Licence Committee - minutes

Centre 0067 (St Mary's Hospital)
Unannounced Targeted Interim Inspection

Thursday, 7 May 2020

Teleconference

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle Karen Conyers (Observing)	Committee Secretary Inspector
Legal Adviser	Darryn Hale	DAC Beachcroft LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

Papers enclosed:

- Targeted Interim Inspection Report
- Licensing Minutes:
  - 2019-12-06 Licensing Officer Record of Consideration - Variation of Licence Holder (LH)
  - 2019-11-07 Licence Committee Minutes - Executive Update to Renewal Inspection
  - 2019-05-02 Licence Committee Minutes - Renewal Inspection

1. Background

1.1. St Mary's Hospital, centre 0067 is located in Manchester. The centre has held a licence with the HFEA since 1992 and provides a full range of fertility services.

Renewal Inspection – March 2019

Inspection

1.2. The centre had a licence renewal inspection on 5 and 6 March 2019 and three critical, seven major and four other areas of non-compliance were identified. Of particular concern were the non-compliances relating to critical areas which included medicines management, legal parenthood and consent to storage and major areas including import and export and surrogacy.

Licence Committee Decision

1.3. The Licence Committee considered the report of the renewal inspection at its meeting held on 2 May 2019.

1.4. The committee considered the non-compliances and noted that the PR had committed to fully implement all of the recommendations to address the non-compliances and to provide evidence of action taken, and where required, to audit the effectiveness of those actions within the required timescales.

1.5. The PR had also agreed to a voluntary cessation of treatments with donor sperm for new patients until such time as the HFEA was satisfied that the centre's procedures for obtaining effective consent to legal parenthood are robust. The Executive advised the PR that, if he provides treatment under exceptional circumstances, the Medical Director should undertake a risk assessment, all consents should be checked by the PR, and that these actions should be documented in the patient's records.

1.6. The committee had some concerns about whether the character of the proposed PR was such as is required for the supervision of the licensed activities and on balance, decided that he was suitable. However, the committee wanted to see further evidence that the PR would discharge his duties under section 17 of the HFE Act 1990 (as amended).

1.7. The committee granted a three year licence, rather than the usual four. The committee agreed that the Executive should complete a targeted interim inspection within one year, to assess the implementation of the recommendations and the centre's general compliance.

1.8. The committee agreed that a progress report on the implementation of the recommendations and results of completed audits should be considered by the Licence Committee at its meeting in November 2019, so that the committee could be satisfied that the licence could remain in force without restriction.

Licence Committee Meeting – November 2019 - Executive Update to Renewal Inspection

1.9. At its meeting on 7 November 2019, the Licence Committee considered the Executive's update to the renewal inspection carried out in March 2019.

1.10. The committee noted that most of the required actions to complete the recommendations had been completed and outstanding action in most cases related to audits to verify the effectiveness of corrective action taken by the centre, and these were not yet due to be submitted to the Executive.

Voluntary cessation of treatments

1.11. The voluntary cessation of new treatments with donor sperm and embryos created with donor sperm implemented in March 2019 continued until 15 August 2019, when the PR was able to provide evidence to satisfy the Executive of the robustness of the centre's current procedures for obtaining effective consent to legal parenthood. The PR provided the findings of audits of treatments carried out since the time of the inspection up to 30 September 2019 and no issues had been identified in these audits.

Success Rates (frozen embryo transfer)

1.12. The PR provided his reviews of the centre's success rates for FET (frozen embryo transfer) in women under 40 years of age in June and September 2019. The centre's clinical pregnancy rate for FET in women under 40 years of age, in the year to 30 June 2019, remained significantly below the national average. The PR committed to keep this outcome under review and to monitor the centre's key performance indicators monthly.

1.13. The committee reviewed the centre's action taken to address the non-compliances and noted that further action is required to ensure the centre reflects suitable practices. The committee noted that areas of concern, in particular critical and major areas, would be reviewed at the targeted interim inspection, which the committee had endorsed to be completed within a year of the renewal licence coming into effect.

Importing Tissue Establishment (ITE) import certificate

1.14. The committee was satisfied that the centre's Importing Tissue Establishment (ITE) import certificate was renewed in line with the licence and noted that compliance with General Direction 0006 will be reviewed at the targeted interim inspection.

Unannounced Targeted Interim Inspection – January 2020

1.15. An unannounced targeted interim inspection was completed on 21 January 2020 and a report of this inspection has been submitted for consideration by the Licence Committee.

2. Consideration of application

Application

Unannounced Targeted Interim Inspection

2.1. The committee noted that an unannounced targeted interim inspection took place on 21 January 2020.

Inspection Process

2.2. The committee noted that in the 12 months to 31 January 2020 the centre provided 1778 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

2.3. The committee noted that for IVF and ICSI, HFEA-held register data for the year ending 31 October 2019 showed the centre's success rates were in line with national averages with the following exception:

- The clinical pregnancy rate following FET (frozen embryo transfer) in patients aged less than 40 years is below the national average at a statistically significant level.

2.4. The committee noted that for the year 2019, the centre reported 18 cycles of partner insemination with no clinical pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

2.5. The committee noted that HFEA-held register data for the year ending 31 October 2019 showed the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 11%. This represents performance that is not likely to be significantly different to the 10% maximum multiple live birth rate target for this period.

2.6. The committee noted that at the time of the unannounced targeted interim inspection on 21 January 2020 there were a number of areas of practice that required improvement, including one critical, three major and two other areas of non-compliance.

Critical areas of non-compliance:

- The PR should seek to improve the pregnancy success rates for FET treatments in women under 40 years of age.

Major areas of non-compliance:

- The PR should ensure compliance with medicines management regulations and best practice guidance.
- The PR should ensure that a patient, partner or donor's travel or medical history with regard to the risks of infections (such as Zika and Ebola), is fully considered prior to treatment.
- The PR should ensure proper records are maintained.

Other areas of non-compliance:

- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA Register.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

2.7. The committee noted that one critical area of non-compliance relating to consent to storage and one major area of non-compliance relating to surrogacy that were identified at the renewal inspection in March 2019 have not been fully implemented. Action is on-going.

2.8. Since the inspection visit, the PR has committed to fully implementing all of the recommendations and to provide further information or audits of practice where applicable.

Management Review Meeting – January 2020

2.9. The committee noted that due to the findings of the unannounced targeted interim inspection, the Executive held management review meetings on 28 January 2020 and 4 March 2020, in accordance with the HFEA Compliance and Enforcement Policy, to evaluate the centre's performance and to decide a proportionate licensing recommendation regarding the continuation of the centre's licence.

