Licence Committee - minutes

Centre 0067 (St Mary's Hospital)

Renewal Licence

Thursday, 2 May 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle Jennifer Rogerson Amanda Evans	Committee Secretary Research Manager (Staff Induction) Research Manager (Staff Induction)
Legal Adviser	Sarah Ellson	Fieldfisher 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:

- Renewal Inspection Report
- Application form
- Previous licensing minutes up to the last licence renewal:
  - Executive Licensing Panel - Interim Inspection Report - April 2017
  - Executive Licensing Panel - Change of Address - September 2015
  - Executive Licensing Panel - Renewal Inspection Report - April 2015

1. Background

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

Licence

1.2. The centre's current licence was issued for a period of 4 years and was varied to reflect a change of postal address in 2015, this was solely an administrative change. The current licence is due to expire on 31 July 2019.

History of Non-Compliance - Consent to Legal Parenthood

1.3. The centre had failed to ensure that effective consent to legal parenthood was in place, and as a result, in June 2016, a couple treated at the centre had to seek a declaration of parenthood in the High Court.

1.4. In September 2016 an onsite inspection was conducted to review the case, discuss the actions taken by the centre and ensure the centre's processes for taking legal parenthood consent were robust. During this inspection, an anomaly in consent to legal parenthood was identified.

1.5. A 'near-miss' was also identified at the interim inspection in February 2017. This case did not result in a pregnancy.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee noted that the centre had submitted an application for the renewal of the treatment and storage licence.

2.2. The committee noted that the application contains the supporting information required by General Direction 0008 and that the appropriate fee has been paid.

Inspection Process

2.3. The committee noted that in the 12 months to 31 December 2018, the centre provided 1801 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

2.4. The committee noted that for IVF and ICSI, HFEA-held register data for the year ending 31 October 2018 showed the centre's success rates were in line with national averages with the following exception:

- success rates following frozen embryo transfer (FET) in women under 40 years old were lower than average at a statistically significant level.

2.5. The committee noted that for the year 2018, the centre reported 19 cycles of partner insemination with one clinical pregnancy. This represented a clinical pregnancy rate which was comparable to the national average.

2.6. The committee noted that HFEA-held register data for the year ending 31 October 2018 showed the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 10%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

2.7. The committee noted that the renewal inspection took place on 5 and 6 March 2019. The renewal inspection report covers the performance of the centre since the last inspection, the findings from the renewal inspection visit and communications received from the centre. The committee noted that at the time of the renewal inspection there were three critical, seven major and four other areas of non-compliance identified:

Critical areas of non-compliance:

- The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice guidance.
- The PR should ensure that proper consent to legal parenthood is obtained.
- The PR should ensure that there is effective consent in place for all stored gametes and embryos.

Major areas of non-compliance:

- The PR should address the success rate identified as currently being lower than national average.
- 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, to determine if any additional testing may be required, and that these are clearly documented in the notes.
- The PR should ensure that imports and exports of gametes and embryos are compliant with General Direction 0006.
- The PR should ensure that all adverse incidents, including serious adverse events and reactions, as well as near misses, are reported to the HFEA.
- The PR should ensure that all staff are competent to undertake the tasks that they perform.
- The PR should ensure that gamete providers in a surrogacy agreement are suitably assessed and screened as donors.
- The PR should ensure proper records are maintained.

Other areas of non-compliance or poor practice:

- The PR should ensure that systems are in place for the safe storage of gases.
- The PR should ensure that alerts and guidance issued by the HFEA and other relevant bodies is fully considered and actioned by the centre, and that the methodology and scope of audits are consistently documented.
- 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.

2.8. At the renewal inspection, another anomaly in legal parenthood consent had been identified, in a couple who had a live birth.

2.9. The committee noted that the Executive was particularly concerned with the findings in relation to consent to legal parenthood, as the centre has a history of previous failure in this area, resulting in a couple having to seek a declaration of parenthood via the Family Division of the High Court. The Executive also had concerns that intended parents for surrogacy arrangements were not screened as donors, and other concerns include the storage of embryos without effective consent from the gamete providers, the centre's processes for the management of controlled drugs and failure to ensure compliance with General Direction 0006.

2.10. The committee noted that since the inspection visit, the PR has committed to fully implementing all of the recommendations. The PR has also committed to provide evidence that actions have been taken, and where required, to audit the effectiveness of those actions within the required timescales.

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

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

Recommendations

Licence

2.13. The committee noted that, given the number of significant issues identified during the renewal inspection on 5 and 6 March 2019, the Executive carefully considered the centre's licensing history, the ability of the Person Responsible (PR) to discharge his duty under section 17(1) of the HF&E Act 1990 (as amended), and the PR's engagement with the HFEA. The Executive held management review meetings in accordance with the HFEA's Compliance and Enforcement Policy, to evaluate the centre's performance and to decide a proportionate licensing recommendation for the licence renewal application. It was concluded that the issues identified on inspection were significant, and posed direct and indirect risks to patients, and the centre was not able to demonstrate compliance with the HF&E Act 1990 (as amended) and other relevant legal requirements in a number of areas of practice.

2.14. In consideration of the findings at the renewal inspection and the centre's previous failings in relation to legal parenthood, the Executive asked the PR to consider a voluntary cessation of treatments with donor sperm for new patients until such time as the HFEA is satisfied that the centre's procedures for obtaining effective consent to legal parenthood are robust. However, the PR declined and asserted that he was already taking appropriate action by reporting the incident and planning to offer support and guidance to the couple affected. The PR also stated that he had re-audited all relevant records since 2014 and these were found to be 100% compliant.

2.15. Following further communications, on 19 March 2019, the Trust's Director of Clinical Governance confirmed that the centre would take action in line with the HFEA's recommendation, and that a further re-audit of records was to be carried out. The PR later confirmed that he was in agreement with this decision and would be involved in the process and would be implementing the suspension of treatments from 1 April 2019, until a re-audit of records had been undertaken, which was anticipated to be completed by 30 April 2019. The PR considered that there should be exclusions from the suspension of treatments for some patients, e.g. intrauterine insemination, frozen embryo transfer, women aged 38 and women with low ovarian reserve because the delay could have a detrimental effect on the outcome of treatment and/or affect their ability to have treatment in the future due to CCG funding.

2.16. The Executive advised the PR that if he considered that it was necessary to provide treatments to patients against the recommendations of the HFEA, it was expected that he would have a compelling reason to do so.

2.17. A further management review meeting was held on 2 April 2019 to evaluate the PR's responses and engagement with the HFEA since the time of the inspection and the PR's ability to discharge his duty under section 17 of the HF&E Act 1990 (as amended). The PR provided information on other actions that he had taken to address issues identified during the inspection and confirmed that a voluntary suspension of treatments commenced on 1 April 2019. However, the Executive noted that this did not include the 'excluded' categories as determined by the PR, and that he expected that this would be two to three patients a month.

2.18. In view of the number and significance of the inspection findings, the Executive considered that the PR had failed to discharge his duty under section 17(1)(d) and (e) of the HF&E Act 1990 (as amended) because he had failed to ensure that suitable practices are used in the course of activities (notably consent to legal parenthood, consent to storage and management of medicines), and he had failed to ensure that the conditions of the licence were compiled with.

2.19. The Executive had regard to the HFEA Guidance on licensing. Taking into account the centre's licensing history and a range of mitigating factors, the Executive considered recommending a shorter licence, conditional on the PR developing and implementing effective action plans to address all non-compliances. The Executive had also agreed that it would consider making a recommendation for the change of PR if suitable assurances and appropriate plans were not provided.

2.20. However, the PR and Trust's Medical Director attended a meeting with the HFEA on 8 April 2019 to discuss the PR's plans to address the issues identified, and how he proposed to guarantee the future compliance of the centre. The PR acknowledged that he had not given the required focus to his role in recent times due to the number of other roles and responsibilities he held within the centre and the Trust. The PR also reiterated his commitment to fully discharge his duties now and in the future. The Trust's Medical Director assured the Executive that the Trust will provide the PR with the necessary support, and the PR confirmed that he was assured that this will be provided.

2.21. The PR confirmed that he had suspended the provision of donor sperm treatments for new patients since the inspection, in accordance with the advice from the HFEA. The PR also confirmed that he had provided treatment for 15 patients who had already started treatment prior to the inspection. This had not been clear in previous communications. The PR also confirmed that treatments had been provided to two new patients, because of their exceptional personal circumstances. The Executive reiterated to the PR, that for any such cases, 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. The PR assured the Executive that going forward he will have full responsibility for all communications with the HFEA.

2.22. The PR has assured the Executive that immediate actions were taken in response to the inspection findings. The Executive was satisfied with the proposed plans to address the non-compliances identified and considered that they demonstrate that the PR is fully engaged and committed to attaining compliance and good governance, thereby mitigating risks at the centre. The Executive is also assured that the PR will fully discharge his duties.

2.23. The committee noted that the Executive recommended the renewal of the centre's licence for a period of three years, rather than the usual four. This recommendation would allow a targeted interim inspection to be performed within one year.

Legal Advice

2.24. At the request of the committee, the Legal Adviser reminded the committee members that, should they wish to impose conditions on the licence, they would have to be satisfied that one, or more, of the criteria in Section 18(2) of the Act was met, and that the committee, in fact, had the power to revoke the licence. If that threshold was reached, then if it was considered more proportionate, a committee might instead, vary the licence to impose conditions. The power to revoke a licence could arise if the Authority ceased to be satisfied that the PR was a suitable person to supervise the licensed activity, and evidence in relation to this, could be taken from evidence of non-compliance with the various requirements under Section 17 of the Act, such as securing suitable practices, as well as compliance with the HFEA Code of Practice and the character of the PR. The Legal Adviser made reference to the HFEA Guidance on Licensing for further information.

