Licence Committee - minutes

Centre 0067 (St. Mary's Hospital)

Executive Update

Date:	Thursday, 4 March 2021
Venue:	Teleconference
Attendees:	Jonathan Herring (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Ermal Kirby
Executive:	Dee Knoyle – Committee Secretary Sarah Stedman - Inspector (Induction)
Legal Adviser:	Darryn Hale – DAC Beachcroft LLP
Observers:	Alison Marsden - Authority Member (Induction)

1. Declaration of interest

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

2. The committee had before it:

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

3. The following papers were considered by the committee:

Papers enclosed:

- Interim Inspection Report
- Licensing minutes up to the last licence renewal
    - 2021-01-14 Licence Committee Minutes - Executive Update
    - 2020-05-07 Licence Committee Minutes - Unannounced Targeted Interim Inspection
    - 2019-12-06 Licensing Officer Record of Consideration - Variation of Licence Holder
    - 2019-11-07 Licence Committee Minutes - Executive Update to Renewal
    - 2019-05-02 Licence Committee Minutes - Renewal

4. Background

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

Current Licence

The centre's current licence was granted for a period of three years from 1 August 2019 and is due to expire on 31 July 2022.

History of non-compliance: Renewal Inspection – 5 & 6 March 2019

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

4.3. The PR (Person Responsible) had committed to fully implementing all of the recommendations and had also agreed to a voluntary cessation of treatments with donor sperm for new patients.

4.4. The Licence Committee considered the report of the renewal inspection at its meeting held on 2 May 2019 and granted a three year licence, instead of the standard four. The committee agreed that the Executive should complete a targeted interim inspection within one year, to assess the implementation of the recommendations and the centre's general compliance.

Executive Update to Licence Committee on 7 November 2019

4.5. At its meeting held on 7 November 2019, the Licence Committee considered the Executive's update on progress at the centre since the renewal inspection carried out in March 2019. The committee noted that most of the required action to address the recommendations had been completed. The outstanding action in most cases related to audits to verify the effectiveness of corrective action and these were not yet due to be submitted. Imports and exports under General Direction 0006 had resumed and the centre's Importing Tissue Establishment (ITE) import certificate was renewed. The centre's voluntary cessation of new treatments with donor sperm and embryos created with donor sperm started in March 2019 and ended in August 2019.

4.6. However, the centre's clinical pregnancy rate for FET (frozen embryo transfer) in women under 40 years of age, in the year to 30 June 2019, remained significantly lower than the national average. The PR committed to keep this area under review and to monitor the centre's key performance indicators monthly. The committee agreed that further action was required to ensure the centre reflects suitable practices.

Unannounced Targeted Interim Inspection – January 2020

4.7. An unannounced targeted interim inspection was carried out on 21 January 2020 and a report of this inspection was submitted to the Licence Committee for consideration at its meeting held on 7 May 2020. The committee noted that at the time of the inspection one critical, three major and two other areas of non-compliance were identified. The clinical pregnancy rate following FET (frozen embryo transfer) in patients aged less than 40 years was below the national average at a statistically significant level. This was noted as a critical area of non-compliance and a recommendation was made requiring the PR to make improvements. The centre was required to commission an independent review to include, but not be limited to, an assessment of the centre's procedures for cryopreservation, storage and thawing of embryos including stimulation and luteal support protocols. The committee also noted that there was ongoing action for one critical and one major area of non-compliance. The committee endorsed the Executive's recommendation for the continuation of the centre's treatment and storage licence.

Executive Update to Licence Committee on 14 January 2021

4.8. The committee noted that in response to the COVID-19 pandemic, the centre followed General Direction 0014 and professional body guidance to suspend all non-essential treatments in March 2020. The centre was compliant with the requirements of General Direction 0014 for resuming treatment services in May 2020.

4.9. The committee noted that HFEA-held data for the year ending 31 August 2020, showed the centre's clinical pregnancy rates following FET, in women under 40 years old, remained below the national average at a statistically significant level. The PR had commissioned an independent review to find the reasons for this and a report of the findings was submitted to the Executive on 4 November 2020. There were 18 actions recommended by the external expert who carried out the independent review, of which 14 were accepted by the PR and the centre's Clinical Lead and six were recorded as complete. Some of the recommendations in progress required significant capital investment and/or additional staffing. The PR and Clinical Lead did not consider that there was sufficient evidence to implement the expert's recommendation to change the centre's protocol for blastocyst vitrification, or to only proceed to embryo warming if the endometrial thickness is >8mm. The Executive planned to liaise further with the PR to understand the rationale for this. Overall progress in implementing the external expert's recommendations would be followed up at the time of the next inspection in early 2021.

