

Executive Licensing Panel Minutes

Centre 0336 (Simply Fertility)

Interim Inspection Report

Date:	13 July 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Niamh Marren	Director of Strategy and Corporate Affairs Communications Manager Regulatory Policy Manager
Executive:	Bernice Ash	Secretary
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

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

- 1.1.** The panel noted that Simply Fertility is located in Chelmsford, Essex and has held a licence with the HFEA since 2013. The centre is part of 'The Fertility Partnership' group of licensed centres and provides a full range of fertility services, including embryo testing.
- 1.2.** The panel noted that, in the 12 months to 30 April 2021, the centre had provided 614 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom has impacted on treatment numbers.
- 1.3.** The panel noted that, HFEA register data, for the period 1 February 2020 to 31 January 2021, show the centre's success rates for IVF and ICSI are in line with the national averages.
- 1.4.** The panel noted that, at the time of the Desk Based Assessment (DBA) and virtual inspection, the centre had not reported the partner insemination treatments conducted in 2020. On the day of the virtual inspection, the Person Responsible (PR) submitted this information, therefore no further recommendation is considered necessary.
- 1.5.** The panel noted that, HFEA register data, between 1 February 2020 and 31 January 2021, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is likely to be significantly lower than the 10% multiple live birth rate target for this period.
- 1.6.** The panel noted that, 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, new inspection methodologies were developed and implemented. These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.
- 1.7.** The panel noted that HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.
- 1.8.** This centre was last inspected in June 2019; therefore, an on-site inspection should usually be conducted by June 2021. However, due to the Covid-19 pandemic, a DBA/RBA was conducted for the centre's interim inspection. Following this, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.
- 1.9.** The panel noted that a DBA, followed by a virtual inspection, which included videoconferencing with key members of staff, was conducted on 18 May 2021. The centre's own assessment of its service, the progress made in implementing the actions identified at the last inspection and on-going monitoring of the centre's performance was also taken into account.

- 1.10.** The panel noted that at the time of the inspection, there were no recommendations for improvement.
- 1.11.** The panel noted the centre is well led and provides a good level of patient support.
- 1.12.** The panel noted that the inspection team recommends the continuation of the centre's treatment (including embryo testing) and storage licence.

2. Decision

- 2.1.** The panel particularly noted that, in the last twelve months, 242 patients had provided feedback on the centre, through the 'Choose a Fertility Clinic' facility available on the HFEA website; on average, this gave the centre a five-star rating. Several patients had also provided individual comments to the HFEA, complimenting the caring nature of the centre's staff.
- 2.2.** The panel congratulated the centre on its low multiple birth rate of 3%.
- 2.3.** The panel was satisfied the centre was fit to have its treatment (including embryo testing) and storage licence continued.

3. Chair's signature

- 3.1.** I confirm this is a true and accurate record of the meeting.

Signature



Name

Clare Ettinghausen

Date

19 July 2021

Interim Licensing Report



Centre name: Simply Fertility

Centre number: 0336

Date licence issued: 27 November 2019

Licence expiry date: 26 November 2023

Date of inspection: 18 May 2021

Inspectors: Louise Winstone (lead), Polly Todd and Sarah Stedman (HFEA observer)

Date of Executive Licensing Panel: 13 July 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, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law). 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).

This is a report of an interim inspection, at the mid-point of the licence period.

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, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

This centre was last inspected in June 2019; therefore, an on-site inspection should usually be conducted by June 2021. However, following the DBA/RBA for this clinic it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection. This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by DBA followed by a virtual inspection, which included videoconferencing with key members of centre staff.

The current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the 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 low multiple birth rate and the positive comments made by patients in relation to their experiences.

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

The ELP is asked to note that this report makes no recommendations for improvement.

Information about the centre

Simply Fertility is located in Chelmsford, Essex and has held a licence with the HFEA since 2013. The centre is part of 'The Fertility Partnership' group of licensed centres and provides a full range of fertility services, including embryo testing.

The centre provided 614 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2021. In relation to activity levels this is a medium centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers during 2020.

The centre's licence has been varied to reflect the following:

- February 2021 - variation of licence to add embryo testing
- February 2020 - change of Licence Holder

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 outcomes¹

For IVF and ICSI, HFEA held register data for the period 1 February 2020 to 31 January 2021 show the centre's success rates are in line with national averages.

At the time of the DBA and virtual inspection the centre had not reported the partner insemination treatments carried out in 2020. On the day of the virtual inspection the PR submitted this information therefore no further recommendation is considered necessary. In 2020 the centre reported eight cycles of partner insemination with no pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

^{1,2} 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 $p \leq 0.002$.

Multiple births²

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

Between 1 February 2020 and 31 January 2021, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is likely to be statistically lower from the 10% multiple live birth rate target.

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 virtual inspection but was able to discuss witnessing with staff and review the centre's own audit of witnessing. These activities indicated that witnessing procedures are compliant with HFEA requirements.

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.

During the inspection process, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

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

The inspection team considered that staffing levels in the clinic were suitable for the activities being carried out, following assessment of information provided as part of the DBA and discussions with the PR during the virtual inspection. The PR regularly reviews staffing requirements in light of changes in working practices due to the Covid-19 pandemic.

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 and consent to storage.

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:

- imports of gametes and embryos from outside the EU/EEA
- the use of CE marked medical devices
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding screening requirements
- HFEA alert re incident; systems for managing complex patients.

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.

Documentation provided as part of the DBA indicate that the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance.

Prescription of intralipid 'off label'

Intralipid is an intravenous nutritional supplement sometimes prescribed during 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.

Documentation provided as part of the DBA and discussions during the virtual inspection indicate that the clinic's infection control practices are compliant with guidance.

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'.

As part of the DBA, the inspection team reviewed the centre's own audit of CE marked equipment and materials. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Patient feedback

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience at a clinic. Two hundred and forty-two patients have provided feedback in the last 12 months, giving an average five-star rating to the clinic. Several patients provided individual comments to the HFEA complimenting the caring nature of the staff at the clinic.

The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to, but there were some negative comments regarding higher than anticipated medication costs which were discussed with the PR. The PR informed the inspection team that actions have already taken to address this matter, including further work to increase the accuracy of individualised costed treatment plans and a wider range of medication suppliers being made available to patients. The inspection team recommend the centre to continue to monitor patient feedback to ensure the actions taken are effective.

On the basis of this feedback, 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 during the DBA and virtual 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 DBA and virtual inspection, 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 2019, recommendations for improvement were made in relation to three major and one 'other' area of non compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Since the last renewal inspection in June 2019 the centre has received one risk tool alert related to performance, to which the PR has responded appropriately, providing evidence and information that the issue has been addressed.

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.

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.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in June 2019, legal parenthood consenting processes were found to be robust.

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. Four 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

using screenshare technology during the virtual inspection. 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.

Leadership

The centre is compliant with HFEA guidance regarding effective 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.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

 **Critical areas of non compliance**

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

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

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



'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 partially compliant with requirements.

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

▶ **‘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.			

Additional information from the Person Responsible

Many thanks to the team for conducting our Interim inspection. The inspection was very well organised and the team at Simply gained some valuable learning in being part of the process.

We are delighted with the findings and will strive to continue to provide the best possible outcome for all patients in a safe and secure environment.