Executive Licensing Panel - minutes

Centre 0102 (Guys Hospital)

Interim Inspection Report

Tuesday, 4 June 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Richard Sydee (Chair) Danielle Vincent Dina Halai	Director of Finance and Resources Communications Manager Scientific Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Nora Cooke-O'Dowd	Licensing Manager Head of Research and Intelligence

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

1.1. The panel noted that Guys Hospital is located in central London and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services, including embryo testing and gamete and embryo storage.

1.2. The panel noted that, in the 12 months to 31 October 2018, the centre had provided 3,268 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre.

1.3. The panel noted that, HFEA held register data, for the year ending 31 December 2018, show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

1.4. The panel noted that, in 2018, the centre reported 60 cycles of partner insemination with five pregnancies. This represents a clinical pregnancy rate of 8% which is in line with the national average.

1.5. The panel noted that, HFEA register data, for the year ending 31 December 2018, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is not significantly different to the 10% multiple live birth rate target for this period.

1.6. The panel noted that the interim inspection was initially performed as an unannounced inspection of the centre on 13 February 2019 and a number of areas of non-compliance were identified. In accordance with the HFEA's Compliance and Enforcement Policy, management review meetings were held on 20 and 25 March 2019 to consider the extent of the non-compliances and determine whether any informal or formal regulatory action was required. Whilst it was considered that there were no immediate risks to patients, staff and gametes or embryos, the non-compliances were deemed significant, in particular those regarding legal parenthood consents, storage consents and data submission to the register.

1.7. The panel noted that those attending the management review meetings were not assured that the centre had robust systems in place to document consents to legal parenthood. It was therefore decided that the inspection team should return to the centre to conduct a focussed inspection of the centre's legal parenthood consenting practice and to seek assurances from the Person Responsible (PR) that the non-compliances relating to storage consent and data submission will be addressed as a priority. This second inspection took place on 4 April 2019.

1.8. The panel noted that the inspection report presented represents an evaluation of the findings of both the 13 February 2019 unannounced interim inspection and the focussed inspection conducted on 4 April 2019.

1.9. The panel noted at the time of the initial inspection there were three critical areas of non-compliance concerning consent to storage of cryopreserved materials, obligations and reporting requirements and legal parenthood. There was also one major non-compliance regarding medicines management, alongside four 'other' non-compliances in connection with the Quality Management System (QMS), infection control, the import and export of gametes and embryos and the audit of satellite services. Since the inspection, the PR has provided evidence that the recommendations concerning obligations and reporting requirements, medicines management, infection control and the import and export of gametes and embryos have been implemented. Where required and by the date specified, the PR will provide an update or summary of audits conducted to ensure the corrective actions taken are effective.

1.10. The panel noted that the PR has given a commitment to fully implement the recommendations concerning the consent to storage of cryopreserved materials, legal parenthood, the QMS, infection control and satellite services.

1.11. The panel noted that the inspectorate recommended the continuation of the centre's treatment (including embryo testing) and storage licence, noting three critical non-compliances were identified in the report. Although one critical non-compliance had been addressed immediately, another relating to legal parenthood consenting is complex, so the inspection team recommended that a further targeted inspection takes place within the next 12 months. This will be to ensure that corrective actions taken to implement the recommendations made in the report generally, and specifically related to the legal parenthood consent non-compliance, have been effective in achieving and maintaining compliance.

2. Decision

2.1. The panel particularly noted the outstanding critical non-compliances regarding the consent to storage of cryopreserved materials and legal parenthood.

2.2. The panel was satisfied the centre was fit to have its treatment (including embryo testing) and storage licence continued, supporting the inspection team's recommendation that a further targeted inspection should occur within the next 12 months to ensure that corrective actions taken to implement the recommendations made in the report generally, and specifically related to the legal parenthood consent non-compliance, have been effective in achieving and maintaining compliance.