4.10. The committee was pleased that the centre had taken on board most of the recommendations made by the external expert to improve success rates for FET in women under 40 years old. The committee acknowledged that due to the COVID-19 pandemic there had been some delay in implementing these recommendations, and that a reasonable amount of time should be allowed to see the effectiveness of the centre's actions.

4.11. The committee also acknowledged that it may be difficult to obtain significant capital investment and additional staffing. However, it was agreed that improvements should be made where possible.

4.12. Overall, the committee was very pleased with the centre's progress and welcomed the fact that there would be ongoing discussions with the Executive to help the centre achieve sustainable compliance.

4.13. The PR had provided regular updates on progress with implementing all other recommendations made at the time of the renewal inspection in March 2019 and the unannounced targeted interim inspection in January 2020.

4.14. A further targeted interim inspection was scheduled to take place in early 2021 to allow the PR time to fully implement all recommendations. The report of this inspection has been submitted by the Executive.

5. Consideration of application

Targeted Interim Inspection – 19 January 2021

5.1. The committee noted that the purpose of the targeted interim inspection was to review the centre's progress with the implementation of the recommendations and to ensure that changes and improvements in processes had been embedded into the centre's practices, such that the Executive could be satisfied that the Person Responsible (PR) is suitable.

5.2. The committee noted that in view of the ongoing Covid-19 pandemic, the targeted interim inspection was conducted using videoconferencing technology rather than an on-site inspection. This inspection was undertaken at short notice.

5.3. The Executive noted in particular, the effectiveness of actions taken by the PR and his senior team to address previous areas of non-compliance or poor practice and reported that the centre is well led and provides a good level of patient support.

Inspection

5.4. The committee noted that the centre provided 1,094 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2020. In relation to activity levels this is a large centre.

5.5. The committee noted that HFEA-held register data for the year ending 30 September 2020 showed the centre's success rates in terms of clinical pregnancy rates were in line with national averages with the following exception:

- Clinical pregnancy rates following FET (frozen embryo transfer) in patients aged less than 40 years are lower than average at a statistically significant level.

5.6. The committee noted that in 2020, the centre reported 16 cycles of partner insemination with three pregnancies. This represented a clinical pregnancy rate which was in line with the national average.

5.7. The committee noted that HFEA-held register data for the year ending 30 September 2020 showed the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 9%. This represents performance that is not likely to be significantly different to the 10% maximum multiple live birth rate target for this period.

5.8. The committee noted that at the time of the inspection there were no areas of non-compliance or poor practice identified.

5.9. The PR continues to address one critical non-compliance identified at the time of the renewal inspection in March 2019, to ensure that there is effective consent in place for all gametes and embryos in storage at the centre.

Recommendation

5.10. The committee noted that the inspectorate recommends the continuation of the centre's treatment and storage licence.

6. Decision

6.1. The committee had regard to its decision tree.

6.2. Overall, the committee was pleased with the centre's progress and satisfied that in most cases, corrective action had been effective and the PR has an action plan and timeline to address some of the outstanding issues.

Independent Review of Success Rates - FET (frozen embryo transfer) in women under 40 years of age

6.3. During the inspection, each of the 18 actions recommended by the external expert, in the independent review, were discussed in detail with the PR and Clinical Lead. The inspectorate noted that several actions had been fully implemented.

6.4. The PR confirmed that good progress had been made in purchasing items of equipment recommended by the expert (heated stages and laser), and that the heated stages were now installed and ready for use.

6.5. Following further discussions with their cryopreservation media product supplier and another centre, the PR had committed to introducing new laboratory protocols for vitrification and warming in January and February 2021.

6.6. Recommendations made by the expert in relation to clinical protocols (endometrial thickness, baseline scans) had been discussed further within the centre's clinical team and they were keen to implement changes.