3. Decision

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

Administrative Requirements

Supporting Information under General Direction 0008

Application

3.2. The committee was satisfied that the application was submitted in the form required and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Proposed Person responsible (PR) – Mr Gregory Horne

3.3. The committee was satisfied that the proposed PR possesses the required qualifications and experience.

3.4. The committee had some concerns about whether the character of the proposed PR is such as is required for supervision of the licensed activities but on balance decided that he was suitable. The committee noted that the Executive had considered making a recommendation for the change of PR if suitable assurances and appropriate plans were not provided, and that after further communication and engagement, the Executive was assured that the PR would fully discharge his duties. However, the committee would like to see further evidence that the proposed PR will discharge his duties under section 17 of the HFE Act 1990 (as amended).

Proposed Licence Holder (LH) – Mr Mike Deegan

3.5. The committee was satisfied that the proposed LH is suitable.

Activities

3.6. The committee was satisfied with the suitability of the activities applied for.

Premises – The Department of Reproductive Medicine, Old Saint Mary's Hospital, Oxford Road, Manchester, M13 9WL

3.7. The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for.

3.8. The committee was satisfied that the third-party premises are also suitable.

Licence

3.9. The committee considered that the PR is engaging with the Executive and committed to achieving compliance, and notes that the Trust will now provide the PR with the support he needs to implement all the recommendations and maintain compliance going forward. The committee also considered that the Executive was satisfied with the proposed plans to address the non-compliances identified and will continue to monitor the centre's performance.

3.10. The committee had regard to the HFEA Guidance on licensing and considered the duration of licence it should offer. Carefully weighing all factors in the balance, the committee agreed that a three-year licence, subject to the implementation of the recommendations outlined in the renewal inspection report, was appropriate.

3.11. The committee agreed that the inspectorate should complete a targeted interim inspection within one year, to assess the implementation of the recommendations and the centre's general compliance.

3.12. 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 can be satisfied that the licence can remain in force without restriction.

4. Chair’s signature

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

Signature

Name

Kate Brian

Date

30 May 2019

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 5 and 6 March 2019.

Purpose of inspection: Renewal of a licence to carry out 'Treatment and storage'.

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Karen Conyers, Mhairi West, Grace Lyndon, Sandrine Oakes, Neil McComb, Rosie O'Grady and Finn Bamber (observer from the Office of National Statistics).

Date of Licence Committee: 2 May 2019.

Centre name	St Mary's Hospital
Centre number	0067
Licence number	L/0067/18/b
Centre address	The Department of Reproductive Medicine, Old Saint Mary's Hospital, Oxford Road, Manchester, M13 9WL, United Kingdom
Person Responsible	Mr Gregory Horne
Licence Holder	Mr Mike Deegan
Date licence issued	01 August 2015
Licence expiry date	31 July 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

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

The centre provided 1801 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2018. In relation to activity levels this is a large centre.

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

The current licence has been varied to reflect a change of postal address in October 2015. The centre had not changed its physical location and the change of address was a solely administrative change.

In June 2016 a couple treated at the clinic had to seek a declaration of parenthood in the High Court as the centre had failed to ensure effective consent to legal parenthood was in place. In September 2016 a site visit was conducted to review the case, discuss the actions taken by the centre and ensure the centre's processes for taking legal parenthood consent were robust. During that inspection in September 2016 an anomaly in consent to legal parenthood was identified by the inspection team, and a further issue was noted at the centre's interim inspection in February 2017. In the latter case no pregnancy resulted therefore it was considered a 'near-miss'. At this renewal inspection, another anomaly in legal parenthood consent has been identified in a couple who have had a live birth. This finding is of great concern to the executive and is discussed in detail in the 'Legal Parenthood' section of this report.

Given the number of significant issues identified during the inspection reported on here, the executive has carefully considered the centre's licensing history, the ability of the Person Responsible (PR) to discharge his duty under section 17(1) of the HF&E Act 1990 (as amended), and the PR's engagement with the HFEA in order to inform a recommendation on the length of licence to be offered. As a result of the executive's concerns management review meetings in accordance with the HFEA's Compliance and Enforcement policy were held on 8 March 2019 and 2 April 2019. Another meeting was held on 14 March 2019 to discuss the PR's initial response to the executive's recommendation of 8 March 2019. Following the management review meeting on 2 April 2019, the PR was required to attend a meeting with the HFEA executive to discuss the seriousness of the executive's concerns with his responses and engagement with the HFEA since the time of the inspection. These actions enable the executive to be able to make a recommendation to the Licence Committee which is discussed in detail in the 'Recommendations to Licence Committee' sections of this report.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year ending 31 October 2018 show the centre's success rates are in line with national averages with the following exception (see recommendation 4; SLC T2):

- success rates following frozen embryo transfer (FET) in women under 40 years old are lower than average at a statistically significant level.

For the year 2018 the centre reported 19 cycles of partner insemination with one clinical pregnancy. 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 2018 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008, Standard Licence Conditions (SLCs) and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR will discharge his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable with the exception noted in the body of the report;
- the centre's practices are suitable with the exceptions noted in the body of the report;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

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

Since the inspection visit, the PR has given a commitment to fully implement all the recommendations, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

Critical areas of non-compliance:

- **The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice guidance.**
- **The PR should ensure that proper consent to legal parenthood is obtained.**
- **The PR should ensure that there is effective consent in place for all stored gametes and embryos.**

Major areas of non-compliance:

- The PR should address the success rate identified as currently being lower than national average.
- 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, to determine if any additional testing may be required, and that these are clearly documented in the notes.
- The PR should ensure that imports and exports of gametes and embryos are compliant with General Direction 0006.
- The PR should ensure that all adverse incidents, including serious adverse events and reactions, as well as near misses, are reported to the HFEA.
- The PR should ensure that all staff are competent to undertake the tasks that they perform.
- The PR should ensure that gamete providers in a surrogacy agreement are suitably assessed and screened as donors.

- The PR should ensure proper records are maintained.

'Other' areas of non-compliance or poor practice:

- The PR should ensure that systems are in place for the safe storage of gases.
- The PR should ensure that alerts and guidance issued by the HFEA and other relevant bodies is fully considered and actioned by the centre, and that the methodology and scope of audits are consistently documented.
- 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.

Recommendation to the Licence Committee

As noted above, at inspection the centre had three critical and seven major areas of non-compliance. Four 'other' areas of non-compliance or poor practice were also identified.

The inspection team notes the success rates following FET in women under 40 years old are lower than average at a statistically significant level. The centre's multiple clinical pregnancy/ live birth rate is not likely to be significantly different to the 10% multiple live birth rate target. The PR should ensure that the Quality Management System (QMS) is used to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients. Significant improvement is required in order for the centre to reflect suitable practices.

Given the number of significant issues identified during this inspection on 5 and 6 March, the executive held a management review meeting on 8 March in accordance with the HFEA's Compliance and Enforcement Policy, to evaluate the centre's performance and to decide a proportionate licensing recommendation regarding the licence renewal application. The management review meeting found that the issues identified on inspection were significant, and posed direct and indirect risks to patients, and concluded that the centre was not able to demonstrate compliance with the HF&E Act 1990 (as amended) and other relevant legal requirements in a number of areas of practice. Of particular concern were the findings in relation consent to legal parenthood, the storage of embryos without effective consent from the gamete providers and the centre's processes for the management of controlled drugs. The failure to ensure compliance with General Direction 0006, and that intended parents in surrogacy arrangements were not being screened as donors, were also noted as areas of concern.

The issues in relation to consent to legal parenthood were of particular concern as the centre has a history of previous failure in this area resulting in a couple having to seek a declaration of parenthood via the Family Division of the High Court. In consideration of the findings on this inspection and the centre's previous failings in relation to legal parenthood, the executive contacted the PR soon after the management review meeting on 8 March 2019 to ask him to consider a voluntary cessation of treatments with donor sperm for new patients until such time the HFEA is satisfied that the centre's procedures for obtaining effective consent to legal parenthood are robust.

The PR responded on 14 March 2019 saying that they 'do not see a reason to voluntarily cease the provision of new treatment cycles with donor sperm or embryos created with donor sperm.' The PR asserted that he was taking appropriate actions to address the case identified as having anomalous legal parenthood consents, that he would be offering

support and guidance to the couple affected, and that he had reported this case as an incident in line with HFEA guidance. The PR also stated that he had re-audited all relevant records since 2014 and these were found to be 100% compliant.

The executive held a further meeting to discuss the PR's response that same day. At this meeting it was agreed that given the centre's previous failings, the HFEA was not assured that the centre's processes for taking, checking and auditing consent to legal parenthood were robust and that the gravity of the executive's concerns should be reiterated to the PR, giving him the option to reconsider his decision. This was communicated to the PR by email later that same day, 14 March 2019.

Following a series of further communications, on 19 March 2019 the Trust's Director of Clinical Governance wrote to the centre's inspector to confirm that the centre would take action in line with the HFEA's recommendation and that a further re-audit of records was to be carried out. The executive responded on 20 March 2019, to seek confirmation from the PR that he was in full agreement with the contents of the letter. The executive also sought further assurances in relation to the specific actions set out in the letter.

Over a week later, on 28 March, the PR confirmed that he was in agreement with the Trust's Director of Clinical Governance and that he had had 'full input into the drafting of the response and the actions planned.' The PR informed the executive that he would be implementing the suspension of treatments from 1 April 2019 until a re-audit of records had been undertaken, which was anticipated to be completed by 30 April 2019. The PR also informed the executive that there were a number of categories of patients that he considered should be excluded from the suspension of treatments (such as intrauterine insemination, frozen embryo transfer, women aged 38, women with low ovarian reserve) because the delay could have a 'detrimental effect upon the outcome of treatment and/or affect their ability to have treatment in the future due to CCG funding'.

The executive responded the same day, 28 March, seeking clarification from the PR as to why the suspension of treatments was to commence on 1 April when he had been advised on 8 March 2019 that the HFEA's concerns were such that an immediate suspension of treatments was recommended. Furthermore, the executive advised the PR that the HFEA could not at this time agree a date on which such a suspension of treatments could be lifted. Further clarification was also sought as to the reason why the PR considered the suspension would have a detrimental effect on the patients in the categories listed, and how many were included in each of those groups. The executive advised the PR that if he considered that it was necessary to provide treatments to patients against the recommendations of the HFEA, it was expected that he would have a compelling reason to do so.

