregnancies. This represents a clinical pregnancy rate of 11% which is in line with the national average.

1.11. The panel noted that, HFEA register data, for the period between 1 August 2018 and 31 July 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. This represents performance that is not likely to be significantly different from the 10% multiple live birth rate target for this period.

1.12. The panel noted that a short notice inspection took place on 6 and 7 August 2019.

1.13. The panel noted that at the time of inspection there were three major areas of non-compliance concerning consent to storage of gametes and embryos, pre-operative assessment and the surgical pathway, alongside import and export. There was also one 'other' non-compliance relating to data submission. Since the inspection visit, the PR has provided evidence that actions have been taken to implement the recommendation regarding consent to storage of gametes and embryos. The PR has given a commitment to fully implementing the recommendations concerning pre-operative assessment and the surgical pathway, import and export and data submission.

1.14. The panel noted that the inspectorate recommended the continuation of the centre's treatment and storage licence, particularly noting the changes implemented by the PR and the improvement in the centre's success rates for IVF treatments involving fresh embryos in women under 38 years old.

2. Decision

2.1. The panel expressed concern that non-compliances, identified at the renewal inspection, conducted on the 6 and 7 March 2018, had not been fully addressed by the PR within the prescribed timescales. The panel therefore requested the inspectorate to submit an update report to ELP, within the next six months, to confirm whether non-compliances identified at the interim inspection had been completed within the prescribed timescales.

2.2. The panel was satisfied the centre was fit to have its treatment and storage licence continued.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

4 February 2020

Targeted inspection Report

Centre name: Homerton Fertility Centre
Centre number: 0153
Date licence issued: 3 October 2018
Licence expiry date: 2 October 2021
Additional conditions applied to this licence: None
Date of inspection: 6 and 7 August 2019
Inspectors: Julie Katsaros and Sara Parlett
Date of Executive Licensing Panel: 28 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).

The HFEA undertook a renewal inspection of this centre in March 2018. The Licence Committee (LC) in September 2018, which considered the renewal inspection report, renewed the centre's licence for three years, rather than the usual four, and required that a further inspection be performed within one year to ensure that the recommendations made in the report had been effectively implemented.

This is a report of a short notice announced inspection focusing on the non-compliances found at the renewal inspection in March 2018.

The report represents an evaluation of the centre's progress in addressing the non-compliances identified on the previous inspection. The aim is to provide the Authorities Executive Licencing Panel (ELP) with information on which to make a decision about the continuation of the centre's licence.

Summary for the Executive Licencing Panel.

Summary for licensing decision – post review of draft by PR

The inspection team recommends the continuation of the centre's licence.
In particular we note the changes implemented by the Person Responsible (PR) and the improvement in the centre's success rates for IVF treatments involving fresh embryos in women under 38 years old.

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

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendation:

Major' areas of non-compliance:

- The PR should ensure there is effective consent in place for all cryopreserved samples**.**

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

Major' areas of non-compliance:

- The PR should ensure that swab counts performed during surgical procedures are compliant with best practice guidance and the centre's own standard operating procedure (SOP).
- When importing sperm, the PR should ensure that money or other benefits provided to donors are compliant with General Direction 0001, if the import is to be undertaken under the authorisation provided by General Direction 0006.

'Other' area of practice that require improvement:

- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Information about the centre

The Homerton Fertility Centre is located in London and has held a treatment and storage licence with the HFEA since 1995 and provides a full range of fertility services.

The centre provided 1158 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2019. In relation to activity levels this is a large centre.

The centre's renewal inspection in March 2018 reported eight major and eight 'other' areas of non-compliance or poor practice. The executive consequently held two management review meetings, in accordance with the HFEA Compliance and Enforcement Policy, to evaluate the centre's performance. The first meeting in May 2018 was held to consider whether there were any serious or urgent risks to patients and the safety of gametes and embryos and a subsequent meeting in June 2018 to consider the PR's responses to addressing the non-compliances and implementation of the recommendations made in the report. After careful consideration the executive deemed that any potential risks, to the safety of patients, gametes and embryos, were not urgent or serious risks, and it was evident that the PR had shown commitment to implementing the recommendations made by the inspection team.