6.7. The committee deliberated on the quality of service provided to patients before and during the COVID-19 pandemic and had serious concerns. The committee acknowledged that the Executive expects to see improvements soon, however the centre's staffing limitations during the current pandemic could impact on a patient's chance of a successful pregnancy. The committee agreed that all patients should have the opportunity to receive the best service at all times, remembering that treatment provided by the centre could be a patient's only chance of having a child and that all patients should be given the best chance.

6.8. The committee requested that the Executive discusses the centre's performance and timescales for improvements with the PR. The Executive should also discuss with the centre a voluntary cessation of treatments for FET in women under 40 years old, until such time that the Executive is satisfied that the external expert's recommendations, which the centre has agreed to implement, have been fully implemented.

6.9. The committee was pleased that the centre is engaging with the Executive and urges the PR to act in the best interest of all patients at all times.

6.10. The committee was satisfied that the centre was fit to have its licence continued.

7. Chair's signature

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

Signature

Name

Jonathan Herring

Date

23 March 2021

Targeted Interim Report

Centre name: St Mary's Hospital
Centre number: 0067
Date licence issued: 1 August 2019
Licence expiry date: 31 July 2022
Date of inspection: 19 January 2021
Inspectors: Karen Conyers (lead), Sandrine Oakes and Karen Campbell (HFEA observer).
Date of Licence Committee: 4 March 2021

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLCs).

The HFEA undertook a renewal inspection of this centre in March 2019. The Authority's Licence Committee considered the renewal inspection report in May 2019 and renewed the centre's licence for three years, rather than the usual four. Licence Committee also recommended that a targeted interim inspection be performed within one year, and this took place in January 2020, at which time a number of issues were identified. Therefore, the executive recommended that a further targeted inspection take place within one year. In May 2020, the Licence Committee endorsed the executive's recommendation and stated that they wished to see the report of the next inspection.

In March 2020 the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, a decision was taken by the HFEA to suspend all inspections at least until November 2020, after which prevailing circumstances will be reviewed on a case by case basis before a decision is taken with regard to inspection activities. A revised inspection methodology was subsequently adopted to take into consideration measures to contain and mitigate the spread of the virus. These methods enable compliance to be reviewed through desk-based assessment (DBA) of documents submitted by the centre as well as the use of live video technology where available and appropriate. A risk-based approach (RBA) is then applied, balancing the risks of on-site inspection against those resulting from potential non compliances, identified during DBA, not being adequately investigated.

In view of the ongoing Covid-19 pandemic the executive determined that the targeted inspection recommended by the executive and endorsed by Licence Committee could be conducted using videoconferencing technologies rather than an on-site inspection. This

removed potential risks to staff and patients associated with HFEA inspectors attending the clinic for an on-site inspection during the Covid-19 pandemic.

This is a report of that targeted interim inspection which was undertaken with short notice and was focused on reviewing actions taken by the centre in response to the findings of the inspections in March 2019 and January 2020.

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

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note the effectiveness of actions taken by the Person Responsible (PR) and his senior team to address previous areas of non-compliance or poor practice.

The centre is well led and provides a good level of patient support.

The Licence Committee to note that at the time of this inspection no non-compliances or areas of poor practice were noted.

The PR continues to address one critical non-compliance identified at the time of the renewal inspection in March 2019, to ensure that there is effective consent in place for all gametes and embryos in storage at the centre. This was reviewed during the inspection and is discussed in the main body of the report.

Information about the centre

St Mary's Hospital is located in Manchester and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services. Other licensed activities of the centre include storage of gametes and embryos. The centre's licence was varied in December 2019 to reflect a change of Licence Holder.

The centre provided 1,094 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2020. In relation to activity levels this is a large centre.

The centre's licence was renewed in 2019 for a period of three years rather than the usual four in view of the number and seriousness of the non-compliances identified during the renewal inspection in March 2019. The report of that inspection was considered by the Licence Committee in May 2019 and the committee recommended that an interim inspection was carried out within a year of the licence coming into force. At the interim inspection in January 2020 a number of issues were identified including one critical, three major and two 'other' areas of non-compliance or poor practice. At that time the executive had significant concerns about the PR's suitability and recommended a further inspection should be carried in late 2020/early 2021. The executive considered that if significant improvements were not seen in the implementation of all recommendations made in 2019 and 2020, it would cease to be satisfied that the PR is suitable.