3. Chair's signature

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

Signature

Name

Richard Sydee

Date

11 June 2019

Interim Licensing Report

Centre name: Guys Hospital
Centre number: 0102
Date licence issued: 01 July 2017
Licence expiry date: 30 June 2021
Additional conditions applied to this licence: None
Date of inspection: 13 February 2019 and 4 April 2019
Inspectors: Victoria Lamb (lead), Polly Todd (clinical), Sandrine Oakes (observer), Nicola Lawrence (observer).
Date of Executive Licensing Panel: 4 June 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 interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

This interim inspection was initially performed as an unannounced inspection of the centre on 13 February 2019. A number of areas of non-compliance were identified. In accordance

with the HFEA's Compliance and Enforcement Policy, management review meetings were held on 20 and 25 March 2019 to consider the extent of the non-compliances and 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 non-compliances were deemed significant, in particular those regarding legal parenthood consents, storage consents and data submission to the register. Those attending the management review meetings were not assured that the centre had robust systems in place to document consents to legal parenthood. It was decided therefore that the inspection team should return to the centre to: conduct a focussed inspection of the centre's legal parenthood consenting practice; and to seek assurances from the PR that the non-compliances relating to storage consent and data submission will be addressed as a priority. This second inspection took place on 4 April 2019.

This inspection report represents an evaluation of the findings of both the unannounced interim inspection on 13 February 2019 and the focussed inspection on 4 April 2019.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence but notes there are three critical non-compliances identified in this report. Although one has been addressed immediately, another related to legal parenthood consenting is complex, so the inspection team recommends that a further targeted inspection takes place within the next twelve months; to ensure that corrective actions taken to implement the recommendations made in this report generally, and specifically related to the legal parenthood consent non-compliance, have been effective in achieving and maintaining compliance.

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

Since the inspections, the PR has provided evidence that the following recommendations have been implemented. Where required and by the date specified, the PR will provide an update or summary of audits conducted to ensure the corrective actions taken are effective.

Critical non-compliance

- **The PR must ensure that all licensed treatment activity is reported to the HFEA within the timeframes required by General Direction 0005.**

Major non-compliance

- The PR should ensure that medicines management practices are compliant with regulatory requirements and best practice guidance and that the storage of medicines is compliant with medicines storage requirements.

'Other' area of non-compliance

- The PR should ensure that a valid ITE certificate is in place before imports occur.

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

Critical non-compliance

- **The PR must ensure that there is effective consent to storage for all cryopreserved stored materials.**
- **The PR should ensure that procedures for legal parenthood consenting of patients are robust and compliant with statutory requirements and regulatory guidance.**

'Other' non-compliance

- The PR should ensure that the quality management system is effective and fit for purpose.
- The PR should ensure compliance with infection prevention and control regulations.
- The PR should ensure that all satellite services are audited in line with regulatory requirements.

Information about the centre

Guys Hospital (Assisted Conception Unit) is located in central London and has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services including embryo testing and gamete and embryo storage.

The centre provided 3268 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2018. In relation to activity levels this is a large centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

HFEA held register data for the year ending 31 December 2018 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2018, the centre reported 60 cycles of partner insemination with five clinical pregnancies. This represents a clinical pregnancy rate of 8%, which is comparable to the national average.

Multiple births[2]

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

HFEA held register data for the year ending 31 December 2018 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is not significantly different to the 10% multiple live birth rate target for this period.

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: discard of embryos and patient ID check prior to an embryo transfer under sedation. All of the procedures observed were witnessed using a manual and electronic witnessing system in accordance with HFEA requirements.

These activities indicate that witnessing procedures are compliant with HFEA requirements.

[1] The data in the Register may be subject to change as errors are notified to us by centres, or picked up through our quality management system. 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%.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility centres. 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 stored gametes and embryos and the accuracy of storage logs and consent records were reviewed; the 'bring-forward' system was also discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos with the consent of the gamete providers are not compliant because 63 sperm samples were being stored after the expiry of their consented storage periods. There was also one embryo donated to research, which was recorded on the storage log spreadsheet as being stored but was not in the storage vessel.

At the additional targeted inspection on 4 April 2019, the PR confirmed that all embryos in storage have effective 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; 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 able to carry out witnessing activities when required. The potential contribution of staffing levels to the storage consent and data submission non-compliances was discussed; the inspection team was assured, and no recommendations were considered necessary at this time. See 'Provision of information to the HFEA' section of this report.

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

- The centre has not documented corrective actions to address non-conformances identified in the audit of stored gametes and embryos.
- The centre has not documented corrective actions to address non-conformances identified in the witnessing audit.

The inspection team also considered whether the centre's processes for implementing learning are effective. If a centre 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 centre's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- Provision of information to the HFEA.
- Consent.
- Surrogacy.
- Screening.
- Imports of gametes and embryos from outside the EU/EEA.

