Licence Committee - minutes

Centre 0327 (Boston Place)
Targeted Interim Inspection

Thursday, 9 January 2020

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle Nora Cooke-O'Dowd (Observing - Induction) Victoria Brown (Observing – Induction)	Committee Secretary Head of Research & Intelligence Inspector
Legal Adviser	Darryn Hale	DAC Beachcroft LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

Papers enclosed:

- Targeted interim inspection report
- Previous licensing minutes for the last three years:
  - 2 May 2019 - Licence Committee Minutes - Renewal
  - 23 April 2019 - Executive Licensing Panel Minutes - Special Directions to permit continuation of licensed activity
  - 7 March 2019 - Licence Committee Minutes - Renewal
  - 10 May 2018 - Executive Licensing Panel Minutes - Change of Person Responsible
  - 15 December 2017 - Licensing Officer Consideration - Change of Licence Holder
  - 13 January 2017 - Executive Licensing Panel Minutes - Interim

1. Background

1.1. Boston Place, centre 0327 is located in central London. The centre has held a licence with the HFEA since May 2013 and provides a full range of fertility services including embryo testing.

1.2. The centre is part of The Fertility Partnership, a group of fertility centres which do not currently operate under common practices and procedures.

Current Licence

1.3. The centre's current licence was issued for a period of three years in May 2019 and is due to expire in May 2022.

Licence Committee Decision - May 2019

1.4. At its meeting in May 2019, the Licence Committee considered the report of the renewal inspection carried out at centre 0327 in December 2018. The inspectorate had identified two critical, six major and nine other areas of non-compliance.

1.5. The committee decided to renew the centre's licence for a period of three years, rather than the usual four, and required that a targeted interim inspection be performed within one year.

1.6. A report of the targeted interim inspection has now been submitted for consideration by the Licence Committee.

2. Consideration of application

2.1. The committee noted that an announced targeted interim inspection was carried out with short notice at centre 0327 on 1 October 2019. This inspection was focused on reviewing the implementation of the recommendations made in the report of the renewal inspection completed in December 2018, and in consideration of further issues that emerged following audits of practice undertaken by the centre since that time. The inspection also reviewed areas of practice which would usually be considered at an interim inspection.

2.2. The committee noted that in the 12 months to 31 August 2019, the centre provided 368 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

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

- the clinical pregnancy rate following frozen embryo transfer in patients aged less than 40 years was above the national average at a statistically significant level.

2.4. For the year 2018, the centre reported 20 cycles of partner insemination with four clinical pregnancies. This represented a clinical pregnancy rate comparable to the national average.

2.5. The committee noted that HFEA-held register data for the year ending 31 May 2019 showed the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 7%. This represents performance that is not likely to be significantly different to the 10% maximum multiple live birth rate target for this period.

2.6. The committee noted that at the time of the targeted interim inspection on 1 October 2019 there was one major area of non-compliance identified:

Major areas of non-compliance:

- The Person Responsible (PR) should ensure that the centre's register of controlled drugs is accurately completed.

2.7. Since the inspection the PR has committed to fully implementing all of the recommendations within the required timescales.

Medicines management

2.8. The committee noted that the inspectorate identified some issues in the controlled drugs register, including that several entries had no unit of measurement for the drug and two entries were missing the time of administration. There was also inconsistency in the recording of zero wastage and it was not always witnessed.

2.9. The inspectorate recommended that the PR ensures that the centre's register of controlled drugs is accurately completed and reviews the centre's practices and procedures in relation to the completeness and accuracy of the controlled drugs register, and investigates why the issues have occurred.

2.10. The PR was required to submit a summary report of the findings of the review, including corrective action and timescales for implementation, to the inspectorate by 1 January 2020. The PR has provided a summary report of the findings of the review into the centre's practices and procedures and confirmed that training was completed on 11 November 2019.

2.11. The PR was also required to audit the effectiveness of changes introduced in this area of practice within three months and submit a summary report of the findings to the inspectorate by 1 April 2020. The report is not yet due and still awaited.

2.12. The PR has confirmed the action taken to date and that he will provide all of the requested evidence and audits of practice within the required timescales.

Consent to storage of cryopreserved gametes and embryos – Critical Non-Compliance identified at the Renewal Inspection

2.13. At the renewal inspection in December 2018 the inspectorate identified issues in relation to the storage of cryopreserved gametes and embryos. These issues related to gametes and embryos that had been received and stored at centre 0327 in early 2017 as part of a bulk transfer of 944 samples from the Wolfson Fertility Centre - Hammersmith Hospital, centre 0078. This transfer of samples was arranged between the previous PRs of centres 0327 and 0078, and was undertaken within a relatively short period of time. The areas identified for improvement included:

- apparent storage without consent (unclear whether proper consent in place at this time)
- inadequate audit of records related to stored material
- inadequate understanding amongst relevant staff of the regulations and requirements governing statutory storage periods and their extension
- inadequate actions to address non-conformances in the storage records
- inadequate records of storage consent and of decisions related to the discarding of material at the end of storage.