As a result of these protracted communications with the PR, a further management review meeting was held on 2 April 2019 to evaluate the PR's responses and engagement with the HFEA since the time of the inspection. During this meeting, the executive also considered the PR's ability to discharge his duty under section 17 of the HF&E Act 1990 (as amended). The PR's response to the executive's communication of 28 March 2019 was received while this meeting was in progress. In this letter the PR confirmed that a voluntary suspension of treatments commenced on 1 April 2019, however the executive notes that this does not include the 'excluded' categories as determined by the PR, and that he expects this will to be 2-3 patients a month. In this letter the PR also provided information on other actions that he has taken to address issues identified during the inspection.

In view of the number and significance of the inspection findings the executive considered that the PR has failed to discharge his duty under section 17(1)(d) and (e) of the HF&E Act 1990 (as amended) because he has failed to ensure that suitable practices are used in the course of activities (notably consent to legal parenthood, consent to storage and management of medicines), and he has failed to ensure that the conditions of the licence are compiled with.

At the same meeting on 2 April 2019, the executive also considered the HFEA's 'Guidance on licensing' (2016), taking into account the centre's licensing history and a range of mitigating factors, including the letter received during the meeting, in order to determine a proportionate recommendation.

Taking all of the above into account the executive concluded that the centre's licence should be renewed for three years. This recommendation was conditional on the PR developing and implementing effective action plans to address all non-compliances in the centre's activities. The executive agreed that the PR would be provided a copy of the draft renewal inspection report and would be required to attend a meeting with the HFEA executive to discuss its concerns. The PR was informed that if suitable assurances and appropriate plans were not provided, the executive would also consider modifying the report's recommendation to seek a requirement for a change of PR at the centre. The executive's decision was communicated to the PR on 3 April 2019.

The PR and Trust's Medical Director attended a meeting with the Chief Inspector and centre's inspector on 8 April 2019. The HFEA executive was able to discuss the PR's plans to address the issues identified, and to discuss how he proposed to guarantee the future compliance of this centre. During this meeting, the PR acknowledged that he had not given the required focus to his role as PR in recent times due to the number of other roles and responsibilities he held within the centre and the Trust. The PR also reiterated his commitment to fully discharging his duties now and in the future. The Trust's Medical Director assured the executive that the Trust will provide the PR with the necessary support, and the PR confirmed that he is assured that this will be provided.

The PR confirmed that in accordance with the advice from the HFEA, he had suspended the provision of donor sperm treatments for new patients since the time of the inspection and has provided treatment to 15 patients who had already commenced treatment prior to the inspection. This had not been clear in previous email communications. The PR also confirmed that treatments had been provided to two new patients, because of their exceptional personal circumstances. The executive reiterated to the PR that for any such cases, the Medical Director should undertake a risk assessment, that all consents should be checked by the PR, and that these actions should be documented in the patient's records. The PR also assured the executive that going forward he will have full responsibility for all communications with the HFEA.

The executive was satisfied with the PR's assurances of the immediate actions he had taken in response to the inspection findings, of his commitment to fully discharging his duties, and of the proposed plans to address the non-compliances identified. The executive considered that these demonstrated that the PR is fully engaged and committed to attaining compliance and good governance thereby mitigating risks at the centre.

On the basis of the discussions held at the meeting and the PR's responses to the report, the executive is assured that the PR will fully discharge his duties and is committed to

ensuring that the centre will achieve and maintain compliance with regulatory requirements. The executive is assured that the PR has the support of the Trust's senior management and governance teams in achieving that aim.

In conclusion, the executive recommends that the renewal of the centre's treatment (with embryo testing) and storage licence should be for a period of three years, rather than the usual four, and that this inspection report is considered by the Licence Committee rather than the Executive Licensing Panel. This recommendation reflects concerns about the centre's level of non-compliance and would allow a targeted interim inspection to be performed within one year of the Licence Committee decision, at which the centre's compliance generally, and with regard to the implementation of this report's recommendations, would be assessed.

The centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The centre was not able to provide evidence of compliance with General Direction 0006 for the donor sperm imported into the centre under its import certificate. Therefore, the inspection team recommends that the centre ceases the import of gametes from its third country supplier until the relevant recommendations of this inspection report are fully implemented. The PR confirmed that he has ceased all imports and exports under General Direction 0006 from 3 April 2019. If this recommendation is fully implemented by the time this report is considered by the Licence Committee, the executive will be able to recommend the renewal of the centre's ITE import certificate in line with the centre's licence.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are partially compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused. The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non-identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor

and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better

Screening of donors (Guidance note 11)
The centre does not document any discussions regarding the 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 (see recommendation 5; SLC T52h). The lead clinician was assured that such discussions did take place with donors and that these would only be recorded if any issue was identified.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm with the exception noted below.

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accreditation by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are partially compliant with guidance.

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

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications, and;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and

that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
It is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety. The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are partially compliant with HFEA requirements.

The centre has been allocated an importing tissue establishment (ITE) import certificate and imports of gametes and embryos from third country suppliers (TCS) outside the EU/EEA have been made since the introduction of the ITE/TCS import certification scheme on 1 April 2018. The centre's imports from the TCS have been compliant with General Direction 0006, with the exceptions noted below.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability to:
- identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- identify the donor and recipient of particular gametes or embryos;
- identify any person who has carried out any activity in relation to particular gametes or embryos; and
- identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements, including those associated with ITE/TCS import certificates, are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage transport and satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by transport and satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)

The centre uses equipment and materials that are compliant with HFEA requirements. All equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
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. The centre's procedures for reporting adverse incidents are partially compliant with HFEA requirements. The centre reports most adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred with the exceptions noted below.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
During the inspection the following issues were noted (see recommendation 11; SLC T17, DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006)):

- The cylinder store outside housed 13 large empty cylinders but these were not chained therefore were at risk of falling over.
- There was no safety signage on the cage to indicate there was a fire risk.

Medicines management (Guidance Note 25)
During the inspection a patient that was scheduled for a procedure was brought into the theatre. A member of staff made an entry into the controlled drugs register with the patient's name and relevant details, and then signed against each section recording the amount of drug supplied, administered and discarded, documenting that they had witnessed that activity. However, none of these steps had taken place as the controlled drug had not yet been removed from the controlled drugs cupboard (see recommendation 1; SLC T2, Misuse of Drugs (safe custody) Regulations 2001, Controlled Drugs in Perioperative Care 2006).

In addition, it was noted that entries for four other patients undergoing a procedure had also been completed including the time the patient was due into theatre, the witness signature and the stock balance. Again, this was before the procedures had taken place. The only area not completed was that by the person who is responsible for giving the controlled drug. The inspection team were concerned that the process for the supply, administration and disposal of controlled drugs are not robust and therefore there is a possibility that the records of dosages given to patients will not be correct, and furthermore, there is a risk that it may not be possible to ensure that all drugs are fully accounted for (see recommendation 1; SLC T2 and Controlled Drugs in Perioperative Care 2006).

In addition, the following issues were noted in the controlled drugs register (see recommendation 1; SLC T2, Misuse of Drugs (safe custody) Regulations 2001, Controlled Drugs in Perioperative Care 2006, and Controlled Drugs; safe use and management April 2016):

- In one instance, the group of patient's details were written on the page for Alfentanil and not Fentanyl, which was the drug that had actually been given to them. An entry denoting 'ERROR' was noted but there was no signature or explanation from the staff member explaining what the error was; as required in accordance with guidance and best practice.
- The entries for some patients had been duplicated in the controlled drugs register. Again, an entry denoting 'ERROR' was written but there was no signature or explanation from the staff member explaining what the error was.
- The register was not fully completed; there were missing signatures in the supplied administration and witnessing sections for several entries.
- The time that the medication was supplied, administered and discarded was not consistently documented. In two instances in the controlled drugs register, only one signature was written against bracketed areas covering three sets of records; the supply, administration and disposal. The inspection team were concerned that the correct procedures for the supply, administration and discard of controlled drugs had not been followed as these signatures should be applied to the record at the time of each activity.
- Signatures are not always legible or identifiable to the staff member.
- The discard of controlled drugs is not done in line with local Trust policy.

The centre had conducted an audit of controlled drugs in December 2018. They noted two discrepancies between the dosage of drug administered to the patient as recorded in the patient's records and the controlled drugs register. They also noted that the time of administration was sometimes left blank. These findings reflect those found by the inspection team. The corrective action identified was to share the findings with the theatre team and anaesthetists. However, the inspection team were concerned that this does not seem to have been effective in addressing these non-conformances as similar issues were noted by the inspection team (see recommendation 1; SLC T36).

Imports and exports (Guidance note 16; General Direction 0006)

The centre exported samples of patient's sperm to Spain in January 2018 but was not able to demonstrate compliance with paragraph 1, Schedule 2 of General Direction 0006 for that export (see recommendation 6; General Direction 0006). The inspection team were concerned that there was no indication that compliance with the requirements of General Direction 0006 had even been considered for this export.

The centre has an arrangement with a sperm bank in the USA whereby they receive bulk imports of donor sperm which are held at centre 0067 until samples are purchased by a patient. Once purchased, the samples are transferred to a UK treatment centre, and any samples that are not purchased are eventually returned to the USA. The centre has an appropriate ITE in place and the imports take place under General Direction 0006. However, the centre was not able to provide evidence of compliance with all requirements of General Direction 0006 (Schedule 3, paragraph 3(f), (g), (h) and (j)) for each of these imports (see recommendation 6; General Direction 0006). The PR was of the view that the samples are not being used in treatment at his centre therefore only the donor's details which are needed to register the import with the HFEA are required. The PR said he was able to request all additional information from the donor sperm bank in the USA if needed. The inspection team accepts that it is likely that all required evidence of

compliance with General Direction 0006 could be obtained upon request particularly in view of the comprehensive third-party agreement that is in place in order to comply with the requirements for an ITE and the Human Fertilisation and Embryology (Amendment) Regulations 2018. However, the inspection team were concerned that the PR and centre staff had not recognised that these imports are taking place under General Direction 0006 therefore evidence of compliance with the relevant schedule should be obtained (see recommendation 6; General Direction 0006 and SLC T110).