The centre is broadly effective in implementing learning from their audits and guidance from the HFEA because:

- The standard operative procedure (SOP) for sperm donor screening does not reflect the requirements of SLC T53, which was updated in October 2018.
- The surrogacy SOP has not been reviewed and updated since 2016 and does not incorporate guidelines from the 'Department of Health & Social Care (DHSC) Practice Guidance for the care of surrogates and intended parents in surrogate births in England and Wales', issued in February 2018.
- The data submission SOP does not reflect the requirements of the current version of General Direction 0005.

See recommendation 5.

Medicines management

It is important that centre's 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 centre's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be partially compliant with guidance because:

- The drugs fridge monitor could not be relied upon to provide accurate temperature measurements because, on inspection, the temperature was noted to be zero degrees centigrade, but had been recorded as three degrees centigrade earlier in the day. Furthermore the minimum and maximum temperature recorded by the monitor ranged from 11 to 30 degrees centigrade.
- There were several illegible signatures in the controlled drugs (CD) register and there was no master list of signatures to identify the signatories.
- There were several entries in the CD register where the carry-over of drugs from one page to another was not countersigned by a witness.
- The ampoule size of the drug was not recorded on every page.

See recommendation 4.

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 the centre has suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, infection control practices were reviewed and found to be broadly compliant with guidance because:

- In two of the scanning rooms, the fabric on the chairs was ripped and therefore did not meet with infection control requirements to have wipe clean, non-porous surfaces. The centre reported that this has been identified in their own infection control audit.
- The chair in the male production room had thick piping around the edges and there was visible debris within this piping. The inspection team were not assured that effective cleaning of this piece of equipment could be achieved.

See recommendation 6.

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: long Gilson tips for insemination, 500ul tips and Sage media. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their centre. Only 19 patients have provided feedback in the last 12 months, giving an average three point five star rating to the centre on the HFEA website. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For a system to work, it is important that every patient knows about the rating system. This was discussed with the PR at the inspection who agreed to address this matter.

No patients were available to speak to inspectors during this visit.

The inspection team reviewed the centre's own patient feedback audit (January 2019). The audit measured 'patient experience' and 'friends and family recommendation'. Of the 316 patients who responded between April 2018 to January 2019, 93% of patients were satisfied with the centre and 93% of patients would recommend the centre to their family and friends.

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.
- has staff who are supportive and professional.
- treats patients with empathy and understanding.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is compliant with HFEA requirements with the following exceptions:

- The centre has imported several samples of donor sperm from the California Cryobank without a valid Importing Tissue Establishment (ITE) import certificate. The centre submitted an application for the required ITE certificate in June 2018 and, as for all applicants, was advised by the Executive that a proportionate approach would be taken to imports undertaken during the application process, given previous quality and safety control systems remained in place. This centre took until February 2019 to revise and resubmit their import certificate application, which the Executive considers excessive. However the Executive also accepts that the centre was not advised of an end to the 'proportionate approach' and has also now obtained an ITE import certificate to ensure imports are compliant. Consequently this non-compliance has been graded as an 'other', rather than a major, non-compliance. See recommendation 7.

- The centre has not audited its satellite services. See recommendation 8.

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 five major and four 'other' areas of non-compliance.

In responding to the report immediately after the inspection, the PR had agreed to implement the recommendations. All actions were completed within the required timeframe.

However, the inspection team has noted that the non-compliance related to reporting licensed activities to the HFEA, has recurred at a significant level at this inspection (see 'Provision of Information to the HFEA'). Therefore this non-compliance has been escalated to a critical non-compliance in this report. See recommendation 2**.**

The inspection team also notes the recurrence of a non-compliance related to not reviewing SOPs within the scheduled timeframe. At this inspection only one SOP review was overdue, so the non-compliance remains as an 'other' area of practice that requires improvement. See recommendation 5.

On-going monitoring of centre success rates

Since the last renewal inspection in January 2017, the centre has received twelve risk tool alerts related to performance to which the PR has responded appropriately. These include:

- Pregnancy rate per cycle for fresh IVF treatment in patients over 38 years.
- Pregnancy rate per cycle for fresh ICSI treatment in patients under 38 years.
- Pregnancy rate per cycle for fresh ICSI treatment in patients over 38 years.