In January 2021, the PR informed the centre's inspector that the Trust had taken the decision to stop provision of fresh treatment cycles from February so as to mitigate potential pressures on the Trust due to the increasing number of Covid-19 cases. Patients will be able to undergo egg collections at Manchester Fertility (centre 0033) as part of a contingency arrangement between the two centres.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

HFEA held register data for the year ending 30 September 2020 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exception.

- Clinical pregnancy rates following frozen embryo transfer (FET) in patients aged less than 40 years are lower than average at a statistically significant level. This area of practice was reviewed in detail during the inspection and is discussed in the section 'Ongoing monitoring of centre success rates' below.

[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 $p \leq 0.002$.

In 2020, the centre reported 16 cycles of partner insemination with three pregnancies. This represents a clinical pregnancy rate which is in line with 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 30 September 2020 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

On-going monitoring of centre success rates

Since the last inspection in January 2020, the centre has received two performance related risk tool alerts in relation to the centre's success rates for FET in women under 40 years old. This has been an ongoing issue since 2019 and the centre's target to improve outcomes for this group of patients by September 2019 has not been achieved. The success rates remain lower than the national average at a statistically significant level.

Following the renewal inspection in March 2019, the PR reviewed the centre's success rates for FET in women under 40 years of age and implemented corrective actions identified during that review. These changes had not impacted on these success rates as they remained lower than the national average at a statistically significant level at the time of the targeted inspection in January 2020. As a result, the executive recommended that the PR commission an independent review to include, but not be limited to, an assessment of the centre's procedures for cryopreservation, storage and thawing of embryos including stimulation and luteal support protocols. In view of the Covid-19 pandemic the review was only completed at the end of October 2020 and the report of the findings was provided to the executive on 4 November 2020. An executive update on the findings of the review and the PR's initial implementation of actions was submitted for consideration by Licence Committee on 14 January 2021.

During the inspection each of the expert's 18 recommendations were discussed in detail with the PR and Clinical Lead. The inspection team noted that several actions had been fully implemented. The PR confirmed that good progress had been made in purchasing items of equipment recommended by the expert (heated stages and laser), and that the heated stages were now installed and ready for use. Following further discussions with their cryopreservation media product supplier and another centre, the PR has committed to introducing new laboratory protocols for vitrification and warming in January and February 2021. Recommendations in relation to clinical protocols (endometrial thickness, baseline scans) made by the expert have been discussed further within the centre's clinical team and they are keen to implement changes. However, restrictions in staffing availability have hampered these efforts.

The executive expects that progress in improving success rates will be seen soon but acknowledges the limitations faced by the centre in view of the impact of the pandemic on its activities and staffing. The executive will monitor the centre's success rates using the

[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%.

HFEA's risk tool alert system and liaise with the PR to ensure further action is taken if no significant improvements are seen in a reasonable timeframe.

Consent to storage of gametes and embryos

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

At the renewal inspection in March 2019, the inspection team identified a critical non-compliance in relation to the storage of cryopreserved gametes and embryos. There were several sets of embryos in storage without effective consent as no written medical opinion was in place. Following the renewal inspection, the executive recommended that the PR should complete a full audit of all samples in storage to establish if there were any further samples without valid consent. Progress with this was reviewed during an on-site visit to the centre in October 2019, and during the inspection in January 2020.

Samples in storage for >10 years

The PR informed the inspection team that the audits of the records of all gametes and embryos in storage at the centre for more than 10 years are now complete. On the day of inspection there remained eight sets of embryos and two sets of sperm in storage for more than 10 years without effective consent. Of these, one gentleman had been due in the clinic to complete consent forms the previous week but had not attended his appointment.

The PR confirmed that he has sought legal advice where necessary and will not discard samples if the gamete providers have indicated that they wish to pursue legal action in relation to their stored material. The Trust and senior management of the centre are committed to supporting patients who wish to pursue legal action. Given these assurances, the inspection team considers it unnecessary to make any further recommendation in addition to that made at the time of the renewal inspection. The executive will continue to liaise with the PR to ensure this matter is fully addressed.

The inspection team discussed the centre's current processes for extending storage which now also includes a review of records and sign-off by the PR and the Clinical Lead. These activities enabled the inspection team to conclude that the corrective actions implemented by the PR have been effective in addressing the issues which were identified at the renewal inspection in March 2019, and that the centre's processes for extending storage are compliant with requirements.