The inspection team noted that the export of partner sperm and import of donor sperm from one sperm bank in the USA are the only gametes or embryos that have been imported or exported by the centre since the time of the last inspection, and that neither of these activities are compliant with General Direction 0006.

The inspection team concluded that centre staff are not sufficiently aware of the requirements of General Direction 0006 and therefore do not seek relevant evidence of compliance, as seen in the export of partner sperm and the import of donor sperm as described above. Furthermore, the centre's SOP for the import and export of gametes and embryos contains very little information to direct staff on how to ensure that imports or exports of gametes or embryos comply with General Direction 0006 (see recommendation 6; SLC T33b).

Given the concerns about the centre's compliance with General Direction 0006 the inspection team recommends that the centre ceases the import of gametes from its third country supplier until the relevant recommendations of this inspection report are fully implemented (see recommendation 6; General Direction 0006). If the recommendation is fully implemented by the time this report is considered by the Licence Committee, the executive will be able to recommend the renewal of the centre's ITE import certificate in line with the centre's licence.

Quality management system (QMS) (Guidance note 23)

The HFEA provides alerts to centres to make them aware of incidents reported within the sector for learning and preventative action. The inspection team discussed one of these recent alerts (the usage of an incorrect gas cylinder to supply incubators) with centre staff to establish what actions had been taken in response. The inspection team could not establish whether any specific action had been taken in response to this alert. On further discussion, centre staff explained that these alerts were usually discussed by senior staff but were not routinely disseminated. The inspection team acknowledge that alerts are considered at the centre's regular 'quality meetings' but were concerned that this forum may not always be the most appropriate as there may not be sufficient specialised knowledge to be able to fully consider appropriate risks and/or necessary actions that may be needed (see recommendation 12; SLC T32). Further to these discussions, the inspection team were satisfied that appropriate actions were now in place to prevent a similar incident to the one reviewed happening at this centre.

The inspection team noted that the methodology and scope of audits was not being consistently documented (see recommendation 12; SLC T36).

Corrective and preventative actions identified by the centre in their audit of controlled drugs carried out in December 2018 did not seem to have been effective in addressing the non-conformances identified in that audit as similar issues were noted by the inspection team, see 'Medicines management' section above.

Adverse incidents (Guidance note 27)
The centre has not reported to the HFEA two adverse incidents, as defined in CoP Guidance 27.1; one of which impacted on embryo quality and safety, the second was a breach of confidentiality by an external party (see recommendation 7; SLC T118 and Interpretation of mandatory requirements 27A). The centre had investigated both incidents, but the inspection team did not consider that the investigations were sufficiently detailed because it was not clear if the root cause of the incident had been established, or whether appropriate actions had been taken to prevent similar incidents from happening again in the future.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

Staff (Guidance note 2)
The centre is partially compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Person Responsible (Guidance note 1)
Given the number and significance of the issues identified during this inspection, the team was concerned that the PR had not fully discharged his duties under section 17(1) of the HF&E Act 1990 (as amended) and had not ensured that activities at the centre were compliant with requirements. These concerns have since been addressed to the satisfaction of the executive, as discussed in the 'recommendation to the Licence Committee' summary section of this report.

Staff (Guidance note 2)
Laboratory staff occasionally take consent for storage of gametes, but there was no evidence of training or assessment of competence for this critical activity (see recommendation 8; SLC T15a).

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed

treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better
Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not carry out embryo testing and therefore this area of practice is not relevant to this inspection.

What the centre could do better
Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only 11 patients have provided feedback in the last 12 months, giving an average 4-star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

The centre also participates in the Trust's patient feedback processes, collecting additional feedback, displaying learning from incidents and complaints on the walls of the centre as well as asking patients:' what matters to you today'. The inspection team noted that the centre had been awarded the Trust's accreditation award as gold standard (highest), this is independently awarded and takes into consideration, amongst other things, the patient journey and leadership in the department.

In the feedback provided directly to the HFEA five patients complimented the centre and three patients had negative comments; such as the difficulty in getting through on the telephone and the lack of personal service. The feedback related to the quality of service is in contrast to the centre's own most recent patient survey carried out between November 2018 and February 2019, where 33 responses were received from 75 patient feedback survey questionnaires that had been handed out in the clinic. In the responses; 91% said that staff were supportive in their journey, 91% rated the overall experience as excellent and 9% rated it as good. Furthermore, 100% of respondents reported that they were likely to recommend the centre to a friend or relative, with 94% saying they would be extremely likely to do so.

The website also gives the ability for patients to comment on the cost of treatment. The majority of patients are NHS funded therefore there was little information regarding whether patients had paid what they expected to.

During the inspection visit no patients were available to speak to the inspectors.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

The PR is urged to consider ways of encouraging patients to provide feedback directly to the HFEA via the 'Choose a Fertility Clinic' page on the website.

Treating patients fairly

Counselling

Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent [and prior to consenting to legal parenthood].

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake egg or sperm sharing, therefore this area of practice was not relevant to this inspection.

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are partially compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Surrogacy (Guidance note 14)
In one set of records reviewed, it was noted that the centre has not screened the gamete providers in the surrogacy arrangements as donors (see recommendation 9; CoP Interpretation of mandatory requirements 14A). The lead clinician explained that the screening of gamete providers in surrogacy arrangements was performed on the basis of risk, however this rationale was not documented in the records.

The centre's surrogacy SOP states that intended parents and surrogates are to be screened as per the centre's donor screening SOP, however this is not being followed in practice. In the set of records reviewed the intended parents providing gametes had not

been screened for cystic fibrosis, chlamydia or gonorrhoea, and the following tests had not been undertaken karyotype and blood group (see recommendation 8; SLC T33b).

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better
Nothing identified at this inspection.

Consent and disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
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.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood.

In June 2016, a couple had to seek a declaration of parenthood via the High Court due to the centre's failure to ensure effective consent to legal parenthood had been in place. As part of the HFEA's ongoing activities relating to 'legal parenthood', inspectors visited the centre in September 2016 to focus on learning that had taken place following that case. The inspectors reviewed a number of aspects including actions taken by the centre since the issue was identified, lessons learned and the robustness of legal parenthood consent taking practices. Some issues were noted, including an anomaly in a consent form for a couple for whom treatment had resulted in a pregnancy. The PR was required to take further actions to ensure that processes for taking and checking consent to legal parenthood are robust. The PR's actions were monitored by the centre's inspector and these processes were again reviewed at the time of the interim inspection in February

2017.

At the time of the interim inspection in February 2017, a further anomaly in consent to legal parenthood was identified but no pregnancy resulted from that treatment, therefore this was considered a 'near-miss'. The executive continued to monitor progress with actions as a result of the focussed inspection in September 2016, therefore no further recommendations or actions were considered necessary at that time.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Seven sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. From these activities the inspection team concluded that the processes used to collect legal parenthood consent at this centre are not compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
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.

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

What the centre could do better

Legal parenthood (Guidance note 6)
In one of seven sets of records audited, the signature on the PP ('*Your consent to being the legal parent'*) form was dated with the year that corresponded to the man's year of birth rather than the year of signing the form. A live birth resulted from this couple's treatment and therefore there is an implication for legal parenthood for that child (see recommendation 2; Sections 37(1) of the Human Fertilisation and Embryology Act 2008 and SLC T47). This error in the consent form occurred in February 2017, and the treatment had taken place in July 2017, which was after the interim inspection at the centre when a similar issue had been highlighted by the inspectors. Furthermore, the inspection team noted that a member of staff had placed a note on that page highlighting that there was an error, but this did not appear to have been corrected or addressed.

Shortly after the inspection, the PR confirmed that these records had been audited by the centre, but this error had not been identified (see recommendation 2; SLC T36). Therefore, inspection team are not assured that effective audit procedures are in place at the centre to ensure on-going compliance with legal parenthood consent taking requirements. This undermines the PR's previous assurances in October 2015, September 2016 and February 2017, that robust consenting and checking processes were in place.

The inspection team were particularly concerned that learning from the previous failings, and again from a near-miss found at the time of the interim inspection had not been embedded in practice, that centre staff had failed to take action on this error they themselves had identified, and that the centre's audit of records had not identified this anomaly in consent.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)

Two discrepancies were found between completed patient/partner disclosure consents in 23 patient files audited and the related consent data submitted for inclusion on the register (see recommendation 13; Chair's Letter (10)05 and General Direction 0005). Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure to researchers. The inspection team noted that whilst the discrepancies do not pose a risk that the HFEA may inadvertently release patient identifying information to researchers, it is not in accordance with the wishes of the patient.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos. The centre's procedures for screening patients are partially compliant with HFEA requirements.

Storage of gametes and embryos (Guidance note 17)

The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed. It is important that gametes and embryos are stored appropriately to maintain their quality and safety and that the centre only stores gametes and embryos in accordance with the consent of the gamete providers.

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

What the centre could do better

Screening of patients (Guidance note 15)

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 (see recommendation 5; SLC T50d). The lead clinician was assured that such discussions did take place with patients and partners and would only be recorded if any issue was identified.

Storage of gametes and embryos (Guidance note 17)
The PR informed the inspection team that there are 47 sets of embryos in storage at the centre beyond ten years and that he estimated that he had the relevant medical practitioner statements in place for 8 of these sets of embryos. Therefore, there may be up to 39 sets of embryos in storage without effective consent to storage (see recommendation 3; The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996), The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009, Schedule 3, 8(2) HF&E Act 1990 (as amended), SLC T79, SLC T80, SLC T81 and SLC T82). The inspection team were concerned that no legal advice had been sought in relation to these cases to provide assurance that effective storage consent was in place or that an extension of storage beyond ten years was in accordance with relevant regulations.