- Pregnancy rate per cycle for frozen embryo transfers in patients under 40 years.
- Pregnancy rate per cycle for frozen embryo transfers in patients over 40 years.
- Multiple pregnancy rate per pregnancy all treatment cycles 16 – 70 years.

These alerts were discussed with the PR on inspection and he provided a commitment to keep success rates in these groups of patients under review. It was also discussed that the non-compliance relating to data submission to the register may have contributed to the significant level of risk tool alerts. The Executive also notes that the centre's success rates are in line with national averages and the multiple pregnancy rate is meeting target, as is discussed earlier in this report.

Provision of information to the HFEA

Centres 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.

This centre is not compliant with requirements to submit information to the HFEA because:

- There are a high volume of missing patient and partner registration forms.
- There are a high number of missing early outcome forms (118) and final outcome forms.
- There are a large number of late submissions of intention to treat and outcome forms.

The register team reports that this centre has one of the highest number of errors in the sector and these errors have been repeatedly identified to the centre. This was a non-compliance at the last inspection and despite an initial improvement in data submission, the following issues remain:

- The HFEA has not received a registration form that matches the patient number for 102 register entries between 23 February 2018 and 22 February 2019.
- The Patient / Donor 'Current Surname' does not match that on the Registration / Donor form received for 65 register entries between 23 February 2018 and 22 February 2019.
- Partner sperm has been used in treatments but the HFEA has no record of a current male partner for 60 register entries between 23 February 2018 and 22 February 2019.

This indicates that the centre has not implemented effective, robust mechanisms to monitor, record and submit data to the HFEA.

At the additional inspection on 4 April 2019, the PR confirmed the centre has had 'unprecedented administrative issues', some of which were unanticipated. Experienced administrative staff have now been recruited on a temporary basis to support the data submission work and train current staff members. Temporary contracts have been made substantive and the PR has provided assurance that he does not envisage a recurrence of this non-compliance going forward. The PR reports that significant progress has been made to address the data submission back log but that the following remain outstanding:

- There are now 18 missing early outcome and final outcome reports.
- There are eight outstanding registration forms that do not match the 'patient/donor current surname'.

- There are now 10 register entries in which the current male partner is not recorded, even though partner sperm was used in treatment.

See recommendation 2.

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.

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 showed that one couple was affected by legal parenthood consent anomalies. This case was concluded in May 2016 following a declaration of parenthood being made by the Family Division of the High Court.

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 responded to this communication and provided the required reassurances to the satisfaction of the Executive.

Inspectors visited the centre in August 2016, to determine whether learning from the legal parenthood consent anomalies had been embedded in the centre's practices. As part of that visit, the inspection team reviewed 30 patient records where consent to legal parenthood may be required. No anomalies were identified.

To provide further assurance of the effectiveness of the centre's procedures during the renewal inspection in January 2017, legal parenthood consenting records were reviewed in the notes of eight patients who had recently been treated with donor sperm. In two instances, consent to legal parenthood was required. Effective consent to legal parenthood with a prior offer of counselling was seen to be in place before treatment in both cases. In summary, the inspection team considered the processes used to obtain consent to legal parenthood at this centre to be compliant with HFEA requirements.

During the interim inspection on 13 February 2019, to review the compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed ten sets of records from patients treated with donor sperm. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent were partially compliant with HFEA requirements because:

- Four of the records reviewed had discrepancies in legal parenthood consents forms (i.e. the WP form ('your consent to your partner being the legal parent'), the PP form

('your consent to being the legal parent') and the PBR form ('your consent to being registered as the legal parent in the event of your death')).

- In one patient record where treatment was provided in 2017, the WP consent form had not been completed even though the patient was unmarried. This non-conformance had not been identified by the centre during checks of the consent forms. It had not been detected by audit because no live birth resulted and so the records were not included in the 2017 legal parenthood audit.
- In two records, there were discrepancies with the dates of signing the PBR consent forms which had not been rectified and in a further record, the PBR consent form had been signed by the patient having treatment rather than by her spouse.
- There was no evidence in any of these records that the patients had been contacted about the discrepancies.