Samples in storage for <10 years

Since the time of the renewal inspection the PR has been undertaking regular 'rolling' audits of the records of all gametes and embryos that have been in storage for less than 10 years and this is also now complete. The PR confirmed that immediate corrective actions have been taken to address findings, and where necessary these have included discussions with relevant staff. A summary of the findings of these audits will be discussed with relevant members of the centre to identify any trends or themes. Whilst some issues in accuracy and completeness of consent forms were identified, these were generally considered to be historic and that staff involved no longer work at the centre. The PR

confirmed that the Trust has agreed to the purchase of an electronic consent platform which will address some of the typographical errors that had been noted in these audits.

The inspection team notes the PR's continued commitment to compliance in this area.

Bring-forward system

The inspection team reviewed the centre's 'bring-forward' system with the PR and centre's Clinical Lead. From these discussions, the inspection team was assured that the bring forward system is now more robust than it had been previously.

Consent to legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

At the renewal inspection in March 2019, issues were identified in relation to legal parenthood consenting processes including an error on the PP ('*Your consent to being the legal parent'*) form of a patient which had implications for legal parenthood for the child who was born following treatment. The couple affected by the anomaly in consent to legal parenthood wish to seek a court declaration to establish legal parenthood and are still continuing with this process. The PR provided his assurance that he and the Trust's legal team continue to support the couple affected in accordance with HFEA guidance and will update the executive on the outcome of the case.

In January 2020, the inspection team audited five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required and no issues were identified. Following the inspection, the PR continued to provide audits of consent to legal parenthood to the centre's inspector and no further issues have been identified.

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. Five 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 (via videoconferencing) and no issues were identified.

These activities enabled the inspection team to conclude that the corrective actions implemented by the PR have been effective in addressing the issues which were identified at the renewal inspection in March 2019 and the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

The PR will continue to conduct audits into this area of practice on a quarterly basis and the inspection team notes the PR's continued commitment to compliance in this area.

Consent to disclosure to researchers

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

At the renewal inspection in March 2019, two discrepancies were found between completed patient/partner disclosure consents in 23 patient records audited and the related consent data submitted for inclusion on the Register. Following these findings, the PR reviewed this area of practice and implemented corrective actions to address this non-compliance. Subsequent audits confirmed the effectiveness of these, and further corrective actions implemented, as the incidence of discrepancies continued to decrease. Two discrepancies in a sample of 10 records reviewed were noted during the inspection in January 2020. The team considered that these records were from a time period prior to more recently implemented corrective actions. No discrepancies were identified in subsequent audits provided to the centre's inspector in February and March 2020.

In November 2020, the centre undertook an audit of records of consent to disclosure to researchers covering a date range from 2009 to date. This audit included 1563 sets of records with 2976 consent forms and an overall 'error rate' of 10%. Of further concern was an unacceptably high 'error rate' of 45-50% in the earliest time period of 2009 to 2011. Since 2012 there has been an improvement in the centre's processes and staff training, and the number of errors has reduced to 5-8% of records audited. Since completing the audit a number of corrective actions have been implemented which the PR is confident will further minimise errors going forward.

The findings of this audit were discussed with the PR during the inspection. Given the high error rate in this sample of records audited, the PR and executive have mutually agreed that the HFEA will put a temporary block on the release of the centre's data for use in research so that there is no risk that the HFEA releases patient identifying information to researchers without their consent. The PR has committed to audit all of its patient records so as to provide assurance of the accuracy of the entries recorded on the HFEA Register.

To provide assurance of the centre's current processes for recording consent to disclosure to researchers, the inspection team audited 10 records of patients (via videoconferencing) who had undergone treatment at the centre in the last two months and no issues were identified. In view of this the executive does not consider a formal recommendation is necessary at this time as the failings appear to relate to older records identified by the PR which he has already committed to addressing. However, given that this is a large data set (circa 16,000 records) which is now blocked to use in research the executive expects this to be addressed as a matter of urgency.

In responding to the report, the PR has confirmed the action plan and timeline to undertake the audit of all patient records of consent to disclosure to researchers, with a target date for completion of March 2022. The inspection team considers this is reasonable considering the

number of records involved. The executive will liaise with the PR to ensure this audit is completed in a timely manner.