2.10. The Executive found that although several issues identified at the renewal inspection in March 2019 remain to be fully addressed, there has been significant improvement in some areas and there are limited concerns about the safety of patients, gametes and embryos. The PR has engaged with all inspections and regulatory meetings and the PR and his team are committed to fully implementing the recommendations made at the renewal inspection in March 2019.

2.11. However, if significant improvements are not seen with regards to the full implementation of all recommendations made in the unannounced targeted interim inspection report and the report of the renewal inspection in March 2019, by the time of the next inspection, due to take place late 2020/early 2021, the Executive will cease to be satisfied that the PR is suitable.

Recommendations

Licence

2.12. The committee noted that the Executive recommends the continuation of the centre's licence.

2.13. The Executive considered that it was proportionate to make a recommendation to continue the centre's licence to allow the PR time to fully implement all of the recommendations in the renewal report.

3. Decision

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

Licence

3.2. The committee deliberated on the non-compliances and the PR's response to the unannounced targeted interim inspection report. The committee endorsed the Executive's recommendation for the continuation of the centre's treatment and storage licence and agreed that the report of the renewal inspection should be submitted to the Licence Committee for consideration.

Success Rates (frozen embryo transfer) – Independent Review Required

3.3. The committee was concerned that the centre's success rate for FET (frozen embryo transfer) in women under 40 years of age remains lower than the national average at a statistically significant level. The centre is required to commission an independent review to include, but not be limited to, an assessment of the centre's procedures for cryopreservation, storage and thawing of embryos including stimulation and luteal support protocols. A summary report of the findings of the review, including timescales for implementation of corrective action identified, should be provided to the Executive on completion. The PR is also required to provide the Executive with quarterly updates on the actions taken to address the success rates, with a goal to improving the success rates by 21 July 2020. The centre's independent review should be submitted to the Licence Committee for consideration.

3.4. The committee discussed patient information and agreed that the centre should be transparent about its practices, in particular those relating to FET (frozen embryo transfer) success rates in women under 40 years of age.

Monitoring

3.5. The committee acknowledged the PR's engagement with the Executive and requested to see the report of the next inspection.

3.6. The committee agreed that, if significant improvements are not seen with regards to the full implementation of all of the Executive's recommendations made in the unannounced targeted interim inspection report and the report of the renewal inspection in March 2019, by the time of the next inspection scheduled late 2020/early 2021, the Executive will cease to be satisfied that the PR is suitable.

Timescales

3.7. The committee noted that in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic, centres were required to suspend fertility treatments in March 2020. Therefore, the Executive will liaise with the PR to consider appropriate timescales for submissions and full implementation of outstanding recommendations.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

1 June 2020

Targeted Interim Inspection Report

Centre name: St Mary's Hospital
Centre number: 0067
Date licence issued: 01 August 2019
Licence expiry date: 31 July 2022
Date of inspection: 21 January 2020
Inspectors: Victoria Brown (lead), Julie Katsaros and Louise Winstone
Date of Licence Committee: 7 May 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 (SLCs).

The HFEA undertook a renewal inspection of this centre in March 2019. The Licence Committee in May 2019, which considered the renewal inspection report, renewed the centre's licence for three years, rather than the usual four, and required that a targeted interim inspection be performed within one year. This is a report of that targeted interim inspection which was unannounced. The inspection was focused on reviewing all actions taken by the centre in response to the findings of the renewal inspection in March 2019.

The aim of this report is to provide the Authority's Licence Committee with information on the centre's progress with actions taken in response to findings so it can decide about the continuation of the centre's licence.

Summary for the Licence Committee

Summary for licensing decision

The executive recommends the continuation of the centre's licence.

The Licence Committee is asked that at the time of the inspection there were a number of areas of practice that required improvement including one critical, three major and two 'other' areas of non-compliance or poor practice.

Since the inspection visit, the PR has given a commitment to fully implement all of the following recommendations and to provide further information or audits of practice where applicable. In view of the current suspension of treatment services due to the COVID-19 pandemic, the centre's inspector will liaise with the PR to consider appropriate timescales for the implementation of the recommendations.

Critical areas of non compliance:

- **The PR should seek to improve the pregnancy success rates for FET treatments in women under 40 years old.**

Major areas of non compliance:

- The PR should ensure compliance with medicines management regulations and best practice guidance.
- The PR should ensure that a patient, partner or donor's travel or medical history with regard to the risks of infections (such as Zika and Ebola), is fully considered prior to treatment.
- The PR should ensure proper records are maintained.

'Other' areas of non compliance:

- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA Register.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

In addition, one critical and one major non-compliance identified at the time of the renewal inspection in March 2019 remains to be fully addressed, though actions are on-going:

- **The PR should ensure that there is effective written consent in place for all gametes and embryos in storage at the centre. This area of practice was reviewed during the inspection and is discussed in the main body of the report.**
- The PR should ensure that gamete providers in a surrogacy arrangement are suitably assessed and screened as donors. This area of practice was reviewed during the inspection and is discussed in the main body of the report.

Given the findings of this inspection, in accordance with the HFEA's Compliance and Enforcement Policy, management review meetings were held on 28 January 2020 and 4 March 2020 to evaluate the centre's performance and to decide a proportionate licensing recommendation regarding the continuation of the centre's licence.

These management review meetings found that although several issues identified at the renewal inspection in March 2019 remain to be fully addressed, there has been significant improvement in some areas and there are limited concerns about the safety of patients, gametes or embryos.

In addition, the PR has engaged with all inspections and regulatory meetings and the executive notes the commitment of the PR and his team to fully implement the recommendations made at the renewal inspection in March 2019.
Therefore, it was concluded that a recommendation to continue the centre's licence to allow the PR time to fully implement all recommendations of the renewal report was a proportionate course of action.

However, the executive is of the view that if at the centre's next inspection, due to take place in late 2020/early 2021, significant improvements are not seen with regards to the full implementation of all recommendations made in this report and the report of the renewal inspection in March 2019, the executive will cease to be satisfied that the PR is suitable.

Information about the centre

St Mary's Hospital is located in Manchester and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

Other licensed activities of the centre include storage of gametes and embryos.

The centre provided 1778 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2020. In relation to activity levels this is a large centre.

The centre's renewal inspection on 5 and 6 March 2019 reported three critical, seven major and four 'other' areas of non-compliance or poor practice. The report of that inspection was considered by the Licence Committee on 2 May 2019.

The minutes of the Licence Committee meeting were provided on 4 June 2019 and recorded the committee's decision to issue a three year licence rather than the usual four, with a targeted interim inspection to be undertaken within a year of the licence coming into force.

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 year ending 31 October 2019 show the centre's success rates are in line with national averages with the following exception:

[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 $p \leq 0.002$.