The inspection team reviewed two sets of records and noted that the 10-year storage period had ended in November 2018 and December 2018, respectively. The initial forms were signed by the patients in 2008 consenting to five years of storage. Subsequent forms signed 5 years later in 2013 were intended to extend storage beyond the 10-year period but there was no corresponding medical practitioner statement in either of these patients records. The PR was under the impression that the extension of consent beyond 10 years was not likely to be appropriate for these couples as they probably did not meet the criteria for 'premature infertility' which is required in order to comply with storage of embryos beyond 10 years. The PR considered that they should remain in storage because the couples had signed an extension of consent to storage form and would therefore believe that the embryos would be stored in accordance with their consent. However, these two couples had also been sent a standard letter advising them that their consent to storage expired in November 2018 or December 2018 (as applicable) and the embryos would be allowed to perish if the couples did not respond to the letter by contacting the centre. The couples had not contacted the centre; therefore, it could be assumed that they agreed to the content of the letter and understood that their embryos would be allowed to perish in November 2018, or December 2018 as stated in the letter.

The inspection team have the following concerns (see recommendation 3):

- Several sets of embryos are in storage at the centre without effective consent as there was no medical practitioner statement in place. This has further implications on whether the embryos can be used in treatment, should the couples wish to do so in the future.
- The PR has not sought legal advice regarding these cases and it is unclear exactly how many such cases there may be.
- The letter sent to couples states the embryos will be allowed to perish, therefore they are likely to believe that this has happened and are therefore not aware the embryos remain in storage.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
Good medical records are essential for the continuity of the patient's care. The centre's procedures for keeping records are partially compliant with HFEA requirements to ensure that accurate medical records are maintained.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements.

What the centre could do better

Record keeping (Guidance note 31)
The inspection team noted a number of issues in the patients records audited during the inspection (see recommendation 10; SLC T37, SLC T38, SLC T46 and SLC T47):

- In one MT form ('*Men's consent to treatment and storage form'*) the sections indicating the patient's wishes in the event of in his death or mental incapacity were not clear. In the last section of the consent form, '*Do you consent to being registered as the legal father of any child born as a result of your partner's treatment after your death?*', the man wrote 'not applicable' appearing to indicate that he had not consented to the use of the embryos in the event of his death and therefore this section was not relevant. However, he had not completed the previous section of the form to record his wishes regarding the use of the embryos in the event of his death or mental incapacity. The inspection team were concerned that the consent form was incomplete, and the patient's wishes were not clear.
- An egg donor had correctly completed a WD form ('*Your consent to donating your eggs'*). However, a WT form ('*Women's consent to treatment and storage form*') was also present in the notes even though this was not applicable to her.
- In one egg donor record, the woman's date of birth had been incorrectly documented as two numbers had been transposed. The error appeared to have been noted at some point and corrected, but several sections of the records still had the incorrect date of birth.
- In two of the records reviewed, alterations or corrections that had been made in the consent forms were not signed by the patient.
- There is no record of how, and by whom a patient, partner or donor has been identified.
- A number of documents in the records had various amendments which were not made in accordance with good record keeping practices such as some sections of a laboratory sheet had been covered in liquid paper and in another case a piece of

paper was stuck on top of the records.
- In one surrogacy case, the surrogate and intended parents' notes were filed together. The centre had identified this issue in their audit, but the records had not been separated.
- 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.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
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 (see recommendation 14; General Direction 0005 and SLC T41):

- 2% (3/133) of the IVF, and 3% (3/88) of the DI treatments reviewed at inspection had not been reported to the HFEA.
- 11% (14/130) of the IVF, and 20% (17/85) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005.
- The centre has a few small data quality issues that they have been asked to correct.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, recommendations for improvement were made in relation to one major area of non-compliance and one 'other' area of practice that required improvement.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. However, a number of non-compliances have reoccurred since the time of the interim inspection in 2017 and the renewal inspection in February 2015; legal parenthood, medicines management, management of stored materials and adverse incidents.

On-going monitoring of centre success rates

In December 2017 and July 2018, the centre was asked to review procedures for the provision of ICSI in women under 38 years old. In December 2017 and January 2019, the centre was also asked to review procedures for the provision of FET in in women under 40 years old. The PR responded to these requests and provided a commitment to keep success rates in this group of patients under review. However, at the time of the inspection it is noted that the outcomes for FET in in women under 40 years old remain lower than average at a statistically significant level and further action to address this has been recommended (see recommendation 4; SLC T2).

Areas of practice requiring action

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, General 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 carried out.

Critical area 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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of 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. Management of medicines A number of issues with medicines management practices and the centre's audit of controlled drugs were noted by the inspection team. These are described in the body of the report. SLC T2 and SLC T36. Misuse of Drugs (safe custody) Regulations 2001.	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. The PR should investigate why corrective actions taken to address non-compliances	We acknowledge that corrective actions put in place after the last HFEA inspection have not proven successful. An internal audit on 11th December 2018 showed non-compliances in recording drug dose, wastage and time of administration. Further staff education was put in place after this and a repeat audit carried out on 21st February 2019, which showed 100% compliance with standards.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided an update on immediate actions that have been taken to address the issues identified by the inspection team. The executive notes that the PR has taken this matter

Controlled Drugs in Perioperative Care 2006. Controlled Drugs; safe use and management April 2016. It is noted that the HFEA's assessment framework recommends classification of this as a 'major' non-compliance but in consideration that similar recommendations were made at the time of the interim inspection and further issues have arisen in this area of practice, the inspection team conclude that there is a significant risk of harm to patients and significant shortcoming from the statutory requirements. Therefore, this has been graded as a critical non-compliance.	identified at the time of the interim inspection and in the centre's own audit of practice have not been effective. A summary of the findings of that investigation should be provided to the centre's inspector when responding to this report. The PR should commission an independent review of the centre's procedures for the management of medicines and confirm the timescales by which this will be completed when responding to the report. This review should include, but not be limited to the issues identified in this report and staff training requirements. It is expected that this review should be completed by 6 June 2019 and a summary report of the findings including corrective actions and timescales for implementation should be provided to the centre's inspector. 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	Hence, it is especially disappointing to us that non-compliances were once again identified at the HFEA inspection. We take this matter extremely seriously and this has been escalated to the Director of Pharmacy of the Trust and the Director for Nursing and Midwifery for the service. A full review of medicines management procedures will be undertaken by an independent team comprising the Trust Director of Pharmacy, the Hospital Head of Nursing and an anaesthetic consultant not involved in the delivery of clinical care within the Department of Reproductive Medicine. The review will be undertaken, completed and shared with relevant staff members by 24th May 2019, and reported into the Hospital and Group Quality and Safety Committees and the Hospital Management Board.	extremely seriously and the issue has been escalated to the Director of Pharmacy of the Trust. The PR has confirmed that an independent review of centre's procedures for the management of medicines has been commissioned and that a summary report of the findings will be provided to the centre's inspector by 6 June 2019. An audit to evaluate the effectiveness of changes in this area of practice due by 5 September 2019 is awaited. **Further action is required**.

	and maintaining compliance. A summary report of the audit findings should be submitted to the centre's inspector by 6 September 2019.	The review will focus on, but not limit itself to; a. Manchester Foundation Trust (MFT) policy for the prescribing and administration of controlled drugs and the compliance of this policy with CQC standards. b. Differences in methods of recording controlled drug usage in the DRM compared to main hospital theatres. c. Differences between adherence to trust policy in the Department of Reproductive Medicine (DRM) and hospital theatres. d. Staff competencies for the safe management of controlled drugs. e. Why corrective actions following the last HFEA inspection have failed. The findings and recommendations of the review will be shared with all relevant staff – medical, nursing and administration. Any identified actions will commence from 27th May	

		2019. The findings of the review will be sent to HFEA by 6th June 2019. Building on the monthly quality of care rounds undertaken by the Matron there will be a separate independent audit of practice undertaken after three months. The audit will take place the week commencing 19th August 2019 for submission to the Centre's inspector by 6th September 2019. A Trust Medicines Optimisation Board is being set up from the 30th April 2019 and will have oversight of these issues.	
2. Legal parenthood In one of seven sets of records audited, the signature on the PP ('*Your consent to being the legal parent*') form was dated with the year that corresponded to the man's year of birth rather than the year of signing the form. A live birth resulted from this couple's treatment and	The PR should ensure that proper consent to legal parenthood is obtained. The centre should seek legal advice regarding the anomaly in consent to legal parenthood identified during the inspection. When responding to this report, the PR should provide a summary of the legal advice obtained and	We have contacted the couple whose PP form contained an erroneous date. The couple have been informed of the potential implications for legal parenthood. The couple have been offered an appointment to see one of the senior medical consultants in the DRM and the Person	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided an update on immediate actions that have been taken to inform and support the couple affected by the anomaly in

therefore there is an implication for legal parenthood for that child. Sections 37(1) of the Human Fertilisation and Embryology Act 2008. SLC T36. This has been graded as a critical non-compliance because it undermines the PR's reassurance, provided in October 2015, September 2016 and February 2017 that effective consent, checking and audit procedures are in place at the centre to ensure on-going compliance with legal parenthood consent requirements.	detail of the actions planned in response to this advice, including how the centre intends to communicate with, and support, the couple affected. The PR should ensure all relevant staff are competent to collect legal parenthood consents from patients. Further training should be provided. Evidence of staff training, and competence assessment should be provided to the centre's inspector by 6 June 2019. Shortly after the inspection the Trust's Director of Clinical Governance advised the centre's inspector that the Trust's internal audit team (independent of centre staff) would be undertaking an audit of the centre's consents to legal parenthood. Staff undertaking this audit and any future audits should be properly trained, competent and fully understand the requirements of this area of practice in order to ensure that the audit is robust, and that the findings can be relied upon. Details about the audit scope and methodology should	Responsible. The couple will be offered legal advice to allow confirmation of legal parenthood, the costs of such advice will be met by MFT. The centre will forward a report of both the legal advice and outcome for the patients to the centre's inspector once available. If the couples are unable to attend the appointment we will write to them explaining the potential problem. We have suspended all treatment with donor sperm and donor embryos but have asked to be allowed to proceed with treatment in a small number of exceptional cases where a delay to an individual patient would cause significant compromise to the patient's chance of a successful outcome. It is anticipated that the number of patients falling into the exceptional group will number no more than one or two per month. This group would include: a. Female partner aged	consent to legal parenthood, and that he will continue to do so in accordance with HFEA guidance. The centre's inspector will follow up progress with this action with the PR. The PR has confirmed that they have suspended all treatments with donor sperm and embryos created with donor sperm apart from in a small number of cases that they consider exceptional. The PR confirms that he expects this will be no more than one to two per month. The executive reminds the PR that for any such cases, the Medical Director should undertake a risk assessment, that all consents should be checked by the PR, and that these actions should be documented in the patient's records The PR has confirmed that bespoke staff training in taking and checking of consent to legal parenthood, consent to storage and