2.14. The committee noted that the inspectorate made recommendations to address these issues, noted as a critical area of non-compliance. The inspectorate recommended that the PR ensures that there is effective written consent in place for all stored gametes and embryos and completes a systematic and detailed audit of the consent to storage forms in place for all stored samples received from centre 0078, to clarify which storage consent anomalies pertained to these samples. The inspectorate also recommended that the PR reviewed the centre's bring-forward system and procedures for auditing cryopreserved materials. The PR has audited all consent to storage records for the 944 bulk transferred samples from 2017.

Task Force

2.15. On completion of the audit in August 2019, the PR and General Manager established a task force with four other members of staff. Members meet weekly to manage cases with consent to storage anomalies, making arrangements to communicate the issues to patients and verify whether the patients hold any relevant records of consent to storage or medical practitioner's opinions.

2.16. At the time of the inspection the PR confirmed that they identified a total of 57 cases in which there was doubt over the effectiveness of the gamete providers' consent to storage. Of these, 24 cases had been resolved because the PR managed to obtain copies of missing consents to storage, or other evidence to satisfy the relevant regulations, from patients, and in some cases the gamete providers confirmed that they no longer wished to keep their samples in storage. The task force will continue in operation until the remaining 33 cases with storage consent anomalies are addressed.

2.17. The inspectorate reviewed three of the remaining cases and was assured by the PR and General Manager that patients are offered counselling throughout this process. Patients are also offered a consultation with the PR to discuss their personal circumstances free of charge. The inspectorate was assured that these offers are made verbally and recommended that they are also conveyed to patients in writing.

2.18. The committee noted that the PR has been asked to provide updates on action taken to address the remaining consent to storage anomalies every two months.

2.19. On the basis of the discussions with the PR and the review of records, the inspectorate is assured that there are no further cases of storage of gametes or embryos without effective consent, apart from the remaining cases associated with the bulk transfer of stored materials from centre 0078. The inspectorate is also assured that the PR is committed to completing the plan of action established by his task force with a view to resolving all cases by February 2020. The inspectorate considers the time this is taking to be reasonable, recognising that the PR has acted effectively to audit a considerable number of samples and associated consent records.

Recommendations

Licence

2.20. The committee noted that the inspectorate recommends the continuation of the centre's treatment (including embryo testing) and storage licence.

3. Decision

3.1. The committee noted the content of the inspection report.

Medicines Management

3.2. The committee was satisfied that the PR has provided a summary report of the findings of the review into the centre's practices and procedures and noted that training has been provided.

3.3. The committee is also satisfied that the PR has committed to providing all of the requested evidence and audits of practice within the required timescales.

Consent to Storage of cryopreserved gametes and embryos

3.4. The committee noted that the task force action model supports proper analysis of each case where there are anomalies, and consistent robust action, with effective oversight from the PR, informing gamete providers of the matters of concern, their options and providing them with access to support from a single and well briefed point of contact and a counsellor, if required.

3.5. The PR has been asked to provide updates to the inspectorate every two months regarding actions to address the remaining consent to storage anomalies, the first of which was provided on 29 November 2019 when the PR confirmed that a total of 40 cases have been resolved. The committee is satisfied that the task force will continue until the remaining cases are addressed. The committee noted that the PR confirmed that he has sought legal advice where necessary. The centre's storage inventory is scheduled to be legally compliant by February 2020.

3.6. The committee noted that the inspectorate has reviewed the centre's bring-forward system, which the PR is currently taking responsibility for managing, and the inspectorate is assured that the system is robust.

Licence

3.7. The committee agreed that the content of this targeted interim inspection report provided sufficient assurances for it to agree with the inspectorate's recommendation for the continuation of the centre's treatment (including embryo testing) and storage licence, and commended the PR for his efforts.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

24 January 2020

Targeted Interim Inspection Report

Centre name: Boston Place
Centre number: 0327
Date licence issued: 25 May 2019
Licence expiry date: 24 May 2022
Date of inspection: 1 October 2019
Inspectors: Karen Conyers (lead) and Andrew Leonard
Date of Licence Committee: 9 January 2020

Purpose of the report

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

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

The HFEA undertook a renewal inspection of this centre in December 2018. The Licence Committee in May 2019 which considered the renewal inspection report, renewed the centre's licence for three years, rather than the usual four, and required that a targeted interim inspection be performed within one year. This is a report of the targeted interim inspection which was announced but undertaken with short notice. The inspection was focused on reviewing all actions taken by the centre in response to the findings of the renewal inspection in December 2018, and in consideration of further issues that emerged following audits of practice undertaken by the centre since that time. The inspection also reviewed areas of practice which would be usually considered at an interim inspection.