- The clinical pregnancy rate following frozen embryo transfer in patients aged less than 40 years is below the national average at a statistically significant level (see recommendation 1).

For the year 2019, the centre reported 18 cycles of partner insemination with no clinical pregnancies. This represents a clinical pregnancy rate 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 October 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target.

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. The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are partially compliant with guidance.

At the renewal inspection in 2019 the inspection team identified a number of issues in relation to medicine management practices and the completion of the controlled drugs register (CD register) which was not in accordance with professional guidance and best practice guidelines. Pre-population of the CD register caused the inspection team to be concerned that the processes for the supply, administration and disposal of controlled drugs were not robust and therefore there was a possibility that the records of dosages given to patients would not be correct. Furthermore, there was a risk that it may not have been possible to ensure that all drugs were fully accounted for.

The centre's own audit of controlled drugs had identified similar issues, however the corrective actions implemented had not been effective.

During this inspection, the centre's CD register and audit of controlled drugs were reviewed. The inspection team noted that corrective action implemented to address the issues with pre-populating the CD register identified at the last inspection had been effective.

The inspection team did however note some issues in the CD register, including several entries where:

- a signature to the witness of the discard of controlled drugs was not recorded.
- the time of the discard of controlled drugs was not recorded.
- the process for the carry over of stock levels from one page to the next was not fully completed for all pages of the CD register.

[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%.

The centre's own audit, performed in December 2019, failed to identify the inspection team's findings that the time of discard of some controlled drugs for that period was not recorded.

The stock balance for drugs being administered was consistently entered into the incorrect column in the CD register, despite a pictorial diagram in the centre's own SOP directing staff on how to complete this section (see recommendation 2).

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.

At the renewal inspection in March 2019, the inspection team identified a number of non-compliances in relation to the storage of cryopreserved gametes and embryos. These included several sets of embryos in storage without effective consent as there was no medical practitioner statement in place. The PR had not sought legal advice regarding these cases and the letter sent to couples stated the embryos would be allowed to perish, therefore they were likely to believe that this had happened and were therefore not aware the embryos remained in storage.

Following the renewal inspection, the executive recommended that the PR should complete a full audit of all samples in storage to establish if there were any further samples without valid consent. On the 23 October 2019, the executive attended a meeting with the PR to discuss the findings of an audit of embryos that have been in storage for more than 10 years, completed by the PR. This audit identified a number of issues which raise doubt over the effectiveness of the consent to storage. The PR subsequently sought specialist legal advice and following the inspection, on the 29 February 2020, an update was provided to the centre's inspector. Thirty one cases have been found to be compliant with the storage regulations, 16 cases have been found to be unable to comply with regulations and will be discarded after the patients have been fully informed and further legal advice regarding the compliance of the remaining 56 cases is awaited. The PR has committed to continue to provide the centre's inspector with regular updates.

An auditor has been appointed specifically to audit all gametes in storage at the centre for more than 10 years and the PR anticipates that this will be completed by August 2020. The member of staff undertaking this audit has received no training nor had their competency assessed in their understanding of storage regulations. However, the PR assured the inspection team that the standards and scope of the audit had been set by himself and the clinical lead. Once the data has been collected by the auditor this will then be analysed by the PR and clinical lead, seeking legal advice where required, to establish the number of samples (if any) that are in storage without effective consent. The scope of the audit and data collected to date was reviewed by the inspection team and appears to be appropriate.

The PR is undertaking regular 'rolling' audits of the records of all embryos that have been in storage for less than 10 years and is providing the summary of the findings to the centre's inspector on an ongoing basis.

On the basis of the discussions with the PR and the review of the audits provided by him, the inspection team is assured that the PR is committed to completing the action required in relation to storage of gametes and embryos. The PR also confirmed that he has sought and will seek legal advice where necessary. Given these assurances, the inspection team considers it unnecessary to make any further recommendation in addition to that made at the time of the renewal inspection.

The PR has been asked to provide updates to the centre's inspector regarding actions to address the remaining storage consent anomalies.

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.

At the renewal inspection in March 2019, issues were identified in relation to legal parenthood consenting processes including; an error on the PP ('*Your consent to being the legal parent'*) form of a patient which has implications for legal parenthood for the child who was born following treatment. This error had been identified by a member of staff, however no further action was taken. In addition, this error had not been identified in the centre's own audit. Therefore, the inspection team was not assured that effective audit procedures were in place at the centre.

The PR has confirmed that the couple affected by the anomaly in consent to legal parenthood wish to seek a court declaration to establish legal parenthood, however these legal proceedings have not yet begun. The PR provided his assurance that he and the Trust will continue to support the couple affected in accordance with HFEA guidance and will continue to update the executive on the outcome of the case.

To provide assurance of the compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team audited five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. The PR has also provided legal parenthood audits to the centre's inspector on a monthly basis since the renewal inspection and no further issues have been identified. These activities enabled the inspection team to conclude that corrective action implemented by the PR has been effective in addressing the issues which were identified at the renewal inspection in March 2019 and the processes used to collect legal parenthood consent at this centre are now compliant with HFEA requirements. The PR will continue to conduct audits into this area of practice on a quarterly basis and the inspection team notes the PR's continued commitment to compliance in this area.

Screening patients, partners and donors

The centre's procedures for screening patients, partners and donors are partially 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.

At the renewal inspection in March 2019, it was identified that the centre does not document any discussions regarding the patient or partner's travel or medical history with regard to the risks of infections (such as Zika and Ebola), or whether any additional testing may be required prior to treatment. Following the inspection, the PR provided a summary of his assessment of the risk to patients and donors resulting from the previous failure to perform this assessment and a summary report of an audit of the effectiveness of changes introduced, in which no issues were identified.

To provide assurance of the effectiveness of the centre's procedures for the assessment of risk of infections, the inspection team reviewed five sets of records of patients who had received treatment at the centre recently. In four out of five of the records reviewed, discussions regarding the patient or partner's travel or medical history with regard to the risks of infections had not been documented. In addition, in December 2019, the centre had an internal incident in which a clinician from the centre referred a patient for sperm freezing. The patient had just returned from a Zika virus risk area, something that was not identified by the clinician and resulted in the patient's treatment being postponed for three months.

These findings enabled the inspection team to conclude that the centre does not consistently document any discussions regarding the patient or partner's travel or medical history and in some instances these discussions may not be taking place at all, as evident from the centre's internal incident. This demonstrates that the corrective actions implemented by the PR to address this non compliance identified at the renewal inspection have not been effective (see recommendation 3).

Import and export

At the renewal inspection in March 2019, several issues were identified which led the inspection team to conclude that centre staff were not sufficiently aware of the requirements of General Direction 0006 and therefore did not seek relevant evidence of compliance prior to export or import of gametes and/or embryos.