The report of the renewal inspection was initially presented to the ELP on 12 July 2018, but due to the concerns expressed by the panel regarding the number and extent of non-compliances identified at the renewal inspection, the meeting was adjourned and referred to LC with a request for an executive update regarding:

- pregnancy success rates;
- witnessing;
- medicines management;
- imports and exports;
- traceability;
- the QMS;
- consent to storage;
- pre-operative assessment and the surgical pathway;
- multiple births;
- equipment and materials;
- staff;
- disclosure of information held on the HFEA register, for use in research and record keeping and documentation.

The report of the renewal inspection along with an executive update was presented to LC on 6 September 2018.

The committee expressed disappointment regarding the history and recurrence of non-compliances at the centre. The committee was concerned by the PR's lack of response regarding a request from the executive for information relating to imports and exports. They were also particularly concerned about the length of time taken to investigate the low success rates for IVF treatments involving fresh embryos in women under 38 years at the centre, and the lack of data about the reasons for this.

The committee carefully considered the duration of licence and agreed that a three-year licence was appropriate, with no additional conditions, subject to the implementation of the recommendations set out in the renewal inspection report, including the provision of the results of the pregnancy success rates review and that they be provided with an update as soon as the outstanding information regarding imports and exports and success rates for IVF treatments involving fresh embryos in women under 38 years was available.

The committee also agreed that an inspection should take place within the first year of the licence to ensure that the recommendations made in the report had been effectively implemented.

As requested, on 2 May 2019, LC was provided with a further executive update regarding the outstanding information in relation to imports and exports and success rates for IVF treatments involving fresh embryos in women under 38 years. The PR had provided the outstanding information regarding imports and exports and the executive was assured that the centre's processes in this area were now compliant with requirements. Following an independent review of all clinical and laboratory practices and procedures that could have an impact on pregnancy success rates, the executive received a summary report which included recommendations, along with an action plan for the implementation of the recommendations, some of which the PR had already implemented at the time of the executive writing their update. The PR committed to keeping the success rates for these patients under close review.

Following the LC meeting the PR has regularly updated the centre's inspector with his actions and the progress that he has made in achieving compliance.

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]

For IVF and ICSI, HFEA held register data for the period 1 August 2018 to 31 July 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported 88 cycles of partner insemination with 10 pregnancies. This represents a clinical pregnancy rate of 11%, which is in line with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between 1 August 2018 and 31 July 2019 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[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%.

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 activities were observed in the course of the inspection: egg collection, egg thawing and embryo transfer, all of which involved a combination of manual and electronic witnessing in accordance with HFEA requirements. The inspection team also discussed witnessing procedures with staff and performed an audit of witnessing records. 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.

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed. The 'bring-forward' system was discussed with staff and storage records were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective, with one exception.

At the renewal inspection in March 2018 a review of patient records identified one case in which there was a period of lapsed storage consent between the expiry of the original

storage consent and the signing of storage extension consent, with completion of the Medical Practitioner Statement (MPS) form outside the relevant period. The PR has sought specialist legal advice and further guidance from the HFEA, however further action is required. 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 SOPs 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: witnessing, consent to storage, welfare of the child, controlled drugs and infection control.

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

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:

- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding: screening requirements and patient support

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

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.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance.

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.

Pre-operative assessment and the surgical pathway

It is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively. The centre has policies and procedures in place that are partially compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. The inspection team was concerned that swab counts were not being undertaken in such a manner as to protect patients from a swab being retained within the body because:

Two egg collection procedures observed by the inspection team identified that the centre's procedures for ensuring robust swab counting processes did not follow best practice guidance:

- swab counts undertaken prior to, during and following procedures were not clearly witnessed and confirmed by both the person performing the procedure and the theatre assistant

- it was not until after observing these procedures that the inspection team learned of an incident in May 2019 when an incorrect swab count was discovered following an egg collection procedure. Although a swab had not been retained inside the patient, a root cause analysis identified several areas where changes in practice were required to minimise future risks. However, these changes had not been implemented at the time of inspection. The centre's SOP had not been updated with the additional checks required and the page for recording swab counts in patients' records had not been updated to provide for a two signature confirmation of a correct swab count. See recommendation 2.

