Licence Committee - minutes

Centre 0067 (St Mary's Hospital)
Executive Update to Renewal

Thursday, 7 November 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 Bernice Ash (Observer)	Committee Secretary Committee Secretary
Legal Adviser	Alistair Robertson	DAC Beachcroft LLP
Specialist Adviser		
Observers	Darryn Hale (Induction)	DAC Beachcroft LLP

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:

- Executive Update – Renewal Inspection
- 2 May 2019 - Licence Committee Minutes - Renewal
- Paper set considered by the Licence Committee on 2 May 2019:
  - Cover sheet
  - Renewal Inspection Report
  - Renewal Application form
  - Previous licensing minutes up to the last licence renewal:
    - April 2017 – Executive Licensing Panel Minutes - Interim
    - September 2015 – Executive Licensing Panel Minutes - Change of Address
    - April 2015 – Executive Licensing Panel Minutes – Renewal

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 3 years from 1 August 2019 and is due to expire on 31 July 2022.

History of Non-Compliance

Licence Committee Decision – 2 May 2019 – Renewal

1.3. At its meeting on 2 May 2019, the Licence Committee considered the report of the renewal inspection carried out on 5 and 6 March 2019 at centre 0067.

Consideration

1.4. The Licence Committee noted that at the time of the renewal inspection there were three critical, seven major and four other areas of non-compliance identified. The Executive was particularly concerned with:

Critical areas of Non-Compliance:

- Medicines Management

  The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice guidance.

  The committee noted the issues with the centre's processes for the management of controlled drugs

- Legal parenthood

  The PR should ensure that proper consent to legal parenthood is obtained.

  The committee noted that the centre has a history of failings in this area, resulting in a couple having to seek a declaration of parenthood via the Family Division of the High Court.

- Consent to Storage

  The PR should ensure that there is effective consent in place for all stored gametes and embryos.

  The committee noted the Executive's concern in relation to the storage of embryos without effective consent from the gamete providers

Major areas of Non-Compliance:

- Import & Export

  The PR should ensure that imports and exports of gametes and embryos are compliant with General Direction 0006.

  The Executive was concerned with the centre's failure to ensure compliance with General Direction 0006.

- Surrogacy

  The PR should ensure that gamete providers in a surrogacy agreement are suitably assessed and screened as donors.

  Intended parents for surrogacy arrangements were not screened as donors.

1.5. The PR had committed to fully implementing all of the recommendations to address the non-compliances and to providing evidence that actions have been taken, and where required, to audit the effectiveness of those actions within the required timescales.

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

Legal Advice

1.7. At the Licence Committee's request, its Legal Adviser reminded the members of Section 18(2) of the HF&E Act 1990 (as amended) and the criteria to be met if the committee wanted to revoke the centre's licence. The members were also reminded that it did in fact have the power to revoke the centre's licence, or if it was considered more proportionate, to vary the licence to impose a condition. The members were reminded that 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 e.g. not securing suitable practices and failure to comply with the HFEA Code of Practice.

1.8. The committee noted that 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 was also assured that the PR would fully discharge his duties.

Decision

Person Responsible

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

Licence

1.10. The committee agreed that a three-year licence, subject to the implementation of the recommendations outlined in the renewal inspection report, was appropriate.

Inspection

1.11. 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.

Monitoring

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

1.13. The Executive have provided the Licence Committee with an update on the centre's progress since the renewal inspection.

2. Consideration of application

2.1. The committee noted the Executive update which includes a progress report of areas of concern at the time of the renewal inspection.

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

2.3. The committee noted that further action is required to ensure the centre reflects suitable practices.

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

2.5. The committee noted in particular the centre's progress in the following areas:

Critical Areas of Non-Compliance

Medicines Management

2.6. The committee noted that no further action is required.

2.7. On 6 June 2019 the PR provided a summary of the independent review of the centre's procedures for the management of medicines along with an action plan to implement corrective actions.

2.8. On 6 September 2019 the PR provided confirmation that the action plan had been implemented. The PR also provided confirmation of the last five monthly audits of this area of practice. The Executive noted that no issues were identified in all but one of these audits.