	be provided to the HFEA. A report of the findings of this audit is to be provided to the centre's inspector when completed, which was anticipated to take 4 weeks. On receipt of the information the HFEA executive will liaise with the PR to determine what further actions and/or recommendations are required. The PR should conduct a root cause analysis into the circumstances which led to the failure of the centre's processes to identify the consent anomaly found by the inspection team. A copy of the root cause analysis should be provided to the centre's inspector by 6 June 2019. Again, on receipt of the information the HFEA executive will liaise with the PR to determine what further actions and/or recommendations are required.	38 years and over b. Female partner has evidence of reduced ovarian reserve as indicated by AMH and / or antral follicle count. c. Female partner has had a poor ovarian response to previous stimulation. Patients will only be classed as exceptional and hence allowed to proceed to treatment after a review of the case by a medical consultant and documentation of the reasons for exceptionality and the consultant's agreement. All relevant consents in such cases, will be checked by the consultant who has given agreement and re-confirmed by the Person Responsible. An audit will be undertaken of all patient records of patients who underwent fresh IVF treatment within the centre from January 2015 to present. The audit will be undertaken by the MFT audit department. Dr Sue Montgomery (the Person Responsible for CARE Manchester) has sent	consent to disclosure to researchers has been initiated. The executive notes that this training is being provided by the PR or Quality Manager. Confirmation that this training has been completed should be provided to the centre's inspector. The PR has confirmed that the Trust's internal audit team (independent of centre staff) will be undertaking the audit of consents to legal parenthood and that the audit methodology to be used has been provided by the PR of another centre that has also previously experienced failings in legal parenthood consent for their patients. The executive reminds that PR that he should be assured that staff undertaking this audit and any future audits should be properly trained, competent and fully understand the requirements of this area of practice in order to ensure that the audit is robust, and that the findings can be relied upon. The PR

		us a copy of an audit they performed on a similar group of patients. We will adapt our audit based on the CARE audit. The audit will examine valid consent to legal parenthood and will also establish for each cycle the name of the birth partner (for WP) and the non-birth partner (PP) to make sure the forms were the right way round. Once completed, the report will be sent to the HFEA the week commencing 13th May. A root cause analysis has commenced for the incident which occurred. We feel that it would be more informative for this to be undertaken by a member of the MFT governance team not within the DRM. The report from this will be sent by 6th June 2019 as requested. The findings of the inspection in relation to legal parenthood were shared with the wider team by the PR and quality manager at the MDT meeting on 12th March 2019 following	indicates that a summary report of the findings will be provided to the centre's inspector week commencing 13 May 2019. The PR has confirmed that the Trust's governance team has commenced the root cause analysis and that a report will be provided to the HFEA by 6 June 2019. The executive will continue to liaise with the PR in order to be able to determine when it is satisfied that the centre's procedures for obtaining effective consent to legal parenthood are robust, so that the suspension of treatments with donor sperm for new patients can be lifted. It is anticipated that once treatments are resumed, the executive will require that the PR provides monthly audits of records of all patients undergoing treatment with donor sperm or embryos created with donor sperm to provide ongoing assurance of

		which guidance was sent out via the Quality Management System (Q-Pulse). Bespoke training sessions have commenced for all staff involved in both taking and checking of consent for legal parenthood, consent to disclosure of information and consent to storage of gametes and embryos. These sessions will also include information regarding the importance of record keeping in line with MFT policy and will be attended by all medical and nursing staff in the centre. The sessions will be delivered by the Quality Manager or Person Responsible, in the presence of a senior medical consultant. All relevant staff will be mandated to attend a session. Any staff unable to attend the session will not be allowed to take or check legal parenthood or embryo storage consent. Three training sessions have been arranged (16th April, 7th May and 14th May) and attendance will be recorded	the effectiveness of the centre's procedures for obtaining consent to legal parenthood. **Further action is required**.

		and this record will be provided by 16th May.	
3. Consent to storage A number of non-compliances in relation to the storage of cryopreserved samples were noted on inspection, as discussed in detail in the body of the report. These are related to: • Several sets of embryos are in storage at the centre without effective consent as there was no medical practitioner statement in place. • The PR has not sought legal advice regarding these cases. • The letter sent to couples states the embryos will be allowed to perish, therefore they are likely to believe that this has happened and are therefore not aware the embryos remain in storage. The Human Fertilisation and Embryology (Statutory	The PR should ensure that there is effective consent in place for all stored gametes and embryos. When responding to this report, the PR should provide the centre's inspector with an update on the number of patients for whom gametes and/or embryos remain in storage without effective consent. The PR should complete a full audit of all samples in storage to establish if there are any further samples without valid consent. The PR should ensure that relevant staff are provided with training in the regulations and requirements governing gamete and embryo statutory storage consent and their extension, prior to undertaking this audit. A summary of this audit should be provided to the centre's inspector by 6 June 2019. In all cases where there has been a failure to comply with the relevant storage regulations, the PR should seek independent	An audit is being undertaken of notes of all patients with embryos in store for more than 10 years and will be provided to the HFEA by 6th June. The purpose of the audit is to identify the following 1. Whether appropriate patient consent exists for extended storage of embryos, in the form of HFEA ES form. 2. Whether a completed medical practitioner certificate exists 3. Whether the reason for allowing extended storage is documented (premature infertility) Since 2015, we have had strict criteria for allowing extension of storage of gametes and/or embryos beyond 10 years (SOP attached). In this period we have only extended storage for 4 couples. These notes have been audited as a priority and in all cases, ES	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided an update on actions taken to review the cases where embryos remain in storage at the centre for more than 10 years. Given the number of patients involved, the executive agrees to accept the findings of this audit by 6 June 2019. The centre's inspector will follow up progress with this action with the PR. The PR has reviewed the four cases since 2015 for whom storage has been extended to beyond ten years and no issues were identified. The executive is not clear if this includes the two cases reviewed by the inspection team. Further clarification will be sought from the PR.

Storage Period for Embryos) Regulations 1996. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. Schedule 3, 8(2) HF&E Act 1990 (as amended). SLC T79, SLC T80, SLC T81 and SLC T82. It is noted that this area of practice was also identified as a non-compliance at the renewal inspection in 2015.	legal advice on how to proceed, including whether affected patients ought to be informed. A plan of the actions to be taken and the anticipated timescale for their implementation should be provided to the centre's inspector by 6 June 2019. Thereafter, the PR should provide monthly updates to the HFEA on progress in implementing the proposed actions. The PR is reminded of HFEA guidance in relation to the timely disposal of cryopreserved material (see Chair's letter CH(03)03).	forms and Medical Practitioners Certificate are present. However, the audit being performed will help us assess historical practice (prior to 2015). If any variances are identified, we will obtain legal advice for the affected patients.	The PR has confirmed that if any cases are identified where there has been a failure to comply with the relevant storage regulations, he will seek independent legal advice on how to proceed, including whether affected patients ought to be informed. **Further action is required.**

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 to a 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
- 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	Executive Review
4. Success rates The centre's success rates for FET in women under 40 years old is lower than the national average at a statistically significant level. SLC T2.	The PR should address the success rate identified as currently being lower than national average. The PR should provide a review of the centre's success rate for FET in women under 40 years old when responding to the report. Following this the PR should provide quarterly updates on the actions taken to address this success rate with an aim to improve outcomes by 6 September 2019.	We have been alerted to a decline in pregnancy rates per frozen embryo transfers (FET) cycle in women under 40 years of age. This issue has arisen, in the main, because of the lack of timely reporting of pregnancy outcomes. We appreciate the importance for timely reporting as discussed below (Obligations and reporting requirements). We are inputting all recent outcome data and will review FET success rates from the updated CUSUM plots.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a review of the centre's success rate for FET in women under 40 years old. The PR considers that the centre's lack of timely reporting may be contributing to the centre's success rates in this category, therefore the impact of the improvements being made in this area will continue to be monitored by

		We have internally reviewed our FET results for women under 40 years within the past three months. Our clinical pregnancy rate per treatment started in the period 1st December 2018 to 28th February 2019 in women under 40 is 30.7%. Pregnancy rates per FET cycle are affected by various factors including the stage of embryo transfer (blastocyst or cleavage-stage) and number of embryos thawed (which will impact on embryo selection and the number of embryos transferred). As a centre we have been active in researching the outcome of children conceived through prolonged embryo culture. This has led us to adopt a cautious approach in using blastocyst culture in frozen embryo cycles. As a result we do cleavage-stage embryo transfer in approximately 45% of FER cycles. This is likely to be a higher proportion than the	the centre's inspector. The PR's next quarterly update on progress in improving these success rates due by 6 June 2019 is awaited. **Further action is required.**

		national average and will inevitably affect our clinical pregnancy rate per FER cycle. In order to maximize cumulative pregnancy rate, our policy is to limit the number of embryos thawed which may reduce the pregnancy rate per frozen cycle, but increases the cumulative pregnancy rate. We also strive to reduce multiple pregnancy rates, which will also impact on pregnancy rates per cycle (although not per embryo transferred). In 2017 and 2018 our multiple pregnancy rates per frozen blastocyst cycle were 3.6% and 5.2% respectively. Pregnancy rates following both fresh and frozen cycles are part of our KPIs and are thus reviewed in an ongoing basis by the multidisciplinary team. Concerns identified will be reported up to the divisional Quality and Safety committee.	