Multiple births

The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

Imports and exports

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

The centre has imported donor sperm from a sperm bank within the European Economic Area (EEA), with which it has a service level agreement which describes a fixed rate payment scheme of 45 Euros per donation visit, provided to donors 'irrespective of any actual expenses, loss of earnings and other costs or inconveniences incurred in connection with the donation.' This compensation scheme is non-compliant with General Direction 0001.

These donor sperm samples have been imported into the UK under General Direction 0006, which requires that compensation to providers of gametes to be imported, should be compliant with General Direction 0001. The PR could provide no evidence that payments to sperm donors have been compliant.

The centre has a history of non-compliances in relation to the various requirements of General Direction 0006 which were also previously cited in the inspection reports of 2014 and 2018. This appears to suggest a general lack of understanding by staff of the requirements of General Direction 0006. See recommendation 3.

Traceability

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

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: culture and vitrification media, media supplements and plastic ware. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Disclosure of information, held on the HFEA Register, for use in research

The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing Artificial Reproductive Therapy (ART) and those born following ART treatment.

Screening of patients
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 and/or embryos.
The centre's procedures for screening patients are compliant with requirements.

Record keeping and document control
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.

Patient experience
As this area of practice was not a focus for this inspection, it was not reviewed during the course of the inspection.

Compliance with HFEA standard licence conditions
Information reviewed during the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is compliant with HFEA requirements except for those areas identified in the body of the report

On-going monitoring of centre success rates
Since the last renewal inspection in March 2018 the centre has received one risk tool alert related to multiple pregnancy rates for all treatment cycles to which the PR responded and provided a commitment to keeping the centre's multiple pregnancy rates under review.

Legal parenthood
Where a couple to be treated with donated gametes or embryos are 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.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit did not identify any consent anomalies.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR did not respond to this correspondence.

This prompted a management review meeting on 13 November 2015, in line with the HFEA Compliance and Enforcement Policy, at which it was decided that a site visit should take place to review legal parenthood consenting practices. The centre was informed of this visit and directed to review all the records of patients who had undergone treatment with donor

sperm and donated embryos created with donor sperm since 6 April 2009 when consent to legal parenthood laws changed. The audit undertaken by the centre in January 2016 identified one parenthood consent anomaly. The PR has reported to the HFEA the actions taken to support the couple involved and to address this consenting anomaly. The executive considered these actions to be appropriate. The centre also reviewed and revised its legal parenthood consent procedures, undertook staff training and provided assurance that it would continue to monitor and audit legal parenthood consent.

At the renewal inspection in March 2018 legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Ten sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also 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.

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 clinic is broadly compliant with requirements to submit information to the HFEA. This centre currently has a number of minor data submission issues related to treatments with unregistered donors, outstanding validation errors and missing forms and the centre is working with the HFEA register team to resolve the issues identified. See recommendation 4.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2018, recommendations for improvement were made in relation to eight major and eight 'other' areas of non-compliance.

The PR subsequently provided information and evidence that some of the recommendations were fully implemented within the required timescales.

The following recommendations have now been implemented but were not completed within the required timescales:

- The PR should ensure compliance with the Trust's protocols and best practices guidelines for safe handling of controlled drugs;
- The PR should review the centre's procedures for import and export of gametes and/or embryos to compliance with General Direction 0006 before gametes and/or embryos are imported or exported (non-compliance in this area has re-occurred, see 'import/export' section of this report);
- The PR should establish documented procedures to ensure that all gametes and embryos and critical equipment are traceable from procurement, to patient treatment or disposal. The PR should ensure that all containers used in the course

of procurement, possessing, use and storage of gametes are labelled with the patient's full name and a further identifier.