Following the management review meetings on 20 and 25 March 2019, it was considered proportionate to seek further assurance of the centre's legal parenthood consenting processes. Therefore, at the additional targeted inspection on 4 April 2019, a further 16 sets of records of patients who had recently received treatment with donor sperm, were audited by the inspection team. The findings of this audit gave further concerns to the inspection team, who were able to conclude that the centre's processes used to collect legal parenthood consent were not compliant because:

- There were a number of legal parenthood consent forms that had missing patient identifiers (eg passport number/CHI number/ NHS number).
- On one PP form the centre had used a sticker in place of writing the patient's name on the form. The sticker contained the names of both patients, so it was unclear which patient was providing consent to being the legal parent.
- In one record the WP consent form had been signed on 16/02/18 on one page and 24/01/18 on another page. In the same record there were missing legal parenthood consent forms, which took more than one hour to find. One of the consent forms present, had been filed in the wrong patient record.
- The centre's legal parenthood SOP (reviewed in August 2018) makes no mention of the need for married couples to be informed about, and for the partner to consider completing, the PBR consent form. It also incorrectly directs staff to have the partners of married patients complete the PP consent form to document a consent to posthumous birth registration. The PBR form rather than the PP form has been in use for this purpose since 2017.
- The centre does not audit the presence or completion of the PBR consent form.
- The centre's legal parenthood consenting audit does not include records where a patient treated with donor sperm fails to conceive or has a miscarriage. This concerns the inspection team as such legal parenthood consent forms, which may contain anomalies, may be later relied upon in subsequent treatments.
- In one set of records where a married couple had received treatment with donor sperm, there was no PBR consent form or even a PP consent form, to indicate consent to posthumous birth registration, and no record to say that the patient had declined to give this consent. This meant that the husband would not have been able to be registered as the legal parent in the event of his death.
- During the inspection, the person who conducts the legal parenthood audits made an unjustified assumption that counselling had been offered to a patient, when there was no record of an offer in the patient's notes. This was of concern to the

inspection team, as if similar assumptions have been made previously they will have undermined the validity of the centre's audits.

- In another set of records reviewed, the patient had previously had treatment with a partner and had returned for a subsequent treatment as a 'single' person. No checks were made to see if the patient remained legally married or in a civil partnership when she came for treatment as a single person, even though her status has relevance to legal parenthood. This record had also been excluded from the centre's legal parenthood audit.
- The centre's legal parenthood consent checking process before treatment, and auditing process after treatment, are not robust, as neither have identified the non-compliances noted in this report.
- The inspection team are not assured that the audit of legal parenthood records is performed by someone who has an appropriate knowledge and understanding of the requirements for legal parenthood consents to be effective.

See recommendation 3.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non-compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. **Consent to storage of cryopreserved materials**. On the day of the inspection the centre did not have written effective consent for the storage of 63 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 stored materials The PR must; • Provide an accurate report of the number of patients for whom gametes and/or embryos remain in store beyond their consented storage period.	The PR acknowledges that the number of sperm samples from oncology patients have exceeded the legal storage period that the patient had consented for a variety of reasons. The PR is seeking appropriate legal advice (which will be shared with the HFEA) in that respect and continues to ensure that there	The inspection team note the PR's response and commitment to implementing this recommendation. The inspection team acknowledge receipt of the report of the number of patients for whom gametes remain in storage beyond their consented storage period and note that

Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. SLC T57, T79.	• Identify those samples stored for patients that have undergone chemotherapy where the consented period has expired. • 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	is no increase in retained materials (embryos and gametes) beyond the statutory retention periods. There are documented processes in place to ensure the on-going management of consent expiry. It is inevitable that at any given time samples will be approaching and/or recently expired but will be dealt with in accordance with the documented procedures. The PR Questions the accuracy of classifying this non-compliance as critical and would refer to the HFEA definition of "critical" *[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.]* and would propose that this classification is reconsidered	the centre has now identified 69 samples that do not have effective written consent for storage. The inspection team acknowledge receipt of the action plan implemented to address this non-compliance. The inspection team note the PR's comment on the grading of this non-compliance. The inspection team's position is if patients are unable to use their gametes lawfully in the United Kingdom because they do not have effective written consent, this is quite likely to cause them significant harm, albeit of a psychological nature. This is no less important from any physical harm that may or may not be caused to patients. It is this consideration and the extent of the non-compliance that have contributed to its grading. The inspection team await receipt of the outcome of the legal opinion.