Following the inspection, the PR provided a summary of his review of the centre's procedures to ensure compliance with the requirements of General Direction 0006. Based on this information, the executive recommended that the centre's ITE import certificate was renewed in line with the licence. An audit of the effectiveness of changes introduced identified no non-compliances.

On this inspection, the inspection team reviewed the records of one export and two imports that had recently taken place at the centre under General Direction 0006. This led the inspection team to conclude the centre's procedures for import and export of gametes and embryos are now compliant with HFEA requirements.

Adverse incidents

Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

At the renewal inspection in March 2019, it was found that the centre had not reported, to the HFEA, two adverse incidents that met the criteria to be so, as defined in CoP Guidance 27.1. The inspection team did not consider that the investigations into these incidents were

sufficiently detailed nor appropriate actions taken to prevent similar incidents from happening again in the future.

The PR subsequently conducted a review of the centre's processes for submitting and investigating adverse incidents and the PR is conducting an audit into this area of practice on a monthly basis.

The inspection team reviewed the centre's adverse incidents log and the investigation reports for a recent incident. This led the inspection team to conclude that the centre's procedures for reporting and learning from adverse incidents are now compliant with HFEA requirements.

Staffing

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

At the renewal inspection in March 2019, the inspection team had some concerns in relation to the competencies of laboratory staff who were taking consent for egg cryopreservation. The PR has confirmed that consent to storage of gametes is now undertaken only by clinicians at the centre whose competence has been documented. In addition, he undertook an audit of all cases where consent had been taken by members of staff who had not had their competency assessed. These assurances allowed the inspection team to conclude that the centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services.

Surrogacy

At the renewal inspection in March 2019, it was noted that the centre had not screened the gamete providers in the surrogacy arrangements as donors. Following the inspection, the PR audited all surrogacy treatments carried out in the centre since February 2015. This audit identified further cases in which gamete providers had not been screened as donors prior to treatment. The PR contacted the surrogates to advise them of the screening failures and to offer them the opportunity to be tested for the infections for which the gamete providers were not screened. The surrogates all either declined or were uncontactable. The PR sought expert advice regarding the potential risks to the surrogates associated with the screening failures identified in the centre's audit and has undertaken appropriate action based on the advice received.

At the time of this inspection, the centre has not undertaken any new cases of surrogacy. The inspection team reviewed the centre's surrogacy SOP and found it to be compliant with HFEA requirements. A report of the centre's audit to evaluate the effectiveness of changes introduced was due by 6 December 2019. As the centre had not undertaken any new cases of surrogacy the deadline for this audit has been extended to July 2020. The inspection team is assured that the PR is committed to completing the action required in relation to surrogacy. Given these assurances, the inspection team considers it unnecessary to make any further recommendation in addition to that made at the time of the renewal inspection.

Record keeping

Good medical records are essential for the continuity of the patient's care. At the renewal inspection in March 2019, a number of issues with record keeping were noted. These

included consent forms being filled in or amended incorrectly, the completion of irrelevant consent forms, no record of how, and by whom a patient, partner or donor was identified. In addition, the inspection team noted that it was hard to find relevant information in the records, and to follow the patient journey because the continuation sheets were not always filed together or chronologically.

Following the inspection, the PR reviewed this area of practice and implemented corrective actions. An audit submitted to the centre's inspector in August 2019 identified continued issues. Further corrective action was put in place and the PR committed to re-audit this area in January 2020.

At this inspection, the inspection team noted a number of issues in patients' records audited during the inspection:

- In all records audited, there was no record of how, and by whom a patient, partner or donor was identified despite this being identified at the renewal inspection.
- It continued to be difficult to find relevant information in the records or to follow the patient journey despite this being identified at the renewal inspection.
- No patient identifiers were recorded on several anaesthetic charts filed in patient notes.

The inspection team notes there has been improvement in some major areas, namely no errors with consent forms were identified on this inspection. Therefore, corrective action implemented by the PR to address this issue has been effective. However, there are areas of this non compliance that remain to be addressed, in particular, no action appears to have been taken in regard to recording that the identity of patients, partners or donors has been verified. This led the inspection team to conclude that the centre's procedures for keeping records are partially compliant with HFEA requirements to ensure that accurate medical records are maintained (see recommendation 4).

Premises and facilities

At the renewal inspection in March 2019, issues were noted with the safe storage of empty gas cylinders and safety signage. Following the inspection, the PR confirmed that appropriate actions had been taken. At this inspection, the storage area for gas cylinders was found to be appropriate. This leads the inspection team to conclude that the centre's premises are suitable.

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.

At the renewal inspection in March 2019, it was noted that the centre did not routinely disseminate HFEA alerts to staff members and no action had been taken in response to a recent HFEA alert relating to the usage of an incorrect gas cylinder to supply incubators. The inspection team noted that the methodology and scope of audits was not being consistently documented. In addition, the inspection team noted that corrective and preventative actions identified by the centre in an audit of controlled drugs did not seem to have been effective in addressing the non-conformances identified in that audit.

Following the inspection, the PR undertook a review of the QMS and implemented corrective actions.

At the time of this inspection, no further alerts had been issued by the HFEA since the renewal inspection in March 2019. Therefore, the effectiveness of corrective action implemented by the PR to address this issue could not be assessed. The PR has been providing legal parenthood and consent to storage audits to the centre's inspector on a monthly basis and on inspection the reports for the centre's most recent medicines management and infection control audits were reviewed. With the exception noted in the 'medicines management' section of this report the centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

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

The HFEA Register is a rich source of information about treatment using assisted reproductive technologies (ART). It can be used by researchers and linked to other health registers to improve knowledge about the health of patients who have undergone ART and those born as a result of it. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA, so that the HFEA holds an accurate record of patients' consent and only releases patient identifying information to researchers with a patient's consent.

At the renewal inspection in March 2019, two discrepancies were found between completed patient/partner disclosure consents in 23 patient records audited and the related consent data submitted for inclusion on the Register. Following these findings, the PR reviewed this area and implemented corrective actions to address this non-compliance. In an audit, submitted to the centre's inspector in December 2019, carried out to evaluate the effectiveness of changes made to address this non-compliance, six discrepancies were identified by the clinic in 90 forms checked. Further corrective action was put in place and a re-audit was provided to the centre's inspector in January 2020. This audit showed one discrepancy out of 60 forms audited.