- The PR should ensure that assessments of competence in obtaining consent to storage for oncology patients are undertaken and documented.

During this inspection it became apparent that the following recommendation had not been implemented fully:

- The PR should ensure that there is consent in place for all gametes and embryos that are in storage (see consent to the storage of cryopreserved material section in the main body of the report and recommendation 1).

The PR is reminded of his obligations to fully implement recommendations within the directed timescales.

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.

‘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
1.Consent to storage of gametes and embryos A review of patient records undertaken at the inspection in March 2018 identified one	The PR should ensure there is effective consent in place for all cryopreserved samples**.** The PR should seek further legal advice from a representative that is	Our protocols ensure that consents are effective for all patients The sample in question was from UCL where	The executive notes the PR’s response, however, the PR is responsible for ensuring that any cryopreserved samples received by the centre have effective consent in place at

case in which there was a period of lapsed storage consent between the expiry of the original storage consent and the signing of storage extension consent, with completion of the MPS form outside the relevant period. Despite the PR having sought specialist legal advice and further guidance from the HFEA, this case is still unresolved. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 and SLC T79.	conversant with the HFEA Act 1990 (as amended) and the HFEA statutory storage regulations to discuss this case in particular and to determine what actions he should take to resolve the issues identified. The PR should consider a thorough review of the patient's records. This could include a review of other healthcare records (such as oncology records) that may contain information pertaining to the patient's fertility status. On receipt of the legal advice the PR should inform the centre's inspector of the actions that he is going to take to ensure compliance with the statutory and regulatory requirements. It is expected that this information will be provided to the centre's inspector by 9 February 2020.	sperm was frozen prior to Chemotherapy in 2002 . The Samples were extended at UCL in 2012 with a lapse of consent for 4 months . The MPS was signed in 12/2012 2 ampoules were brought in 2015 and the consents at time from UCL were valid . The majority of the samples continue to be at UCL . We had contacted the legal team after the HFEA inspection and the legal advice was ----. Since the HFEA meeting, wehere additional advice was given , we have enquired from UCL to send us a copy of medical document adving the freezing of samples due to Chemotherapy. The patients has requested us to discard the sample at Homerton	the time of acceptance, in this case the lapse in storage consent was not identified prior to accepting the sample but following the transfer, therefore the executive cannot reconcile with the PR's response that the centre's protocols ensure that consents are effective for all patients. As the sample concerned has been discarded no further action is required.

		.We have discarded the sample on 16/12/2019.Our protocols have been changed to Check for all consents from date of freezing . We have obtained the letter from the oncology department at UCL recomending freezing of sperm for Cancer from 16th April 2004 and sperm test recommendation in 2002	
2. Pre-operative assessment and the surgical pathway The inspection team were concerned that swab counts were not being undertaken in such a manner as to protect patients from a swab being retained within the body. SLC T2. The Association for perioperative practice (AFPP) 2018.	The PR should ensure that swab counts performed during surgical procedures are compliant with best practice guidance and the centre's own SOP. When responding to this report the PR should provide an explanation as to why recommended actions following the investigation of the incident were not immediately implemented, along with an update on the actions he has taken since the inspection to minimise the risks to patients from a swab being retained	Following the inspection we have changed our protocol .Having spoken to the clinician who carried out the egg collection , she confirmed the swab count was done by 2 people but did not vocalise it so all could hear .Staff now ensure that all theatre staff can hear the count and we immedicately changed the check list to ensure	The executive cannot reconcile the PR's account that a swab count was not vocalised so all could hear, when the inspector observing the procedure clearly heard the clinician state that the swab count was correct at the end of the procedure and the inspector noted that a physical swab count was not undertaken by two people. The executive notes the PR's response and the actions taken since the inspection, however,