	proposes to take to ensure compliance with the Act and the relevant HFEA 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 provide a summary report of the actions to be taken, following the legal advice to the centre's inspector by 13 May 2019. 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 materials. The PR must provide a summary report of this review including any corrective actions taken, to the centre's inspector by 13 May 2019. Three months after the review, the PR must audit storage consent procedures to ensure that corrective actions implemented have been effective	or that the definition modified to include a non-compliance of this nature. The required report of cryopreserved materials outside the consented storage period and action plan is included in this response	**Further action required.**

	in achieving compliance. A summary report of this review should be provided to the centre's inspector by 13 August 2019.		
2. Obligations and reporting requirements. This centre is not compliant with requirements to submit accurate information in a timely manner to the HFEA register. Full detail of the data submission errors leading to this non-compliance are discussed in the main body of this inspection report (see 'Provision of Information to the HFEA'). Due to the extent and the repetition of this non-compliance, and the importance of maintaining an accurate register at the HFEA, this non-compliance has been graded as critical. General Direction 0005 and SLC T41.	The PR must ensure that all licensed treatment activity is reported to the HFEA within the timeframes required by General Direction 0005. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for high error rates. A summary of the findings of the review, any corrective actions and timescales for implementation should be provided to the inspector when responding to this report. It is expected that all data submission discrepancies have been addressed and resolved by 13 May 2019. Following resolution of the data submission discrepancies, the PR should audit data submission procedures to ensure ongoing and continued compliance. A summary report of this audit	The PR acknowledges the previous issues surrounding Obligations and reporting requirements to the HFEA. However, once again the PR does not agree with the judgment made that this non-compliance is graded as critical as the extent of errors has not been considered in relation to a centre of our size and the definition of a critical non-compliance does not define repetition as a cause for such a grading. Our centre has worked hard to implement remedial actions to ensure that we are compliant. Though slippage was also due to EDI down time for 21 days in April/May 2018, which our centre has worked hard to catch up on but has caused an increased submission lag. As the inspectors are aware our centre has also been developing an automated	Further to the two inspection visits the PR has confirmed that only a small number of outstanding data has yet to be submitted to the HFEA. It is expected that all data identified in this report will have been submitted to the HFEA within the specified timescales. Further action required. **Inspection team response post PR's response:** The inspection team note the PR's response and commitment to implementing this recommendation. The inspection team confirms receipt of a completed root cause analysis and action plan. The rationale for the grading of this non-compliance has been explained in this recommendation.

	should be provided to the centre's inspector by 13 August 2019.	submission process using PRISM which has been delayed. The PR appreciates the acknowledgment of the work that had been done to clear the remaining errors between the first and last inspection. The PR offers assurance that the remaining errors will be cleared by the expected date. The PR can also assure that the lag in pregnancy outcomes will be up-to-date within the stipulated time frames. The required action plan is included in this response to ensure on-going compliance. The PR can confirm that the discrepancies are resolved apart from a few errors which our centre is working with the HFEA register to resolve	No further action beyond submission of the audit of data submission due by 13 August 2019.
3. Legal parenthood. Significant errors and concerns were identified in the centre's legal parenthood consenting process and associated quality control procedures, as are discussed in the main body of	The PR should ensure that procedures for legal parenthood consenting of patients are robust and compliant with statutory requirements and regulatory guidance.	Our centres Legal parenthood SOP has been updated to include the use of PBR in the reference to married/civil partnership couples needing to complete the PBR. All clinical staff have received targeted update training in the	The inspection team notes the PR's response and commitment to implementing this recommendation. The inspection team would expect all centres to be proactive in updating practice

this inspection report (see 'Legal Parenthood'): Section 44(1) of Part 2 of the HF&E Act 2008. SLCs T15, T36	The PR should undertake a full review of legal parenthood consenting processes, including staff training requirements and quality control processes. A summary report of this review, including actions to be taken with timeframes for implementation, should be provided to the centre's inspector when responding to this report. The PR should thereafter audit the effectiveness of the corrective actions taken, by reviewing the validity and robustness of legal parenthood consents documented after the implementation of corrective actions. A report of this audit should be provided to the centre's inspector by 13 July 2019. To provide assurance of the validity of all legal parenthood consents currently documented, the PR should conduct a full audit of all such consents, given in circumstances where donated gametes or embryos were/are planned to be used in treatment.	matter of legal parenthood consenting. The inappropriate need for the PP consent has been removed from the SOP. The HFEA has not issued updated guidance as per the Chief Executive's letter 10/02/2014 - CE(14)01 stating that the Legal parenthood audit should be updated to include PBR nonetheless a retrospective audit is planned going back to 03 April 2017. Our centres Legal parenthood auditing followed the guidance from the Chief Executive's letter 10/02/2014 - CE(14)01 where "The audit should include all patients who have received treatment, from 6 April 2009, using donor sperm or embryos (including embryos created with donor sperm or donor embryos) and: • were treated with a partner to whom they were not married or in a civil partnership **or** where	and processes in response to new guidance and the implementation of new consent requirements from the HFEA. Therefore the inspection team would expect that the centre had updated its auditing processes to incorporate the audit of the correct use of the PBR consent form when it came into force in 2017, and not wait for further instruction from the HFEA. **Further action required.**