2.9. This area of practice will be reviewed at the targeted interim inspection planned within one year of the licence being renewed.

Legal Parenthood

2.10. The committee noted that no further action is required.

2.11. The PR has confirmed that the couple affected by the anomaly in consent to legal parenthood wish to seek a court declaration to establish legal parenthood. This case is now being dealt with by the legal teams appointed to handle the matter. The PR provided his assurance that he and the Trust will continue to support the couple affected in accordance with HFEA guidance and will continue to update the Executive on the outcome of the case.

2.12. The PR provided the findings of his audits of all treatments with donor sperm or embryos created with donor sperm since January 2015. No further issues other than those that had previously been identified were noted.

2.13. The PR has also provided the root cause analysis into the circumstances which led to the failure of the centre's processes to identify the consent anomaly found by the inspectorate. The analysis found that the root cause of this case was procedure/task design and several preventative actions had already been developed and implemented as a result of the recommendations in the inspection report.

2.14. The PR provided evidence of training in consent (including consent to legal parenthood) provided to relevant centre staff by an external specialist legal team. Following this training the PR has provided evidence of his assessment of the competence of relevant staff in consent to legal parenthood practices and processes.

2.15. The voluntary cessation of new treatments with donor sperm and embryos created with donor sperm implemented in March 2019 continued until 15 August 2019, when the PR was able to provide evidence to satisfy the Executive of the robustness of the centre's current procedures for obtaining effective consent to legal parenthood.

2.16. The Executive requested that the PR undertakes monthly audits of all records of patients who have been provided with treatments where consent to legal parenthood was required, and to provide reports. The PR provided the findings of audits of treatments carried out since the time of the inspection up to 30 September 2019. No issues had been identified in these audits.

2.17. The PR should provide evidence of on-going compliance of the centre's procedures for obtaining and checking consent to legal parenthood by continuing to submit monthly audits to the Executive. In the event that any new issues or concerns arise, the Executive will recommend a cessation of treatments with donor sperm for new patients with immediate effect.

2.18. This area of practice will be reviewed at the targeted interim inspection planned within one year of the licence being renewed.

Consent to Storage

2.19. The committee noted that further action is required.

2.20. The PR has continued to provide regular updates on progress to implement this recommendation.

2.21. The Executive attended a meeting with the PR and Clinical Lead for the centre on 23 October 2019 and they have completed a comprehensive audit of 104 sets of embryos that have been in storage for more than 10 years, and have identified a number of issues which raise doubt over the effectiveness of the consent to storage. During the meeting, the findings of this audit and the PR's progress with reviewing and resolving these cases was discussed. The PR confirmed that he will seek further specialist legal advice on a number of these cases and will continue to update the Executive on the outcome, including action taken following the legal advice. It is expected that the PR will support any affected patients in accordance with HFEA guidance.

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

2.23. The PR has confirmed that an auditor has been appointed specifically to audit all gametes in storage at the centre for more than10 years and anticipates that this will be completed by August 2020. The Executive considers that this is a reasonable timeframe in view of the number of samples in storage involving approximately 1600 patients.

2.24. This area of practice will be reviewed at the targeted interim inspection planned within one year of the licence being renewed.

Major Areas of Non-Compliance

Success Rates

2.25. The committee noted that further action is required.

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

2.27. A further update from the PR is due by 6 December 2019. This area of practice will be reviewed at the targeted interim inspection planned within one year of the licence being renewed.

Import & Export - General Directions 0006

2.28. The committee noted that no further action is required.

2.29. The PR provided a revised Standard Operating Procedure (SOP) for the import and export of gametes. The findings of a review of the centre's procedures to ensure compliance with the requirements of General Direction 0006 was also provided.

2.30. The committee noted that, based on the information provided by the PR, on 11 July 2019 the Executive recommended that imports and exports under General Direction 0006 resume and that the centre's Importing Tissue Establishment (ITE) import certificate was renewed in line with the licence.

2.31. On 6 September 2019 the PR supplied an audit of the effectiveness of changes introduced and no non-compliances were noted.