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

Summary for the Licence Committee

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note that the centre's success rate for frozen embryo transfer in patients aged less than 40 years is above the national average at a statistically significant level.

The Licence Committee is asked to note that at the time of the inspection there was one major area of non-compliance or poor practice.

Since the inspection visit, the PR has given a commitment to fully implement all the recommendations within the required timescales. The PR has confirmed the actions taken to date and that he will provide all requested evidence and audits of practice within the required timescales.

Major area of non-compliance:

- The Person Responsible (PR) should ensure that the centre's register of controlled drugs is accurately completed.

In addition, one critical non-compliance identified at the time of the renewal inspection in December 2018 remains to be fully addressed though actions to do this are on-going. The PR should ensure that there is effective written consent in place for all gametes and embryos in storage at the centre. This area of practice was reviewed during the inspection and is discussed in the main body of the report.

Information about the centre

Boston Place is located in central London and has held a licence with the HFEA since May 2013. The centre provides treatment to self-funded patients and is part of 'The Fertility Partnership' group of fertility centres. The centres within 'The Fertility Partnership' group do not currently operate under common practices and procedures.

The centre provides a full range of fertility services including embryo testing. Other licensed activities of the centre include storage of gametes and embryos.

The centre provided 368 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2019. In relation to activity levels this is a small centre.

The centre's renewal inspection in December 2018 reported two critical, six major and nine 'other' areas of non-compliance or poor practice. The Executive consequently held a management review meeting, in accordance with the HFEA Compliance and Enforcement Policy, to evaluate the centre's performance and asked the PR to meet with the Executive to set out how he would address the inspection's findings.

The Executive met with the PR on 14 January 2019 and reviewed the PR's action plans to address the issues identified and to guarantee the centre's future compliance. The Executive was satisfied with the action plans and considered that they demonstrated the PR's commitment to attaining compliance and good governance, thereby mitigating risks at the centre. The report of the renewal inspection recommended the renewal of the centre's

treatment (with embryo testing) and storage licence for a period of three years, rather than the usual four. The report also recommended that a targeted interim inspection be carried out within one year of the HFEA Licence Committee decision, to ensure all corrective actions have been taken, and to review the culture of compliance at the clinic. The Licence Committee endorsed the report's recommendations and stated that it wished to consider the report of the targeted interim inspection.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year ending 31 May 2019 show the centre's success rates are in line with national averages with the following exception:

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

For the year 2018, the centre reported 20 cycles of partner insemination with four clinical pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

Multiple births[2]

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

HFEA held register data for the year ending 31 May 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 7%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target.

Consent: To the storage of cryopreserved material

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

At the renewal inspection in December 2018 the inspection team identified a number of non-compliances in relation to the storage of cryopreserved gametes and embryos. These included: apparent storage without consent; inadequate audit of records related to stored material; inadequate understanding amongst relevant staff of the regulations and requirements governing statutory storage periods and their extension; inadequate actions to address non-conformances in the storage records; inadequate records of storage

[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2] The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

consent and of decisions related to the discard of material at the end of storage. These issues related to gametes and embryos that had been received and stored at centre 0327 in early 2017 as part of a bulk transfer of 944 samples from centre 0078 (Wolfson Fertility Centre - Hammersmith Hospital). This transfer of samples was arranged between the previous PRs of centres 0327 and 0078 and was undertaken in a relatively short time period.

Following the renewal inspection, the Executive recommended that the PR completed a systematic and detailed audit of the storage consent forms in place for all stored samples received from centre 0078, to clarify what storage consent anomalies pertained to these samples. The Executive also recommended that the PR reviewed the centre's 'bring forward' system and procedures for auditing cryopreserved materials.

During this inspection the inspectors reviewed the actions taken by the PR since the renewal inspection and discussed the status of the stored samples received at the centre as part of the bulk transfer in 2017. The PR has audited all storage consent records for the 944 transferred samples. On completion of the audit in August 2019, the PR and General Manager established a 'task force' with four other members of staff, which meets weekly to allocate to each member cases with storage consent anomalies. The task force member is then responsible for communicating with the patient(s) to discuss the consent anomalies and potential consequences, and to ascertain if the patients hold any relevant records of storage consent or medical practitioner's opinions. Findings are brought back to the task force to discuss and further actions are decided upon, which are implemented by the task force member responsible for the case.