On this inspection, an audit of consent to disclosure performed by the inspection team noted, in a sample of ten records, two discrepancies between completed patient/partner disclosure consents and the related consent data submitted for inclusion on the Register. The inspection team notes that corrective action following the centre's own audit was only implemented shortly before the inspection, therefore the consent to disclosure information in the notes audited by the inspection team may have been submitted prior to corrective action being implemented. Following the inspection, audits were provided to the centre's inspector in February and March 2020. No discrepancies were identified from the 20 forms audited each month. The PR has committed to continue to audit this area of practice on a monthly basis.

Whilst the inspection team notes there has been improvement in this area since the inspection in January, at the time of the inspection the centre's procedures failed to ensure that the HFEA held an accurate record of consents to disclosure and the centre's procedures for taking consent to disclosure to researchers were broadly compliant with

HFEA requirements (see recommendation 5). This failing leads to a risk that the HFEA may release patient identifying information, to researchers, without consent.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur.

Witnessing was not a non-compliance at the last inspection and therefore not a major focus of this inspection. The inspection team was not able to observe any laboratory activities during the inspection but was able to audit witnessing by reviewing patient records. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Prescription of intralipid 'off label'

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

Infection control was not a non-compliance at the last inspection and therefore not a major focus of this inspection. The centre's most recent audit of infection control was reviewed, and the inspection team noted that no significant issues were identified.

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'.

Equipment and materials was not a non-compliance at the last inspection and therefore was not reviewed during this inspection.

Patient experience

Feedback from patients was not a non-compliance at the last inspection and therefore was not reviewed during this inspection

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 exceptions noted throughout this report.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in March 2019, recommendations for improvement were made in relation to three critical, seven major and four 'other' areas of non-compliance or poor practice that required improvement.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales, albeit actions to address several of the non-compliances were still ongoing at the time of the inspection. The findings of this inspection demonstrate, however, that not all of the recommendations have been implemented adequately and some of the corrective action that has been implemented has not been effective.

On-going monitoring of centre success rates

Since the last renewal inspection in March 2019, the centre has received three performance related risk tool alerts.

The centre's success rates for FET in women under 40 years old remains lower than the national average at a statistically significant level. The centre's target to improve success rates for this group of patients by September 2019 has not been achieved.

Following the renewal inspection, the PR provided his review of the centre's success rates for FET in women under 40 years of age to the centre's inspector in June 2019. Based on this review the centre modified its practice regarding the thawing of pro-nucleate embryos. The PR subsequently provided the clinic's key performance indicator (KPI) results to the centre's inspector in September and December 2019, where no significant improvement was seen in the centre's success rates for FET in women under 40 years old.

This area was discussed with the PR on inspection and the PR confirmed his commitment to keep this outcome under review and to monitor the centre's KPIs monthly. Despite these reassurances, the PR has not taken any further action to review or address this below average success rate, despite the success rate not improving following the centre's adoption of an adapted thawing protocol more than six months ago (see recommendation 1).

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.

At the renewal inspection in March 2019, the HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the HFEA Register.

Following these findings, the PR reviewed this area and implemented corrective actions to address this non-compliance. In an audit, submitted to the centre's inspector in December 2019, carried out to evaluate the effectiveness of changes made to address this non-compliance, 12% (3/25) of IVF cycles audited had been reported to the HFEA outside the

period required by General Direction 0005. No DI treatments were audited by the centre, as no treatments occurred in the period audited.

At this inspection, the HFEA register audit team found that all of the treatments audited had been reported to the HFEA and the number of IVF treatments that were reported to the HFEA outside the period required by General Direction 0005 had reduced slightly to 8% (10/132). However, 36% (18/50) of the DI treatments audited were reported to the HFEA outside the period required by General Direction 0005.

Audits were provided to the centre's inspector in February and March 2020 following the implementation of further corrective action. These audits showed that in the samples audited, 100% of IVF cycles (10/10 in both February and March) and 100% of DI treatments (10/10 in February and 7/7 in March) were reported to the HFEA within the period required by General Direction 0005.

Whilst the inspection team notes there has been some improvement in this area since the inspection in January, at the time of this inspection the centre's procedures for submitting information about licensed activities to the Authority were broadly compliant with HFEA requirements (see recommendation 6).

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non-compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
1. Success rates The centre's success rates for FET in women under 40 years old remains lower than the national average at a statistically significant level. The centre's target to improve success rates for this group of patients by September 2019 has not be achieved.	The PR should seek to improve the pregnancy success rates for FET treatments in women under 40 years old. The PR should commission an independent review as to the reasons why the centre's success rate for FET in women under 40 years old remains	1. The PR will seek to improve the clinical pregnancy rates for FET treatments in women under 40 years old. 2. Please can we clarify that the 'success rate' mentioned in this report refers to clinical pregnancy rate per transfer as this is not clear from the report. The figures	The executive acknowledges the PR's response and commitment to implementing this recommendation. The success rate referred to in the report is the clinical pregnancy rate per cycle started. On the 7 April 2020, the national average for this particular success rate is 37.7%.

SLC T2.	lower than the national average at a statistically significant level. This review should include, but not be limited to, an assessment of the centre's procedures for cryopreservation, storage and thawing of embryos including stimulation and luteal support protocols. The HFEA expects that this person will be independent of the centre and will have a suitable degree of knowledge and expertise in this area. When responding to this report, the PR should give a timescale for the completion of this review. A summary report of the findings of the review, including timescales for implementation of corrective actions identified, should be provided to the centre's inspector upon completion. Following this, the PR should provide the centre's inspector with quarterly updates on the	referred to in the report in relation to the centre's performance against the national average recorded by the HFA have not been shared with the centre. It would be beneficial for this to be made available to inform improvements. 3. It is essential that we are advised on the current performance figures to inform our service improvement plans. It would be helpful if the figures provided include the periods prior to, and since, the HFEA inspection of March 2019 following which changes were introduced in the centre's FET policy. We note that the report states that the HFEA holds national data till the end of October 2019. We would be grateful if this data could be shared with us, by patient age, embryo stage and number of embryos transferred, so that we can work towards improving our centre's performance. 4. In our view, the most	Centre 0067's success rate in the group is 26.6.%, which is lower than the national average at a statistically significant level. Further data held by the HFEA will be shared with the PR to assist in his analysis. Despite measures previously introduced by the centre, the clinical pregnancy rate in FET cycles for patients under the age of 40 has been consistently lower than the national average at a statistically significant level since January 2019. The PR has commissioned an independent review and has committed to review factors which may affect this success rate. In March 2020, the PR suspended fertility treatments in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this, the centre's inspector will liaise with the PR to consider an

	actions taken to address the success rates, with a goal of improving the success rates by 21 July 2020.	likely reason our centre's clinical pregnancy rate per transfer is lower than the national average is due to differences in practice between our clinic and other clinics. Unlike most other clinics, our centre freezes embryos at the pronucleate stage (day 1). Most clinics only freeze embryos at day 5, thereby deselecting embryos that would be frozen at our centre. Also the Centre transfers day 2 or 3 frozen-warmed embryos, as well as blastocysts. 5. It is logical to expect that the clinical pregnancy rate per transfer at the Centre will be lower than that of clinics which are much more selective in their freezing policies, because these clinics may deselect embryos using blastocyst culture. However, the approach taken by the centre has two advantages, which are as follows: i) Early cleavage transfer increases the cumulative pregnancy rate per egg	appropriate timescale for fully implementing all of this report's recommendations taking into account the period of time where treatments are suspended as a result of the pandemic. Further action required.