2.32. This area of practice will be reviewed at the targeted interim inspection planned within one year of the licence being renewed.

Surrogacy

2.33. The committee noted that further action is required.

2.34. On 6 June 2019 the PR provided the summary report of an audit of all surrogacy treatments carried out in the centre since the last renewal inspection in February 2015.

2.35. This audit identified that the commissioning couple had been screened as donors prior to the creation of embryos in only one in seven cases, and in only one in four cases had they been screened as donors by the time of embryo transfer. The PR contacted the surrogates to advise them of the screening failures and to offer them the opportunity to be tested for the infections for which the commissioning couples were not screened. The surrogates all either declined or were uncontactable.

2.36. On 5 July 2019 the PR provided a summary report of assessments of the potential risks to the surrogates associated with the screening failures identified in the centre's audit. The PR has sought expert advice and has undertaken appropriate action based on the advice received.

2.37. The PR provided evidence that the screening practice described in the surrogacy SOP had been revised and that staff would receive appropriate training where required.

2.38. A report of the centre's audit to evaluate the effectiveness of these changes was due by 6 September 2019. As the centre had not undertaken any new cases of surrogacy the deadline for this audit has been extended to 6 December 2019.

2.39. This area of practice will be reviewed at the targeted interim inspection planned within one year of the licence being renewed.

Recommendations

2.40. The committee noted that the Executive will carry out a targeted interim inspection within a year of the renewal licence coming into effect, to evaluate the effectiveness of the changes that have been implemented since the time of the renewal inspection. The report of that inspection will be presented to Licence Committee.

3. Decision

3.1. The committee had regard to the decision tree.

3.2. The committee noted the Executive Update and progress made by the centre since the renewal inspection.

3.3. The committee endorsed the Executive's recommendation to complete a targeted interim inspection within a year of the renewal licence coming into effect and requested that the report of this inspection is submitted for the Licence Committee's consideration.

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

4. Chair's signature

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

Signature

Name

Kate Brian

Date

3 December 2019

Executive Update for Licence Committee
7 November 2019

Centre number	0067
Centre name	St Mary's Hospital
Person Responsible	Mr Gregory Horne

Progress update requested by Licence Committee

Background

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.

2. The centre had a licence renewal inspection on 5 and 6 March 2019 and the report of that inspection was considered by Licence Committee on 2 May 2019.

3. The minutes of the Licence Committee meeting were provided on 4 June 2019 and recorded the committee's decision:

   '**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. This executive summary provides at appendix 1 below, the progress update requested by Licence Committee in relation to the centre's implementation of recommendations to address three critical, seven major and four 'other' areas of non-compliance or poor practice, identified during the inspection on 5 and 6 March 2019. Actions taken are noted in blue text in the 'Executive Review' column.

5. The Executive notes that further actions remain to be completed in relation to one critical, two major and two 'other' areas of non-compliances identified at the time of the inspection. The further actions in most cases relate to audits to verify the effectiveness of corrective actions already taken by the centre, which are not yet due for submission to the Executive.

6. The Executive will carry out a targeted interim inspection within a year of the licence coming into effect, to evaluate the effectiveness of the changes that have been implemented since the time of the renewal inspection. The report of that inspection will be presented to Licence Committee.

Victoria Brown
Inspector

Appendix 1: Update for Licence Committee

Critical areas of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or 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. Controlled Drugs in Perioperative Care 2006. Controlled Drugs; safe use and management April 2016.	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 identified at the time of the interim inspection and in the centre's own audit of practice have not been effective. A	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. Hence, it is especially disappointing to us that non-compliances were once again identified at the HFEA inspection.	The executive acknowledges the PR's response and his commitment to fully implement 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 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

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.	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	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. The review will focus on, but not limit itself to;	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 6 September 2019 is awaited. **Further action is required.** **Progress update:** On 6 June 2019 the PR provided a summary of the independent review carried of the centre's procedures for the management of medicines along with an action plan to implement corrective actions. On 6 September 2019 the PR provided confirmation that the action plan had been implemented and the last five monthly audits of this area of practice. The Executive noted that no issues were identified in all but one of these audits.