Medicines management

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

At the renewal inspection in 2019, the inspection team identified a number of issues in relation to medicine management practices and the completion of the controlled drugs register which was not in accordance with Regulations, professional guidance and best practice guidelines. The centre's own audit of controlled drugs had identified similar issues, however the corrective actions implemented had not been effective. During the inspection in January 2020, further issues were noted relating to entries in the controlled drugs register (signatures, time, carry over, stock balances), and that the centre's own audit, performed in December 2019, failed to identify the inspection team's findings.

The inspection team reviewed this area of practice, including observation of the controlled drugs register entries via videoconferencing and no issues were identified.

These activities enabled the inspection team to conclude that the corrective actions implemented by the PR have been effective in addressing the issues which were identified at the inspections in March 2019 and January 2020. The processes for medicines management at this centre are compliant with HFEA requirements.

Record keeping

Good medical records are essential for the continuity of the patient's care. At the renewal inspection in March 2019, a number of issues with record keeping were noted. These included consent forms being filled in or amended incorrectly, the completion of irrelevant consent forms and no record of how, and by whom, a patient, partner or donor was identified. In addition, the inspection team noted that it was hard to find relevant information in the records, and to follow the patient journey because the continuation sheets were not always filed together or chronologically. Following the inspection, the PR reviewed this area of practice and implemented corrective actions.

In January 2020, the inspection team noted a number of issues in patients' records audited during the inspection such as how the patient, partner or donor was identified, no patient identifiers were recorded on several anaesthetic charts, and it continued to be difficult to find relevant information in the records or to follow the patient journey. Although there had been an improvement in some major areas, namely no errors with consent forms, the inspection team considered that corrective actions implemented by the PR to address all of the issues identified at the renewal inspection had not been effective. Regular audits of this area of practice are undertaken and issues continue to be identified.

During the inspection, the team was able to review records via videoconferencing. Five sets of records selected by the centre were reviewed and no issues were identified.

The inspection team acknowledged the progress made in addressing this issue and urges the PR and centre staff to continue to keep this area of practice under review to ensure good medical records are kept and maintained.

Screening patients, partners and donors

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

At the renewal inspection in March 2019, it was identified that the centre does not document discussions regarding the patient or partner's travel or medical history with regard to the risks of infections (such as Zika and Ebola), or whether any additional testing may be required prior to treatment. Following that inspection, the PR implemented recommended actions and provided a summary report of an audit of the effectiveness of these changes introduced in which no issues were identified. In January 2020, the inspection team noted similar issues in four of five patient records reviewed and concluded that corrective actions implemented by the PR to address this non-compliance identified at the renewal inspection had not been effective. Therefore, further action was recommended.

During this inspection, the team was able to review records via videoconferencing. Five sets of records selected by the centre were reviewed and no issues were identified.

The inspection team acknowledged the progress made in addressing this issue and urges the PR and centre staff to continue to keep this area of practice under review to ensure compliance with these requirements.

Staffing

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

Staffing levels at the centre were discussed with the PR during the inspection. A number of centre staff had contracted Covid-19 in the Autumn. The centre reported these to the HFEA as required and confirmed that this was being managed in line with Trust policy, and that the centre had escalation plans in place for ensuring services remained safe in the event of high staff absence. A small number of staff members are currently required to shield or self-isolate due to potential exposure to the virus. Despite these difficulties, the PR was assured that there are sufficient staff to carry out the activities at the centre.

Adverse incidents

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

At the renewal inspection in March 2019, it was found that the centre had not reported, to the HFEA, two adverse incidents that met the criteria to be so, as defined in CoP Guidance 27.1. The PR subsequently conducted a review of the centre's processes for submitting and investigating adverse incidents and the PR is conducting an audit into this area of practice on a monthly basis. In January 2020, the inspection team reviewed the centre's adverse incidents log and the investigation reports for a recent incident and concluded that the centre's procedures for reporting and learning from adverse incidents were compliant with HFEA requirements.

At this inspection processes for reporting and investigating adverse incidents were discussed with the PR, Quality Manager and centre's Governance team. No issues or concerns were noted.