	The Executive acknowledges that a robust audit of all relevant consents will take a period of time, so the PR should provide a report of the audit to the centre's inspector by 13 July 2019. If any anomalies with legal parenthood consents are found, the PR must inform the HFEA immediately.	the status of the relationship is not known; **and** • Treatment either resulted in a current on-going pregnancy **or** live birth **or** where the outcome is unknown. And would note that no breach was identified in these treatment scenarios and would question the grading as critical considering that no anomalies with legal parenthood consents are found, which would bring the legal parenthood of a child born in dispute. The required action plan is included in this response.	

‘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
4. Medicines management. On inspection the following issues were noted: • The drugs fridge monitor could not be relied upon to provide an accurate temperature measurement. • There were several illegible signatures in the CD register and no master list of signatures to identify the signatories. • There were several entries in the CD register where the carry-over of drugs from one page to	The PR should ensure that medicines management practices are compliant with regulatory requirements and best practice guidance and that the storage of medicines is compliant with medicines storage requirements. The PR should ensure that the monitoring of the drugs fridge is reliable. In any circumstance where the temperature of the drugs fridge cannot be relied upon, the PR should seek immediate advice from the lead pharmacist to ensure ongoing	Since the first inspection in February the CD fridge had been replaced and has a new thermometer and the monitoring of the CD fridge is reliable. The issues of reconciling signatures has been corrected by updating the title and styles book. The PR has provided a report detailing our action plan to ensure on-going compliance by the expected date which will include audit of compliance.	The inspection team acknowledges the PR’s response and commitment to implementing this recommendation and confirms receipt of the required action plan. No further action beyond submission of an audit of medicines management practice due by 13 August 2019.

another was not witnessed. • The ampoule size of the drug was not recorded on every page. NICE Guideline [NG46] April 2016 ‘Controlled drugs: safe use and management’. DH (2007) ‘Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)’.	use of the drugs contained within is safe. The PR should review medicines management practices in relation to the non-compliances identified in this report and provide a summary report of the review with corrective actions implemented to the centre’s inspector by 13 May 2019. Three months after this review the PR should audit medicines management practice to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this review should be provided to the centre’s inspector by 13 August 2019.		

‘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
5. QMS. A number of issues were found related to the QMS: • The centre has not documented corrective actions to address non-conformances identified in the audits of stored gametes and embryos and of witnessing. • Three SOPs – those for donor sperm screening, surrogacy and data submission to the HFEA – do not document current regulatory requirements and/or best practice guidance. The SOP for surrogacy has also not been reviewed or updated since 2016.	The PR should ensure that the quality management system is effective and fit for purpose. The PR should review the QMS including (but not exclusively) the issues identified in this report. A report summarising this review, the actions taken and timescales for implementation should be provided to the inspector by 13 May 2019. The PR should ensure that documents and SOPs are reviewed, revised and reapproved at a frequency that ensures they remain fit for purpose. The maximum	The annual quality management review meeting is scheduled to take place on Monday 13 May 2019. This meeting is to periodically review the units Quality Management structures. A summary of this review will be made available to the inspection team following this meeting. The data submission SOP has been updated to reflect regulatory requirements. The revisions notes to current regulations are largely around implications counselling for the Surrogate and their partner (if they have one and the intended parents. CO-SURR-P1: Counselling for a	The inspection team acknowledges the PR’s response and commitment to implementing this recommendation. The inspection team awaits receipt of a summary of the quality management review meeting. **Further action required.**