	been effective in achieving and maintaining compliance. A summary report of the audit findings should be submitted to the centre's inspector by 6 September 2019.	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.	**No further action is required.** **This area of practice will be reviewed at the targeted interim inspection planned within one year of the licence being renewed.**

		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 therefore there is an	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 detail of the actions planned in	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 Responsible. The couple will be offered legal advice to allow confirmation of legal	The executive acknowledges the PR's response and his commitment to fully implement 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 consent to legal parenthood, and that he will continue to do so in accordance with HFEA

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.	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	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 38 years and over	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 consent to disclosure to researchers has been initiated. The executive

	the audit is robust, and that the findings can be relied upon. Details about the audit scope and methodology should 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	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 us a	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 indicates that a summary report of the findings will be provided to the centre's

	recommendations are required.	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	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 the effectiveness of the centre's procedures for

		manager at the MDT meeting on 12th March 2019 following 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	obtaining consent to legal parenthood. **Further action is required.** **Progress update:** The PR has confirmed that couple affected by the anomaly in consent to legal parenthood wish to seek a court declaration to establish legal parenthood. This case is now being dealt with by the legal teams appointed to handle the matter. The PR provided his assurance that he and the Trust will continue to support the couple affected in accordance with HFEA guidance and will continue to update the Executive on the outcome of the case. The PR provided the findings of his audits of all treatments with donor sperm or embryos created with donor sperm since January 2015. No further issues other than those that had previously been identified were noted.

		May) and attendance will be recorded and this record will be provided by 16th May.	The PR has also provided the 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. The analysis found that the root cause of this case was 'procedure/task design' and several preventative actions had already been developed and implemented as a result of the recommendations in the inspection report. The PR provided evidence of training in consent (including consent to legal parenthood) provided to relevant centre staff by an external specialist legal team. Following this training the PR has provided evidence of his assessment of the competence of relevant staff in consent to legal parenthood practices and processes. The suspension of new treatments with donor sperm and embryos created with

			donor sperm implemented in March 2019 remained in force until 15 August 2019 when the PR was able to provide evidence to satisfy the Executive of the robustness of the centre's current procedures for obtaining effective consent to legal parenthood. The Executive requested that the PR undertakes monthly audits all records of patients who have been provided with treatments where consent to legal parenthood was required, and to provide reports of these to the centre's inspector. To date the PR has provided the findings of audits of treatments carried out since the time of the inspection up to 30 September 2019. No issues have been identified in these audits. No further actions are required. The PR should however continue to submit to

			the Executive the monthly audits of legal parenthood consenting, in evidence of on-going compliance of the centre's procedures for obtaining and checking consent to legal parenthood. In the event that any new issues or concerns arise, the HFEA will recommend that a suspension of treatments with donor sperm for new patients is re-imposed with immediate effect. **This area of practice will be reviewed at the targeted interim inspection planned within one year of the licence being renewed.**
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	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	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	The executive acknowledges the PR's response and his commitment to fully implement 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

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 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).	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 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.	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 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.	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. 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.** **Progress update:**

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	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).		The PR has continued to provide regular updates on progress to implement this recommendation. The Executive attended a meeting with the PR and Clinical Lead for the centre on 23 October 2019. The PR and Clinical Lead have completed a comprehensive audit of 104 sets of embryos have been in storage for more than 10 years, and have identified a number of issues which raise doubt over the effectiveness of the consent to storage. During the meeting, the findings of this audit and the PR's progress with reviewing and resolving these cases was discussed. The PR confirmed that he will seek further specialist legal advice on a number of these cases and will continue to update the Executive on the outcome of this, including actions taken on following the legal advice. It is expected that the PR will support any affected patients

			in accordance with HFEA guidance. The PR is undertaking regular 'rolling' audits of the records of all embryos that have been in storage for less than 10 years and is providing the summary of the findings of each of these to the centre's inspector on an ongoing basis. The PR has confirmed that an auditor has been appointed specifically to audit all gametes in storage at the centre for more than10 years and anticipates that this will be completed by August 2020. The Executive considers that this is a reasonable timeframe in view of the number of samples in storage involving circa 1600 patients. **Further action is required**. **This area of practice will be reviewed at the targeted interim inspection planned within one year of the licence being renewed.**

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 implement 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 the centre's inspector.