		As part of our KPIs we review the pregnancy rates of frozen embryo transfer cycles monthly and will submit this to the centre's inspector with the aim of improving our outcomes by 6th September.	
5. 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, to determine if any additional testing may be required, and that these are clearly documented in the notes. 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 DRM sits within the Division of Gynaecology within Saint Mary's Hospital and as such receives updated advice through MFT's governance cascade of information from NHS England and the Royal College of Obstetricians and Gynaecologists (RCOG) as well as the HFEA. Saint Mary's Hospital is a large NHS hospital treating obstetric and gynaecology patients which has a robust mechanism in place to alert patients and staff to potential public health risks both in the UK and following foreign travel. In recent years, risks associated with Ebola and Zika virus have become evident, although other infections also pose potential risk. The risks of infection in regard	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of the findings of his review of the centre's processes for considering, assessing and documenting discussions in relation to a patient, partner or donor's travel or medical history. The executive acknowledges that the potential risks of infection resulting from travel are being discussed with patients, but these have not been consistently documented. The PR has confirmed that changes have been implemented to ensure that this information is now being consistently recorded.

	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 finding of this review should be provided to the centre's inspector by 6 June 2019. 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 6 September 2019.	to travel are raised with patients at the IVF patient information session (presentation included). At this time Ebola and Zika are specifically mentioned on the slide relating to travel, but this would obviously change dependent on updated advice from the RCOG and NHS England. At the presentation, patients are advised to reduce the risk from travel to affected areas and told to consider any recent travel that they have undertaken as this will be questioned during their clinic consultation. In the clinic consultation a full medical history is taken and this includes details of any recent travel. Patients are advised of any additional quarantine periods that may be necessary if travel to an endemic area has occurred. This has been part of our standard practice for many years and we therefore have full confidence that there has been no risk to patients or donors. We are aware of	The PR should provide a summary of his considerations, with expert advice if necessary, as to whether 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, by 6 June 2019. An audit to evaluate the effectiveness of changes in this area of practice due by 6 September 2019 is awaited. **Further action is required**.

		cases where we have advised against planed travel or delayed treatment for couples who have travelled to areas where endemic communicable diseases are present. We are also confident that we would be aware if one our patients had a pregnancy affected by Zika virus, as we collect outcome data from all pregnant patients. However, we appreciate that travel history is not separately documented in the ICP if there is no relevant travel history. Therefore although this question is asked, it is not possible to audit that it has. We have therefore amended the outpatient ICP to include a specific question with regard to travel to ensure that travel to areas affected by high risk diseases or the absence of travel is documented. We appreciate that it is only by recording absence of travel, that the system can be audited. Audit of new patient	

		consultations is part of our rolling audit program. This audit of the new outpatient consultation will be undertaken in August 2019 and documentation with regard to travel will be included in this. The audit findings will be provided to HFEA by 6th September 2019.	
6. Import & export For the reasons set out in the body of the report, the inspection team conclude that centre staff are not sufficiently aware of the requirements of General Direction 0006 and therefore do not seek relevant evidence of compliance prior to export or import of gametes and/or embryos. The centre's SOP for the import and export of gametes and embryos contains very little information to direct staff on how to ensure that relevant imports and exports comply with General Direction 0006. General Direction 0006, SLC T110 and SLC T33b.	The PR should ensure that imports and exports of gametes and embryos are compliant with General Direction 0006. Before any further import or export of gametes or embryos (including those under the centre's ITE), the PR should review the centre's procedures to ensure compliance with the requirements of General Directions 0006. This review should include, but not be limited to, revising the centre's SOP related to this activity to ensure all relevant requirements are clearly documented and to provide staff training. A summary of the findings of the review	All import and export of all material (gametes and embryos) was suspended on the 3rd of April 2019. We acknowledge the import and storage of donor sperm was not in compliance with General Direction 0006, but can give assurance that no sperm has been used for treatment before all documentation was received and therefore in compliance with the directive. The instruction SOP for import and export has been revised to include General Direction 0006. Staff training will be undertaken to ensure that all staff are familiar with the	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that all imports and exports of gametes and embryos was suspended on 3 April 2019. The executive acknowledges the PR's assurance that prior to use in treatment all evidence of compliance with General Direction 0006 is secured. However, the executive reminds the PR that as the samples are imported under General Direction 0006, and stored at the centre, compliance with those

	including corrective actions and the timescales for implementation should be provided to the centre's inspector by 6 June 2019. Once this recommendation is fully implemented the executive will be able to recommend the renewal of the centre's ITE import certificate in line with the centre's licence. The PR should review the documentation relating to all gametes and/or embryos imported by the centre since the time of the last renewal inspection in February 2015. The HFEA should be provided with a report documenting the status of each import in terms of compliance with General Directions 0006; whether the gametes or embryos have been used in treatment, and; where treatment has been provided, the outcome of that treatment in terms of live birth, ongoing pregnancy and/or creation of frozen embryos. This report should be provided to the centre's inspector by 6	revised SOP. Annual training will be mandated for all staff involved in the export or import of gametes and / or embryos to ensure compliance with General Direction 0006. We have requested all documentation of all donor sperm received since 1st January 2015. They will be checked that everything is in place and complies with General Direction 0006. The 'pen' portrait of all donors has also been requested and will be forwarded to the HFEA as soon as it has been received. All donor sperm imported was registered with the HFEA and gamete 'in' form sent to the HFEA in accordance with General Direction 0006. A full review of the use of imported donor sperm from 2015 has been undertaken.	requirements should be obtained prior to the receipt of the samples. The PR has confirmed that he has reviewed the centre's procedures to ensure compliance with the requirements of General Directions 0006. The SOP has been revised, and staff training in the updated processes will be provided. Once the PR confirms that this staff training has been provided the executive will be able to recommend the renewal of the centre's ITE import certificate in line with the centre's licence. The PR confirms that he has requested the required documentation in order to undertake the review of all gametes and/or embryos imported by the centre since the time of the last renewal inspection in February 2015. A report of this review will be provided to the centre's inspector by 6 June 2019. On receipt of the information the

	June 2019. On receipt of the information the HFEA executive will liaise with the PR to determine a proportionate recommendation about the subsequent use of such gametes and or embryos. 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 6 September 2019.	The full audit report includes compliance with General Direction 0006, the number and type of treatment cycle in which it was used and all outcomes (including ongoing /live birth and embryos cryopreserved). This will be submitted to the centre's inspector by 6th June 2019. This process will be re-audited and the report sent to the centre's inspector by 6th September 2019.	HFEA executive will liaise with the PR to determine whether any further action is required. An audit to evaluate the effectiveness of changes in this area of practice due by 6 September 2019 is awaited. **Further action is required**.
7. Adverse incidents The centre has not reported to the HFEA two adverse incidents, as defined in CoP Guidance 27.1. The centre had investigated the incidents, but the inspection team did not consider that these were sufficiently detailed. SLC T118 and Interpretation of mandatory requirements 27A.	The PR should ensure that all adverse incidents, including serious adverse events and reactions, as well as near misses, are reported to the HFEA. The PR should review all adverse incidents in the centre's incident register since the time of the renewal inspection in February 2015 and retrospectively report to	There is a positive culture of incident reporting within MFT and we are keenly engaged in this. All incidents are reported via MFT incident reporting system and incidents as indicated by Code of Practice (CoP) 27.1 are sent to HFEA by the centre's quality manager. All incidents within the DRM are also discussed at the weekly	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The executive is assured that the centre does not intentionally under-report incidents to the HFEA. The PR has provided a summary of the findings of his

It is noted that this area of practice was also identified as a non-compliance at the renewal inspection in 2015.	the HFEA any which fulfil the criteria of adverse incidents or near misses, as defined in CoP Guidance 27.1. This recommendation should be implemented by 6 June 2019 and confirmation of this provided to the centre's inspector. Whilst it is recognised that the under-reporting of incidents is not intentional, the PR should review the centre's processes for submitting and investigating adverse incidents. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 6 June 2019. 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 6 September 2019.	Quality meeting (attended by the Person Responsible, Medical Consultant Quality Lead and Quality Manager, Matron and Lead nurse, Senior Counsellor and Operational Manager, Laboratory Quality Leads). A request has been made for a summary of all MFT incidents since January 2015 and this will be reviewed against the CoP guidance 27.1 by the Person Responsible. Any incidents or near miss incidents that have not been sent to the HFEA appropriately will be sent retrospectively and any subsequent investigation required will be completed by 6th June 2019 and forwarded to the centre's inspector. A review of the CoP guidance 27.1 and the department's processes will be completed at the quality meeting to ensure that going forward, all appropriate incidents will be sent to the HFEA. Any recommendations or changes	review of the centre's processes for submitting and investigating adverse incidents. The PR will provide the findings of his review of all adverse incidents since the time of the renewal inspection in February 2015 and retrospectively report to the HFEA any which fulfil the criteria of adverse incidents or near misses by 6 June 2019. An audit to evaluate the effectiveness of changes in this area of practice due by 6 September 2019 is awaited. **Further action is required**.

		made following this meeting will be forwarded to the inspector by 6th June 2019. An audit will be undertaken at the end of August 2019 of all incidents that have occurred from 1st June and the results forwarded to the regulator by 6th September 2019.	
8. Staff Laboratory staff occasionally take consent for storage of gametes, but there was no evidence of training or assessment of competence for this critical activity. SLCT15a.	The PR should ensure that all staff are competent to undertake the tasks that they perform. The PR should provide the required training and assessment of competence for staff members involved in taking consent to storage of gametes. Those staff members as identified as needing training and assessment of competence should not undertake this critical activity until this has been completed. The PR should review the consents previously obtained by these staff to ensure that these are effective and compliant with requirements.	This issue relates to the taking of consent to store oocytes by a qualified embryologist who had not had their competency to do so confirmed. In this case, due to a failure of the male partner to produce sperm on the day of oocyte collection, a decision was made to urgently alter the treatment pathway to cryopreserve the oocytes rather than proceed with IVF treatment. An audit has been carried out to examine all cases when this has occurred since January 2015. 15 cases were found where urgent oocyte cryopreservation was undertaken and the consent taken by a qualified	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR is assured that members of staff taking consent to storage of gametes in the exceptional circumstances noted are competent to perform this task, but that this has not been documented. The PR has provided the findings of his review of consent to storage taken by laboratory staff since the time of the last renewal inspection and he is assured that these consents are effective.