The PR confirmed that they identified a total of 57 cases in which there was doubt over the effectiveness of the gamete providers' consent to storage. Of these, 24 cases have been resolved because the PR has been able to obtain copies from patients of 'missing' consents to storage or other evidence to satisfy the relevant regulations, or the gamete providers have confirmed that they no longer wish to keep their samples in storage. The task force will continue in operation until the remaining 33 cases with storage consent anomalies are addressed.

The inspection team reviewed three of the remaining cases that were still to be resolved but where actions are on-going and noted detailed records of regular communications with patients and copies of follow-up email confirmations of verbal discussions. The inspection team was assured by the PR and General Manager that patients are offered counselling throughout this process and a free of charge consultation with the PR to discuss their personal circumstances. Whilst the inspectors were assured that these offers are made verbally, the inspection team recommend that this is reiterated by providing it in writing to patients.

The inspection team reviewed the centre's 'bring-forward' system which the PR is currently taking responsibility for managing. From these discussions, the inspection team were assured that the centre's bring forward system is now more robust than it had been previously.

On the basis of the discussions with the PR and the review of records, the inspection team is assured that there are no further cases of gamete or embryo storage without effective consent, apart from the 33 remaining cases associated with the bulk transfer of stored

materials from centre 0078. The inspection team is also assured that the PR is committed to completing the plan of action established by his task force with a view to resolving all cases by February 2020. The PR also 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. Given these assurances, the inspection team considers it unnecessary to make any further recommendation in addition to that made at the time of the renewal inspection.

The PR has been asked to provide updates to the centre's inspector every two months regarding actions to address the remaining storage consent anomalies, the first of which was provided on 29 November 2019. The PR confirmed that a total of 40 cases were now resolved and the task force will continue until the remaining 17 cases with storage consent anomalies are addressed.

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 December 2018 issues were identified in relation to legal parenthood consenting processes in surrogacy cases including; missing consent forms from the surrogate or intended parent; errors in consent forms; and the failure to act on errors identified in the centre's own audit of surrogacy cases. Immediately after the inspection the PR confirmed that no new surrogacy patients would be accepted and that he would check the documentation for all 'ongoing' surrogacy cases.

To provide assurance of the compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with the PR and reviewed the results of recent legal parenthood consenting audits. The inspection team also reviewed the surrogacy cases undertaken during 2019 and audited three sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

The PR confirmed that 'The Fertility Partnership' is in the final stages of implementing a group-wide unified surrogacy protocol which will be rolled out across all centres in the group in the coming months. As part of this roll out relevant staff at centre 0327 will be provided training and will have their competence assessed in this area of practice. The PR confirmed that no new surrogacy cases will be undertaken until he has provided evidence to the Executive that the centre's processes in this area of practice are robust. The inspection team expects that the implementation of the group-wide policies and protocols will provide the necessary evidence of robustness which the Executive requires.

Staffing

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

At the renewal inspection in December 2018 the inspection team had some concerns in relation to the number, training and competencies of some of the staff at the clinic. Following the inspection, the PR confirmed that he had implemented a number of corrective actions such as staff training by the centre's external legal team, and the implementation of 'The Fertility Partnership' induction programmes. A new General Manager has been appointed at the centre since the renewal inspection and she confirmed that she regularly reviews the centre's workforce requirements. The PR assured the inspection team that staffing levels are suitable for the activities carried out and advised that because the centre is part of 'The Fertility Partnership' group, when necessary, staff from other centres in the group can be seconded to cover any unexpected leave or other changes in workload.

The inspection team considered that staffing arrangements were appropriate.

Witnessing

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

The inspection team was not able to observe any laboratory activities during the inspection but was able to review the centre's most recent audit of witnessing practice. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: medicines management; infection control; legal parenthood; witnessing; surrogacy. The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- leadership
- patient support
- extension of storage consent
- surrogacy
- the centre's audit of legal parenthood
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- HFEA Clinic Focus articles regarding screening requirements

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

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 December 2018 the inspection team identified a number of issues in relation to medicines management practices; carryover of controlled drugs from one page to another was not signed or witnessed in all cases, in one patient record the quantity of controlled drug administered was not recorded in the patient's anaesthetic chart and timelines for the implementation of corrective actions were not recorded in the centre's audit of controlled drugs.