		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	The PR's next quarterly update on progress in improving these success rates due by 6 June 2019 is awaited. **Further action is required.** **Progress update:** The PR provided his reviews of the centre's success rates for FET in women under 40 years of age in June and September 2019. The PR has also confirmed his commitment to keep this outcome under review and to monitor the centre's key performance indicators monthly. A further update from the PR is due by 6 December 2019. The executive notes that the centre's clinical pregnancy rate for FET in those under 40 years of age in the year to 30 June 2019, remains significantly below the national average.

		higher proportion than the 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	**Further action is required**. **This area of practice will be reviewed at the targeted interim inspection planned within one year of the licence being renewed.**

		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	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	The executive acknowledges the PR's response and his commitment to fully implement 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

	should be provided to the centre's inspector with the PR's response to this report. The PR should consider, with expert advice if necessary, if there is any risk to patients or donors resulting from the failure to perform an assessment of past or present Zika or Ebola virus exposure or infection in all patients and donors to date. If risk is present, appropriate risk control measures should be implemented. A summary of the 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.	infections also pose potential risk. The risks of infection in regard 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	this information is now being consistently recorded. 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.** **Progress update:** The PR has provided a summary of his assessment of the risk to patients and donors resulting from the previous failure to perform an assessment of past or present Zika or Ebola virus exposure

		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 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	or infection in all patients and donors. The PR also provided a summary report of an audit of the effectiveness of changes introduced and the Executive notes that no issues were identified. **No further action is required.** **This area of practice will be reviewed at the targeted interim inspection planned within one year of the licence being renewed.**

		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	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	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 executive acknowledges the PR's response and his commitment to fully implement 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

on how to ensure that relevant imports and exports comply with General Direction 0006. General Direction 0006, SLC T110 and SLC T33b.	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 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;	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 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	executive reminds the PR that as the samples are imported under General Direction 0006, and stored at the centre, compliance with those 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

	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 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.	HFEA in accordance with General Direction 0006. A full review of the use of imported donor sperm from 2015 has been undertaken. 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.	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 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.** **Progress update:** The PR provided a revised SOP for the import and export of gametes and the findings of his review into the centre's procedures to ensure compliance with the requirements of General Direction 0006. Based on the information provided by the PR, on 11 July 2019 the Executive recommended that imports and exports under General

			Direction 0006 could resume and that the centre's ITE import certificate was renewed in line with the licence. On 6 September the PR supplied an audit of the effectiveness of changes introduced and no non-compliances were noted. **No further action is required.** **This area of practice will be reviewed at the targeted interim inspection planned within one year of the licence being renewed.**
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.	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	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	The executive acknowledges the PR's response and his commitment to fully implement 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

SLC T118 and Interpretation of mandatory requirements 27A. It is noted that this area of practice was also identified as a non-compliance at the renewal inspection in 2015.	and retrospectively report to 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	also discussed at the weekly 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	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.** **Progress update:** On 6 June 2019 the PR provided a summary report of the review of the centre's processes for submitting and investigating adverse incidents. On 6 September 2019 the PR provided an audit of all

	inspector by 6 September 2019.	sent to the HFEA. Any recommendations or changes 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.	incidents reported internally at the centre between 1 April 2019 and 31 July 2019 and confirmed that all reportable incidents had been reported to the HFEA. The PR also confirmed this area of practice will be audited on a monthly basis. **No further action is required.**
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. undertaking these activities has been evaluated. HF&E Act 1990 (as amended), SLC T56 and CoP Guidance 14.1.	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.	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	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