	An update on progress with this action should be provided to the centre's inspector by 6 June 2019.	embryologist. In all cases consent was found to be effective and compliant. There are therefore no implications for patient care. In the future, all consents to store will be taken by a member of staff whose competency has been assessed.	The PR has confirmed that in future, consent to storage of gametes in these exceptional cases will be undertaken by staff whose competency has been documented. An update on progress with documenting these competency assessments for relevant embryologists should be provided to the centre's inspector by 6 June 2019. **Further action is required.**
9. Surrogacy In one set of records reviewed, it was noted that the centre has not screened the gamete providers in the surrogacy arrangements as donors. The lead clinician explained that the screening of gamete providers in surrogacy arrangements was performed on the basis of risk, however this rationale was not documented in the records. The centre's surrogacy SOP states that intended parents and surrogates are to be screened as per the centre's	The PR should ensure that gamete providers in a surrogacy arrangement are suitably assessed and screened as donors. When responding to this report, the PR should provide the centre's inspector with confirmation that all gamete providers in surrogacy arrangements will be assessed and screened as donors. The PR should audit all surrogacy treatments carried out in the centre since the last	Our current SOP for treatment with surrogacy states that gamete providers should be screened in line with gamete / embryo donors. This will be amended to detail all mandatory screening and also additional tests which may be performed following an individual patient risk assessment. The medical records will document the risk assessment that took place to indicate the need or lack of need for additional investigations.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that all gamete providers in surrogacy arrangements will be assessed and screened as donors. The findings of the audit of all surrogacy treatments carried out in the centre since the last renewal inspection in February 2015 will be provided by 6 June 2019.

donor screening SOP, however this is not being followed in practice. CoP Interpretation of mandatory requirements 14A and SLC T33b.	renewal inspection in February 2015 to determine whether there are further cases where gamete providers were not assessed and screened as donors. A summary of the findings of the audit should be provided to the centre's inspector by 6 June 2019. If cases are identified where the gamete providers in surrogacy arrangements were not assessed and screened as donors the PR should seek expert advice to fully assess if there may have been any risks to the surrogates that have undergone treatment with these gametes. The review should also consider whether surrogates affected are to be contacted and advised of possible risks of their treatment. The PR should inform the centre's inspector of the timeline for completing this risk assessment by 6 June 2019. The PR should audit the effectiveness of changes introduced in this area of	A checklist is being devised which will be completed and checked before patients start treatment to create gametes for use in surrogacy treatment. All surrogacy treatment cycles from 1st January 2015 date will be audited and the report submitted to the regulator by 6th June 2019. If the audit finds any potential risk to patients due to a failure of appropriate screening, the PR will seek expert advice and report the advice received and the need for further action to HFEA by 6th June 2019. An audit of surrogacy cases will be undertaken at the end of August for surrogacy treatment cycles during the preceding three months and the report sent to HFEA by 6th September 2019. Given the small number of such treatment cycles carried out at the centre, it is possible that there will be no cases however a return will still be completed for the HFEA.	The PR has also confirmed that if any issues are identified, he will seek expert advice to fully assess if there may have been any risks to the surrogates that have undergone treatment with these gametes. An audit to evaluate the effectiveness of changes in this area of practice due by 6 September 2019 is awaited. **Further action is required**.

	practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 6 September 2019.	Going forward, all surrogacy treatment cycles will be part of a rolling three monthly audit.	
10. 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 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 implementation should be provided to the centre's inspector by 6 June 2019. 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 6 September	All errors identified at the inspection have been corrected and one patient contacted to renew consent as necessary. MFT medical records policy has been circulated to all members of the staff in the DRM. All staff will be asked to acknowledge that they have read the document via the Quality Management System (Q-Pulse). The importance of record keeping and MFT standards around record keeping will also be raised during the office staff training sessions. We are developing a business case for an electronic patient record, but appreciate the	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of the findings of his review of the centre's processes for record keeping and the actions that have been taken to address the issues identified. An audit to evaluate the effectiveness of changes in this area of practice due by 6 September 2019 is awaited. **Further action is required**.

	2019.	importance of appropriate paper medical records until this happens. An audit will be undertaken of 25 sets of notes from patients treated after April 2019. The audit will be undertaken in August 2019 and will examine a. compliance with MFT records keeping policy b. any errors with completion of consent Following this audit the Matron for Reproductive Medicine will undertake weekly record keeping audits to ensure compliance and a report will be submitted by 6th September 2019.	

’Other’ areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non-compliance, but which indicates 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
11. Premises and facilities During the inspection the following issues were noted. • The cylinder store outside housed 13 large empty cylinders but these were not chained therefore were at risk of falling over. • There was no safety signage on the cage to indicate there was a fire risk. SLC T17 and DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006).	The PR should ensure that systems are in place for the safe storage of gases. The PR should review the gas storage facilities and ensure they comply with regulatory requirements. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre’s inspector by 6 June 2019.	The MFT Estates department was contacted immediately following the inspection and asked to review all signage (both directional and in relation to health and safety) around the premises. MFT Estates have also asked to address the safe storage of the gas cylinders as identified and securing the cylinders to prevent them falling.	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has provided a summary of the findings of his review of this area of practice and the actions that have been taken. An update on progress with fully implementing this action should be provided to the centre’s inspector by 6 June 2019. **Further action is required.**
12. QMS The inspection team could not	The PR should ensure that alerts and guidance issued by	All communication from the HFEA is initially reviewed by	The executive acknowledges the PR’s response and his

establish what actions had been taken in response to an alert issued by the HFEA. The inspection team noted that the methodology and scope of audits was not being consistently documented. Corrective and preventative actions identified by the centre in their audit of controlled drugs carried out in December 2018 did not seem to have been effective in addressing the non-conformances identified in that audit as similar issues were noted by the inspection team, see 'Medicines management' section above. SLC T32 and SLC T36.	the HFEA and other relevant bodies is fully considered and actioned by the centre, and that the methodology and scope of audits are consistently documented. The PR should review the centre's QMS to ensure that the issues identified on inspection are addressed. A summary report of the review, including corrective actions taken, should be provided to the centre's inspector by 6 June 2019.	the PR and then via the Quality meeting; this includes clinic focus guidance, directions changes, HFEA alerts and code of practice changes and is documented within the weekly Quality Management Meeting minutes. Guidance and information is cascaded to staff members from the Quality Meeting as appropriate. A monthly summary of all communications from the HFEA will be sent to the gynaecology Quality and Safety Committee. All HFEA alerts are further reviewed at the annual meeting (most recent November 2018) for key trends and themes. The current Audit schedules are planned with Quality Leads (medical, nursing, IVF laboratory, andrology laboratory, counselling and administrative) in accordance with the HFEA guidance,	commitment to fully implementing this recommendation. The PR has provided a summary of the findings of his initial review of this area of practice. Further information is to be provided by 6 June 2019. **Further action is required.**

		licensed processes, areas identified of concern and those areas requiring further investigation. Audits use the HFEA code of practice standards and since January 2018 have been reformatted to the same consistent standard. Standards are then agreed via the Quality leads and an appropriate team assigned to complete. The audit schedule and depth will be reviewed in collaboration with the Trust Audit Department to ensure the methodology and scope is consistent and any findings acted upon quickly and distributed to all members of the department. Any corrective action would be reviewed in 3 months, reported to the quality meeting and distributed to the whole department. A summary report will be sent to the centre's inspector by June 6th 2019	
13. Disclosure of information, held on the	The PR should ensure that patient/partner consents to	The identified erroneous submissions have been	The executive acknowledges the PR's response and his

HFEA Register, for use in research Two discrepancies were found between completed patient/partner disclosure consents in 23 patient files audited and the related consent data submitted for inclusion on the register. Chair's Letter (10)05 and General Direction 0005). 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.	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 review the centre's systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 6 June 2019. The PR should audit the effectiveness of changes introduced in this area of practice within six months. A summary report of the findings	corrected and submitted to HFEA. The administrative lead for the centre will review the process for submission of disclosure of information to HFEA. Any training needs or corrective actions will be completed immediately and a summary of the findings and corrective actions will be submitted to the Centre's Inspector in line with the deadline of 6th June 2019. A further audit of disclosure submission will be undertaken in November 2019 and submitted to HFEA by 6th December 2019.	commitment to fully implementing this recommendation. The PR has confirmed that the incorrect submissions identified have been corrected. The PR will provide a summary of the findings of his review of the centre's systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms by 6 June 2019. An audit to evaluate the effectiveness of changes in this area of practice due by 6 December 2019 is awaited. **Further action is required**.

	of the audit should be provided to the centre's inspector by 6 December 2019.		
14. 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: • 2% (3/133) of the IVF, and 3% (3/88) of the DI treatments reviewed at inspection had not been reported to the HFEA. • 11% (14/130) of the IVF, and 20% (17/85) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005. • The centre has a few small data quality issues that they have been asked to correct. General Direction 0005 and SLC T41.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should review the systems and processes used for licensed treatment data submission to identify and address the reasons for non-reporting and delayed submissions. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 6 June 2019. The PR should audit the effectiveness of changes introduced in this area of practice within six months. A summary report of the findings of the audit should be provided to the centre's inspector by 6 December	We acknowledge that we have not been able to submit data to HFEA in accordance with General Direction 0005 both for treatment started and outcomes. We are committed to improving this and therefore are appointing a full time (rather than the current part time hours) Data manager whose primary role will be to ensure timely reporting. A business case has been submitted for a new EPR which will both facilitate and monitor timely, high quality reporting. A report will be sent to the centre's inspector by 6th June 2019 and in line with the requirement a further audit will be completed and submitted by 6th December 2019	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of the findings of his initial review of the centre's processes for the submission of licensed treatment data. Further information is to be provided by 6 June 2019. An audit to evaluate the effectiveness of changes in this area of practice due by 6 December 2019 is awaited. **Further action is required**.

	2019.		

Reponses from the Person Responsible to this inspection report
I would like to thank the inspectors for a thorough inspection and 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 and go from strength to strength.