During the inspection the centre's register of controlled drugs and audit of controlled drugs were reviewed. The inspection team noted some issues in the controlled drugs register. There were several entries where no unit of measure of the drug was recorded and two occasions where the time of administration was not recorded. There was also inconsistency in the recording of zero wastage (as either '0', a dash or left blank) and it was sometimes witnessed and sometimes not (see recommendation 1). The inspection team noted that the centre had identified similar issues in their recent audit of practice carried out in September 2019 – which covered records from a period which included that addressed by the inspection team - and corrective actions had been implemented.

Prescription of intralipid 'off label'

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

Infection Control

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

At the time of the renewal inspection in December 2018 one issue related to infection control was identified and this was addressed soon after the inspection. The centre's most recent audit of infection control was reviewed, and the inspection team were assured to note that there were no significant issues identified.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

At the time of the renewal inspection in December 2018 the CE mark status of several medical devices in use at the centre was reviewed. As no issues were identified this area of practice was not reviewed again at this inspection.

Patient experience

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

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Sixty-one patients have provided feedback in the last 12 months, giving an average 4.5-star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. Most patients confirmed that they had paid what they expected to. Thirty patients also provided individual comments to the HFEA, of which 22 included compliments on various aspects of the staff and services at the clinic. Eight patients provided negative comments regarding their experiences which reflected the feedback received by the centre in their own survey.

The centre's patient feedback survey conducted between April 2019 and June 2019 was reviewed. This is an electronic survey sent out to all patients and included a wide range of questions such as; why they chose the centre, cleanliness, availability of counselling, respect privacy and dignity, ease of understanding information, opportunity to ask questions, ease of obtaining emergency advice, the telephone service response to queries and their experiences during treatment. Of 58 responses received, most patients reported their experiences as excellent or good, and 96% would recommend the centre to a friend or relative. There were also some negative comments that reflected those received by the HFEA. The PR and General Manager advised the inspectors that actions had already been taken to address this feedback.

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 observations during the visit to the centre, indicate that the centre is compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in December 2018 recommendations for improvement were made in relation to two critical, six major and nine 'other' areas of non-compliance or poor practice that required improvement.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales, albeit actions to address storage consent anomalies are still ongoing. The inspection team considers the time this is taking to be reasonable, recognising that the PR has acted effectively to audit a considerable number of samples and associated consent records. The task force action model will take time to resolve matters, but it supports proper analysis of each case and consistent and robust actions, with effective oversight from the PR, to address the storage consent issues identified. These actions effectively inform gamete providers of the matters of concern and their options, provide them with access to support from a single well briefed point of contact and the counsellor if required. The centre's storage inventory is scheduled to be legally compliant by February 2020.

On-going monitoring of centre success rates

Since the last renewal inspection in December 2018 the centre has not received any performance related risk tool alerts.

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.

The clinic is compliant with requirements to submit information to the HFEA and there are currently no significant data submission issues at this clinic.

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.			

‘Major’ area of non compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
1. Medicines management The inspection team noted some issues in the controlled drugs register; several entries had no unit of measure for the drug and two entries were missing the time of administration. There was also inconsistency in the recording of zero wastage (‘0’, a dash or left blank) and it was sometimes witnessed and sometimes not. Misuse of Drugs (safe Custody) Regulations 2001 CoP Guidance 25.23.	The PR should ensure that the centre’s register of controlled drugs is accurately completed. The PR should review the centre’s practices and procedures in relation to the completeness and accuracy of the controlled drugs register and investigate why the issues noted have occurred. A summary report of the findings of the review including corrective actions and timescales for implementation should be provided to the centre’s inspector by 1 January 2020.	All staff were notified of the inspection findings. Particular focus was put on communicating this to the anaesthetic and nursing teams. A review of centre's practice was completed on 9th October. An awareness session on accuracy for the nurses to be organised (11th November 2019) in line with double checking for all entries in the CD Register. It was agreed for a weekly check to be completed by the Control Drugs Acountable	The Executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has provided a summary report of the findings of the review into the centre’s practices and procedures in relation to the completeness and accuracy of the controlled drugs register. The PR has confirmed that the planned training was completed on 11 November 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 1 April 2020.	Officer and a monthly audit to ensure ongoing monitoring and review the effectiveness of the changes introduced. The audit summaries will be presented to all staff at the Monthly Quality Management Meetings. Prior to this they will be reviewed alongside the weekly checks at a meeting chaired by the PR with the participation of the Head Nurse (CDAO) and QM. This will form a monthly meeting to review the efficiency of the changes introduced. An update will be provided to our inspector by 1st January 2020.	The findings of an audit to evaluate the effectiveness of any corrective actions taken in this area of practice due by 1 April 2020 is awaited. **Further action is required.**

‘Other’ areas of practice that requires improvement

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

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

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

Additional information from the Person Responsible