		collection, in line with Cochrane review evidence for blastocyst transfer. ii) Cleavage stage transfer avoids the potential risks of blastocyst culture, including monozygotic twinning, changes in birthweight and a higher risk of preterm birth. The centre would draw the Authority's attention to recently published research carried out by the team in Manchester in collaboration with the HFEA using UK register data, which shows that extended culture to blastocyst increases the rate of pre-term birth by an odds ratio of 1.4 compared to cleavage stage transfer (appendix 1). 6. Following the Department's last inspection in 2019, the Centre modified the frozen embryo protocol to include prolonged culture of embryos frozen at the pronucleate stage. From 1st August 2019 to 29th February 2020, the Centre performed 49 such frozen transfers. The clinical pregnancy rate in these	

		cycles is 42.9%. This shows that the change in practice introduced after the previous inspection has led to an improvement in results (albeit through increased use of blastocyst culture), and we would ask that this is reflected in the report. 7. The department has commissioned Dr Marta Jansa Perez, PhD, Director of Embryology at the British Pregnancy Advisory Service, to conduct an independent external review of the centre's policies and practices in relation to frozen embryo transfer. Dr Perez is able to commence her review of the centres protocols immediately, but will only be able to travel to the centre to observe practice once the restrictions on movement due to the Covid-19 pandemic have been lifted. 8. In response to the Covid-19 pandemic the department has suspended treatments in line with HFEA	

		guidance. The centre will as a result of this not be in position to advise HFEA of the success rates by the deadline of 21/07/2020. Once the centre has resumed business as usual any new recommendations made by external reviewer will be implemented within timescales that will be agreed with the HFEA. 9. In order to fully assess other factors that may impact on treatment success, the Centre is also reviewing the luteal support regime in the light of the recent literature.	

‘Major’ area of non-compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
2. Medicines management Several issues were identified in relation to medicines management as outlined in the main body of the report. DH ‘Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)’ (2007) 4.7.1.3. NICE Guideline [NG46] ‘Controlled drugs: safe use and management’ (2016) 1.7.8. The Association of	The PR should ensure compliance with medicines management regulations and best practice guidance. When responding to the report, the PR should provide an update on immediate actions that have been taken to address the issues identified by the inspection team. Additionally, the PR should investigate why the centre’s own audit, performed in December, failed to identify the inspection team’s findings that the time of discard of some controlled drugs for that	1. The PR will ensure compliance with medicines management regulations and best practice guidance. 2. The following actions have been implemented; i. The monthly snapshot audits being undertaken have now been replaced with a weekly snapshot audit. As part of the quality assurance that the audit has been undertaken correctly by the ODP the Matron reviews one set of notes from the weekly audit to ensure the audit process and	The executive acknowledges the PR’s response and commitment to implementing this recommendation. The PR has confirmed that action has been taken to address the issues that were identified on inspection and has reviewed why the centre’s own audit failed to identify the findings of the inspection team. In view of the centre’s suspension of treatments due to the COVID-19 outbreak, the centre’s inspector will liaise

Anaesthetists of Great-Britain and Ireland (AAGBI) 'Controlled Drugs in Perioperative Care'(2019) Good practice for controlled drugs administered directly by registered healthcare professionals in the theatre environment'. SLC T2.	period was not recorded. A summary of the findings of these investigations should be provided to the centre's inspector when responding to this report. The PR should review practices relating to the management of medicines to ensure compliance with regulatory and statutory requirements. A summary report of this review including corrective actions with timescales for implementation, should be provided to the centre's inspector by 21 April 2020. Within three months of the implementation of corrective actions the centre should conduct an audit of practice in this area to ensure that actions implemented have been effective in achieving and maintaining compliance. A summary report of the audit findings should be submitted to the centre's inspector by 21 July 2020.	the findings are correct. ii. Since week commencing 17/02/2020 the Matron has been undertaking a daily recorded check of the CD book to ensure all relevant boxes were completed. This daily check was done up until the 24/03/2020 as this was the last egg collection in theatre. This daily checks is not done at weekends as there is no egg collection. Out of the 27 daily checks completed there were four occasions where there were anomalies discovered, of which two were identified in the first week of the daily check. There were two other two occasions on the 12/03/2020 and the 23/03/2020. In the case where there is an anomaly feedback is given by the Matron on the day to the theatre team, Lead ODP for DRM theatre and the Lead Anaesthetist. iii. The standards within the weekly audit are being amended to include the following:	with the PR to consider an appropriate timescale for fully implementing all of this report's recommendations taking into account the period of time where treatments are suspended as a result of the pandemic. Further action required.

		a. standard which examines the carryover of stock levels being witnessed with two signatures b. standard which examines if the unit (mcg/mg) and strength of the drug recorded is written in full A copy of the new audit tool standards is attached (Appendix 2) with this report which has been approved by the Lead Anaesthetist and Lead Pharmacist in collaboration with Governance Team. Due to the suspension of the governance meetings ratification of the standards has been completed via email correspondence. 3. The Trust CD policy pictorial diagram depicted an example in which the stock level was shown in the top box. However it is accepted that this is usually written in the middle box. The CD policy pictorial diagram will be amended to ensure it is consistent with the practice on	

		how to complete the section on entering the stock balance into the middle box for drugs into the column in the CD register. The CD policy will be amended and sent to the HFEA within 3 months of recommencing services following the COVID-19 pandemic. 4. The PR has reviewed the centres original medicines management audit following the HFEA inspection to determine why there were differences in the respective findings with regard to the disposal of controlled drugs. The original audit standard 9 is as follows “the wastage of controlled drugs recorded in the CD record book should be signed by a registered practitioner and anaesthetist and timed appropriately” This standard was compliant in the original audit and in the repeat audit undertaken by the matron for the same set of 10 records. There were three other areas (standards1, 7	

		and 8) which showed non-compliance in the repeat audit monthly snapshot audit. 5. The Matron shared the findings of the repeat audit with the ODP which identified the following: • The ODP did not have a designated time to undertake the audit and was doing the audit whilst undertaking his theatres duties • The Matron ensured the ODP understood the audit standards and how the information should be collected. 6. As this audit was a snapshot an audit of the whole period of December 2019 was undertaken by Annette Adams Lead Pharmacist (Appendix 3). 7. The outcome of this shows that two standards failed as follows: i. Standard 10- 'The destruction should be signed	

		by a registered practitioner and anaesthetist' demonstrated that all the records that showed no second signatures on destruction were on the same day and by the same person but they had signed the administration line which would not normally be witnessed. ii. Standard 11-'The drug dose recorded as given in the patient anaesthetic record should match the dose given as recorded in the CD record book' iii. On closer examination by the lead pharmacist the five entries that did not match were on two separate days. 8. To ensure the effectiveness of compliance there are weekly audits which have been in place since week commencing the 03/02/202 which showed the following results: • Week commencing 04/02/2020: 97% • Week commencing	