SLC T33b, T36.	interval between reviews should be 12 months.	Surrogacy Arrangement SOP was updated on 9.11.2018.	
6. Infection control. In two of the scanning rooms the fabric on the chairs was ripped and therefore did not meet with infection control requirements to have wipe clean, non-porous surfaces. The chair in the male production room had thick piping around the edges and there was visible debris within this piping. The inspection team were not assured that effective cleaning of this piece of equipment could be achieved. SLC T17 DH Health Building Note 00-09: 'Infection control in the built environment' 2013. DH Health and Social Care Act 2008: Code of practice on the prevention and control of infections and related guidance.	The PR should ensure compliance with infection prevention and control regulations. The PR should ensure that seating identified in this report is replaced with a compliant alternative. It is expected that compliant seating is in place in patient areas by 15 August 2019. The PR should confirm to the centre's inspector when the replacement furniture is in situ.	The PR confirms that all chairs highlighted have been replaced or have replacements on order. The PR will confirm when the chair in the male production room is in situ.	The inspection team acknowledges the PR's response and commitment to implementing this recommendation. No further action required beyond confirmation that compliant seating is in place, due by 15 August 2019.

7. Import and export of gametes and embryos. The centre has imported donor sperm from the California Cryobank without a valid Importing tissue establishment (ITE) certificate. General Directions 0006.	The PR should ensure that a valid ITE certificate is in place before imports occur. A report detailing the imports that occurred without an ITE certificate should be provided to the inspector when responding to this report. The PR should apply for a valid import certificate and ensure that no further samples are imported until a valid ITE certificate is in place.	The PR acknowledges the inspection team confirmation that all ITE are in place and that no further action is required	Since the inspection the centre has applied for and been issued with a valid import certificate. No further action required.
8. Audit of satellite services The centre has not audited its satellite services. SLC T112.	The PR should ensure that all satellite services are audited in line with regulatory requirements. An audit of all satellite services should be performed within the next three months and a summary report, together with actions taken to address any non-compliances should be provided to the centre's inspector by 13 July 2019.	The PR acknowledges that we have 3 satellite centres that do not hold a HFEA licence at this time and these are the only centres that we are obliged to audit. The PR would contest these remarks regarding audit of our satellite services with particular reference to SLC T112. "The centre must evaluate and select third parties on the basis of their ability to meet the requirements of these licence conditions and the guidance set out in the HFEA Code of Practice". It is our understanding that satellite	The inspection team notes the PR's response and awaits a summary report of the audits of the satellite centres due by 13 July 2019. **Further action required.**

		centres that are licenced with the HFEA are inspected and their ability to meet regulatory requirements is assessed via on-going inspection and these reports are assessed in our centre as part of the Quality management review. The PR accepts our obligation to provide a summary report within the stipulated time frame.	

Additional information from the Person Responsible

Critical grading of non-compliance
The PR has responded to this inspection report including supplementary reports prior to the ELP to provide evidence of compliance. The PR was disappointed with the classification of 3 issues raised and feels that these should be classified not as critical areas of non-conformance, but major areas of non-conformance. The PR does however take all the points raised on board and is working with her team to address these issues fully to ensure the very best in patient care.

Legal Parenthood
The Misfiling occurred in a couples notes who were donating egg to each other as the patients were having treatment as a couple this was not a mis-file into someone else notes rather a mis-file into another treatment cycle. The wording suggests that these consents were completely misfiled.
With regard to the assumption that implications counselling was offered. That was an assumption based on the fact that the patient had had implications counselling and once this was clarified the inspection team were satisfied. I would question the inclusion in the final report

Prescription of intralipid 'off label' - Wording suggests that this should be done and our centre 0102 are not doing it – please can this be removed

Inspection team response:

Critical grading:
The rationale for the grading of the non-compliances has been documented in this report

Legal Parenthood:
The inspection team notes the PR's response. The misfiling of any element of a patient's record is a serious matter and should not be minimised. It took the centre a long time to locate the consent forms for these patients and when they were found, they were misfiled in the wrong patient record.

The inspection team's concern was not that counselling may not have been offered, when subsequently found to have been offered. The concerns lay in the fact that an assumption had been made that counselling would have been offered, before confirming this to be the case, in a record where the offer of counselling was difficult to locate.

Prescription of Intralipid 'off label':
The inspection team cannot reconcile the PR's claim on the wording of intralipids in this report. This a standard template wording for reports where centres do not prescribe intralipid therapy.