	The PR should review the consents previously obtained by these staff to ensure that these are effective and compliant with requirements. An update on progress with this action should be provided to the centre's inspector by 6 June 2019.	2015. 15 cases were found where urgent oocyte cryopreservation was undertaken and the consent taken by a qualified 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.	laboratory staff since the time of the last renewal inspection and he is assured that these consents are effective. The PR has confirmed that in future, consent to storage of gametes in these exceptional cases will be undertaken by staff whose competence has been documented. An update on progress with documenting these competence assessments for relevant embryologists should be provided to the centre's inspector by 6 June 2019. **Further action is required.** **Progress update:** On 6 June 2019 the PR provided an update on progress to document the relevant staff competence assessments. **No 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 donor screening SOP, however this is not being followed in practice. CoP Interpretation of mandatory requirements 14A and SLC T33b.	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 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	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. 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	The executive acknowledges the PR's response and his commitment to fully implement 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. 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.

	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 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.	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. Going forward, all surrogacy treatment cycles will be part of a rolling three monthly audit.	**Further action is required.** **Progress update:** On 6 June 2019 the PR provided the summary report of an audit of all surrogacy treatments carried out in the centre since the last renewal inspection in February 2015. This audit identified that in only one in seven cases, had the commissioning couple been screened as donors prior to the creation of embryos, and in only one in four cases had they been screened as donors by the time of embryo transfer. The PR contacted the surrogates to advise them of the screening failures and to offer them the opportunity to be tested for the infections for which the commissioning couples were not screened. The surrogates all either declined or were uncontactable. On 5 July the PR provided a summary report of assessments of the potential

			risks to the surrogates associated with the screening failures identified in the centre's audit. The PR has sought expert advice and has undertaken appropriate action based on the advice received. The PR provided evidence that the screening practice described in the surrogacy SOP had been revised and that staff would receive appropriate training where required. A report of the centre's audit to evaluate the effectiveness of these changes was due by 6 September 2019. As the centre had not undertaken any new cases of surrogacy the deadline for this audit has been extended to 6 December 2019. **Further action is required**. **This area of practice will be reviewed at the targeted interim inspection planned**

			within one year of the licence being renewed.
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 2019.	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 importance of appropriate paper medical records until this happens.	The executive acknowledges the PR's response and his commitment to fully implement 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.** **Progress update:** On 6 August 2019 the PR provided the centre's audit of 'record keeping' which provided assurance that corrective actions implemented have been effective.

		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.	The PR made a commitment to re-audit this area of practice in January 2020. **No further action is required.**

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 0201: 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** **Progress update:** On 6 June 2019 the PR provided an update on

			progress to ensure safe storage of gases which indicated that appropriate actions have been taken. **No further action is required.**
12. QMS The inspection team could not 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.	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 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.	All communication from the HFEA is initially reviewed by 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	The executive acknowledges the PR's response and his commitment to fully implement 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.** **Progress update:** On 6 June 2019 the PR provided an update regarding the implementation of corrective actions in response to the review of the centre's QMS. **No further action is required.**

SLC T32 and SLC T36.		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, 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 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.	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register. The PR should confirm that the incorrect submissions identified have been corrected when responding to this report. The PR should 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	The identified erroneous submissions have been 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.	The executive acknowledges the PR's response and his commitment to fully implement 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.

	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 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.** **Progress update:** On 5 July 2019 the PR provided a summary of his review of the centre's processes which ensure that patient and partner disclosure consent information supplied to the Authority, accurately reflects that recorded on completed disclosure consent forms. A report of the centre's audit to evaluate the effectiveness of any changes introduced following the review, should be submitted to the Executive by 6 December 2019. **Further action is required**.
14. Obligations and reporting requirements The HFEA register audit team found some evidence of	The PR should ensure that all licensed treatment activity is reported to the Authority within	We acknowledge that we have not been able to submit data to HFEA in accordance with General Direction 0005 both	The executive acknowledges the PR's response and his commitment to fully implement this recommendation.

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 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 nonreporting 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 2019.	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 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.** **Progress update:** On 6 June 2019 the PR provided an update regarding the implementation of corrective actions in response to the initial review of the centre's processes for the submission of licensed treatment data. A report of the centre's audit to evaluate the effectiveness of these corrective actions, due by 6 December 2019, is awaited. **Further action is required**.