		10/02/2020: 98% • Week commencing 17/02/2020: 100% • Week commencing 23/02/2020: 100% • Week commencing 03/03/2020: 100% 9. As from the 09/03/2020 the new audit standards for the weekly audit were used but analysis has not been completed due to COVID preparations. This audit was done by the Matron instead of the ODP and these results will be available by the 10/04/2020.This audit will be undertaken by the Matron going forward. 10. The action will be that the Lead Anaesthetist will discuss with the individuals concerned. The Lead Anaesthetist has also asked that all anaesthetists ensure that they review their documentation on the day. A copy of this audit is included with the report appendix 2. The Department will seek advice from the Divisional	

		Governance Lead with regard to repeated non-compliance. 11. There is a patient identification label which is already in place. This sticker will be added to the anaesthetist record by a designated nursing assistant. The department will need to agree whether this is reviewed as part of the medicines audit or the records audit. 12. This will be completed within 3 months of recommencing services following the COVID-19 emergency.	
3. Screening patients, partners and donors The centre does not document any discussions regarding the patient, partner or donor's travel or medical history with regard to the risks of infections (such as Zika and Ebola), or whether any additional testing may be required prior to treatment. SLC T50d and SLC T52h.	The PR should ensure that a patient, partner or donor's travel or medical history with regard to the risks of infections (such as Zika and Ebola), is fully considered prior to treatment. The PR should investigate why corrective actions taken to address non-compliances identified at the time of the renewal inspection have not been effective. A summary of the findings of that	1. The PR will ensure that a patient, partner or donor's travel or medical history relevant to the risks of infection is fully considered prior to treatment. 2. The new ICP (sent to the HFEA in June 2019) contains a section specifically designed to elicit a travel history, as well as a prompt to the clinician to remind the patient/donor to inform the	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has investigated why corrective actions taken to address this non-compliance previously had not been effective and has reviewed the centre's processes for considering, assessing and documenting discussions in relation to travel and medical

	investigation should be provided to the centre's inspector when responding to this report. The PR should review the centre's processes for considering, assessing and documenting discussions in relation to a patient, partner or donor's travel or medical history. A summary of the findings of the review, including corrective actions and the timescales for implementation should be provided to the centre's inspector with the PR's response to this report. The PR should consider, with expert advice if necessary, if there is any risk to patients or donors resulting from the failure to perform an assessment of past or present Zika or Ebola virus exposure or infection in all patients and donors to date. If risk is present, appropriate risk control measures should be implemented. A summary of the findings of this review	clinic of any travel at a subsequent date. 3. The centre acknowledges that there were out of date ICPs stored within the department that did not contain the revised section; this resulted in a further non-compliance. An investigation showed that the process for removing these out of date ICPs was not robust.. This has now been rectified. A new pathway has been created, covering the entire process from ordering, receipt, replacement and destruction of old ICPs. This has been ratified in the Department of Reproductive Medicine and will be forwarded for ratification to the Divisional Clinical Effectiveness Committee. We are happy to provide a copy of this once it has been ratified by this committee. 4. In the new pathway, there is a designated staff member for each part of the process. The Administrative	history. In view of the centre's suspension of treatments due to the COVID-19 outbreak, the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing all of this report's recommendations taking into account the period of time where treatments are suspended as a result of the pandemic. Further action required.

	should be provided to the centre's inspector by 21 April 2020. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 21 July 2020.	staff are tasked with checking each clinic room on a weekly basis to ensure that the correct ICPs are present and any out-of-date documents are removed and destroyed. 5. In addition to alerts and updates from the HFEA, DRM as part of the Division of Gynaecology (Saint Mary's Hospital) receives information from NHS England and the Royal College of Obstetricians and Gynaecologists (RCOG). Saint Mary's Hospital is a large NHS hospital which has a robust mechanism in place (through Infection Control and Governance structures and other resources as required) to advise staff of potential public health risks to patients both in the UK and following foreign travel. 6. All outpatient clinics have been suspended due to the COVID-19 outbreak as from 26/03/2020. An audit of the effectiveness of change will be completed within three months of commencing clinics	

		again.	
4. Record keeping A number of issues with record keeping were noted by the inspection team. These are described in the body of the report. SLC T37, SLC T38, SLC T46 and SLC T47.	The PR should ensure proper records are maintained. The PR should investigate why corrective actions taken to address non-compliances identified at the time of the renewal inspection have not been effective. This review should include an analysis of why no action appears to have been taken in regard to recording that the identity of patients, partners or donors has been verified. A summary of the findings of that investigation should be provided to the centre's inspector when responding to this report. The PR should undertake a review of the centre's processes for record keeping to determine why the various issues identified during the inspection had arisen including consideration of staff training requirements. A summary of the findings of the review including corrective actions and the timescales for	1. The PR will ensure that proper records are maintained. 2. The new ICP contains a section recording how a patient/partner or donor is identified (i.e. passport etc) and the clinician involved confirms this information is correct in the ICP. Compliance for this section of the ICP will be added to future record keeping audits. 3. In May 2019 following the March inspection an audit of Record Keeping using the Trust Clinical Record Keeping Standards (2016) was undertaken. The audit findings showed non-compliance in the following areas: • Name, designation and GMC number • Deletions and alternations must be countersigned, dated and timed • Documentation in the medical records was not in	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has not provided a summary of the findings of an investigation into why corrective actions to address this non-compliance had not been effective. The PR should conduct this investigation and provide a summary of the findings to the centre's inspector as soon as is practical in light of the COVID-19 pandemic. In view of the centre's suspension of treatments due to the COVID-19 outbreak, the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing all of this report's recommendations taking into account the period of time where treatments are suspended as a result of the pandemic.