	within the body. Within three months of actions being taken the centre should conduct an audit of swab count practices and the documentation of swab counts in patient records to determine the effectiveness of actions taken. A summary report of the findings of the audit should be provided to the centre's inspector by 9 May 2020.	the count is confirmed by 2 signatures We will conduct a complaince audit of Swab practices in February and March and send the Audit findings before the 9th of May 2020	the PR has not provided an explanation as to why the recommendations following the investigation of an incident relating to swab counts were not immediately implemented. Further action is required.
3.Import and export The centre has imported donor sperm from a sperm bank within the EEA, with which it has a service level agreement which describes a fixed rate payment scheme of 45 Euros per donation visit, provided to donors 'irrespective of any actual expenses, loss of earnings and other costs or inconveniences incurred in connection with the donation.' This compensation scheme is non-compliant with General Direction 0001. These donor sperm samples have been imported into the	When importing sperm, the PR should ensure that money or other benefits provided to donors are compliant with General Direction 0001, if the import is to be undertaken under the authorisation provided by General Direction 0006. The PR should review all imports of donated gametes since the last inspection and should determine, with the overseas centre if necessary, the level of compensation provided to donors and whether it has been compliant with General Direction 0001. A report of this review should be provided to the centre's inspector by 9 February 2020. The PR should review all the centre's	We can confirm that for imported donor sperm , the 3rd party agreement reflects concurrrence with General direction 0001. The TPA was changed in August 2019 to reflect the adherence to Direction 0001 and 0006 . The donor bank has confirmed and sent a statement stating the payments/compensation to donors between March 2018 to August 2019 which complies with general direction 0001 and 0006 . The	The executive acknowledges the PR response and actions taken since the inspection. Further action is required.

UK under General Direction 0006, which requires that compensation to providers of gametes to be imported, should be compliant with General Direction 0001. The PR could provide no evidence that payments to sperm donors have been compliant.	EEA service level agreements to ensure that they are in line with General Direction 0001, if the import is to be undertaken under the authorisation provided by General Direction 0006 and provide confirmation of the review. Where the agreements are not compliant, he should inform the centre's inspector of the actions he has taken to become compliant by 9 February 2020. The PR should assess the training needs of staff involved in import/export activities and arrange relevant training for staff where required. The PR should confirm that he has undertaken this assessment and provided the necessary training to the centre's inspector by 9 February 2020.	review will be included . The other Donor banks are compliant with the general directions The Laboratory director has reviewed the directions along with retraining has been carried out in the Laboratory meeting . Another training has been planned in January 2020	

‘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
4. **Data submission** There are number of minor data submission issues related to treatments with unregistered donors, outstanding validation errors and missing forms and the centre is working with the HFEA register team to resolve the issues identified. General direction 0005 and SLC T41.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should review the procedures used by the centre to submit licenced treatment data to the HFEA to identify and address the reasons for delayed submissions, poor quality submissions and treatment involving donor gametes by 9 February 2020. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired	At the Homerton , when donor sperm is received from the abroad , we register the donor with HFEA . In a few cases we reistered UK donor samples as new donor . This was realised and corrected after the inspection. We will audit with the annual gamete audit and sumit it in February 2020	The executive acknowledges the PR’s response. Further action is required.

	effect. A summary of the audit should be provided to the centre's inspector by 9 May 2020.		

Additional information from the Person Responsible
Following the HFEA conference , we made efforts to contact the UCL hospital where the recomendaton was made to freeze the sperm for the patient who was the cancer survivor . This letter was dated April 2004 .An earlier semen analysis dated 2002 contained sperm freezing . Since post freezing , samples revealed azoospermia and hence extension to freezing was carried out . The UCL had retained samples of the sperm. We now have all the letters from the oncology department that suggest freezing of sperm for oncology reasons.This was obtained following the advice obtained from the legal team at the HFEA meeting. The sperm at the Homerton has been discarded after patient gave consent for discarding sperm. The Man continues to have sperm stored at the UCL .