Surrogacy

At the renewal inspection in March 2019, it was noted that the centre had not screened the gamete providers in surrogacy arrangements as donors. Following the inspection, the PR audited all surrogacy treatments carried out at the centre since February 2015. This audit identified further cases in which gamete providers had not been screened as donors prior to treatment and the PR sought expert advice regarding the potential risks to the surrogates associated with the screening failures identified and has undertaken appropriate action based on the advice received. The centre's procedures were reviewed, and an audit of surrogacy treatments was to be undertaken to provide assurance of the effectiveness of changes implemented.

At the time of this inspection the centre has not yet undertaken any new surrogacy treatments. The inspection team is assured that the PR and centre staff will continue to keep this area of practice under review to ensure compliance with these requirements. No further action is recommended at this time and this will be reviewed at the time of the centre's next inspection.

Patient feedback

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 eight patients have provided feedback in the last 12 months, giving an average four-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 website also gives the ability for patients to comment on the cost of treatment. All patients confirmed that they had paid what they expected to; however, it is noted that four patients stated they were NHS funded.

Patient feedback provided via the HFEA website was mixed, with compliments about clinic staff and some negative comments which were discussed with the PR, Clinical Lead and Quality Manager. The inspection team was reassured to note that the centre had already identified one concern raised in the feedback in relation to privacy during scans because they had conducted a review of this area of practice. Actions are being taken to address concerns raised by patients they had interviewed, and improvements in how patients' scans are managed have been implemented.

The centre's own most recent patient survey completed in April 2020 was also reviewed by the inspection team. Disappointingly, of 75 questionnaires given out to patients, only 7 were returned. Feedback was positive but it is not possible to reach any overall conclusions due to the low numbers of responses. These findings were discussed with the PR and Quality Manager who explained the actions that had already been taken to address the low level of patient feedback. The PR holds a clinic for FET patients, and he uses this opportunity to promote the patient feedback questionnaire which also has a link to the HFEA website page. The centre report they have already seen a three-fold increase in response rate via this process. The PR is urged to continue to seek patient feedback including how to encourage patients who are not attending the 'FET clinic' to do so.

The inspection was carried out using videoconferencing and the inspectors did not speak to any patients.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment, and discussions and observations during the videoconference inspection indicate that the centre is compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the interim inspection in 2020, recommendations for improvement were made in relation to one critical, two major and three 'other' areas of non-compliance or poor practice. In addition, one critical non-compliance identified at the time of the renewal inspection in March 2019 remained to be fully addressed.

The PR subsequently provided information and evidence that all the recommendations were implemented within the required timescales. Further actions remain in relation to the gametes and embryos in storage at the centre (see section 'Consent to storage of gametes and embryos' above), and auditing records of consent to disclosure (see section 'Consent to disclosure to researchers' above).

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

At the renewal inspection in March 2019, the HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the HFEA Register. Following these findings, the PR reviewed this area and implemented corrective actions to address this non-compliance.

In January 2020, the HFEA register audit team found that all of the treatments audited had been reported to the HFEA and the number of IVF treatments that were reported to the HFEA outside the period required by General Direction 0005 had reduced slightly to 8%

(10/132). However, 36% (18/50) of the DI treatments audited were reported to the HFEA outside the period required by General Direction 0005. Following that inspection, the PR implemented further corrective actions and audits provided to the centre's inspector in February and March 2020 showed that 100% of IVF cycles and DI treatments audited were reported to the HFEA within the period required by General Direction 0005.

Prior to the inspection, the HFEA register audit team confirmed that there are currently no data submission issues at this centre. Therefore, the inspection team concludes that the clinic is compliant with requirements to submit information to the HFEA.

Leadership

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

The centre is compliant with HFEA guidance regarding effective leadership.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None identified.		Thank you	

‘Major’ areas of non compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None identified.		Thank you	

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement are any areas of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate a departure from statutory requirements or good practice.

An ‘other’ area of non compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None identified.		Thank you	

Additional information from the Person Responsible
The inspection went very well and this report demonstrates how much work the whole Department did, many thanks. The centre has identified a designated staff member to check the patients CD consent records with the electronic response sent to the HFEA on the patient's registration form. The work will commence on the 1st of March 2021 and it is envisaged this will be completed by the 31st March 2022. The data will then be validated and open to research once more