	implementation should be provided to the centre's inspector by 21 April 2020. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 21 July 2020.	chronological order 4. As a result of the above findings a bespoke training package on record keeping took place at a multidisciplinary meeting in May 2019. There was also a plan for this audit to be repeated in July 2019. The findings of the July audit showed non-compliance in the following same areas: • Name, designation and GMC number • Deletions and alternations must be countersigned, dated and timed • Documentation in the medical records was not in chronological order 5. The action from the July audit was as follows: • The Clinical Quality Lead reiterated via email in August 2019 the importance for all clinicians regarding the mandatory use of GMC	Further action required.

		number, printed name and designation when documenting in the patient case notes. 6. The audit was repeated in November and completed in January 2020. The audit findings demonstrated no improvements in the areas identified in the previous audits. In addition the documentation in the medical records was not in chorological order (this was compliant in the July audit). The actions from this audit were as follows: • Email reminder sent to all clinical staff in January 2020 reiterating the requirements for clinical documentation. The department acknowledges that the previous actions are not effective and are working towards a more robust governance process with regard to this. In addition a face to face training session for all the clinicians was	

		scheduled for February 2020 but this session was cancelled due to a training competing session. • This session will have to be rescheduled as a priority post COVID. 7. This audit is planned to be repeated at the end of April 2020 with the addition of a new standard to ascertain compliance for identification for ICP donor patient/partner or donor. 8. The administration team in DRM have been advised of the importance of the chronological filing order of patient notes to ensure the patient journey is easier to follow. This will be part of the Record keeping audit at the end of April and the standard is already in place. 9. DRM have a hybrid of both paper and electronic records of fertility treatments i.e. currently AcuBase. There is a Trust strategic plan to	

		replace paper documentation with an electronic paper record by 2024. The plan as above is to continue with the above quarterly audits. 10. The anaesthetic sheets are within an ICP booklet which has the patient identification on the front. There will be a drug administration patient identification label created by the lead anaesthetist to ensure that each page within the anaesthetic booklet will contain a clear patient identifier. This sticker will be added to each page of the anaesthetic ICP by a designated nursing assistant. 11. All outpatient clinics have been suspended due to the COVID-19 outbreak as from 26/03/2020. An audit of the effectiveness of change will be completed within three months of commencing clinics again.	

‘Other’ areas of practice that requires improvement

Other 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	Executive review
5. Disclosure of information, held on the HFEA Register, for use in research An audit of consent to disclosure performed by the inspection team noted, in a sample of ten records, two discrepancies between completed patient/partner disclosure consents within patient records and the related consent data submitted for inclusion on the register. *(NB. The Centre’s designated HFEA Form Returnee has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected).* The inspection team notes that	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA Register. The PR should confirm that the incorrect submissions identified have been corrected when responding to this report. The PR should continue to audit this area of practice and provide the centre’s inspector with the reports on a monthly basis until 21 April 2020. If any further discrepancies are identified the PR should investigate why corrective actions taken to address non-compliances identified have	1. The PR will ensure that patient/partner consents to disclosure of identifying information to researchers are actually recorded on the HFEA Register. 2. The PR can confirm that the incorrect submissions identified have been corrected and correction forms have been sent to the HFEA on the 21/01/2020. The PR proposes that a sample of the historically patients registered with the HFEA are audited to determine the level of compliance with the CD forms are correctly documented on AcuBase. This audit will be schedule once the	The executive acknowledges the PR’s response and commitment to implementing this recommendation. The PR continues to audit this area of practice and has committed to investigate any further discrepancies that are identified. In view of the centre’s suspension of treatments due to the COVID-19 outbreak, the centre’s inspector will liaise with the PR to consider an appropriate timescale for fully implementing all of this report’s recommendations taking into account the period of time where treatments are suspended as a result of the

audits provided to the centre's inspector in February and March 2020 identified no discrepancies.	not been effective.	long-term storage audit is completed in August 2020. 3. There is a monthly audit in place which commenced in December 2019 and the audits are submitted each month to HFEA of which the March audit was submitted on the 06/04/2020. 4. The findings for these audits showed the following: December: the electronic record did not match the paper documentation for one record. This was immediately corrected and HFEA were advised. (Correction form number R97575). January and February: full compliance March: one date error on patient CD form which showed 05/03/88 instead of 05/03/2020. The department is unable to ask patients to attend the unit to correct the form due to current Covid-19 outbreak- patients are being recorded on	pandemic. Further action required.

		central tracker to book appointment once service resumes. 5. The PR will investigate any further discrepancies to see why the corrective actions have not been effective. 6. All outpatient clinics have been suspended due to the COVID-19 outbreak as from 26/03/2020. An audit of the effectiveness of change will be completed within three months of commencing clinics again.	
6. Obligations and reporting requirements The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the HFEA Register as detailed in the main body of the report. The inspection team notes that audits, provided to the centre's inspector in February and March 2020 showed that 100% of IVF and DI cycles audited were	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 continue to audit this area of practice and provide the centre's inspector with the reports on a monthly basis until 21 April 2020. If any further problems with the timeliness and accuracy of the centre's submission of data to the HFEA register are	1. The PR will ensure that all licensed treatment activity is reported to the HFEA within the timeframe required by General Direction 0005. 2. Monthly audits are submitted to HFEA and the next audit (March data) is due for submission is 6 April. 3. These monthly audits have been in place since November 2019.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The PR has continued to audit this area of practice on a monthly basis. Further problems with the timeliness and accuracy of the centre's submissions of data to the HFEA register have been identified and the PR has committed to undertake further investigations.

reported to the HFEA within the period required by General Direction 0005.	identified the PR should investigate why corrective actions taken to address non-compliances identified have not been effective.	4. The audits showed the following findings: November: non-compliant December and January showed 100% compliance February: non-compliant March: non-compliant 5. Following the March audit there is an action in place for the Matron and the Principle Embryologist to investigate both late IUI data and late submissions of early outcomes. 6. As a result of the March audit the department are in the process of mapping the paper and electronic pathways to ascertain how we can ensure compliance among all staff groups. 7. All outpatient clinics have been suspended due to the COVID-19 outbreak as from 26/03/2020. An audit of the effectiveness of change will be completed within three months of commencing clinics again.	In the view of the centre's suspension of treatments due to the COVID-19 outbreak, the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing all of this report's recommendations taking into account the period of time where treatments are suspended as a result of the pandemic. Further action required.

Additional information from the Person Responsible
I would like to thank the inspectors eand welcome the findings submitted in this report. I appreciate and welcome the many positive remarks on the quality of our service and have informed all staff of these best practice reports. Likewise I have informed all members of staff our short comings and areas requiring improvement. I would like to reassure the Authority that we have taken on board the importance of your findings recorded in this report and will strive to improve the service.