Executive Licensing Panel - minutes

Centre 0109 (King's Fertility)

Interim Inspection Report

Tuesday, 4 June 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Richard Sydee (Chair) Danielle Vincent Dina Halai	Director of Finance and Resources Communications Manager Scientific Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Nora Cooke-O'Dowd	Licensing Manager Head of Research and Intelligence

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.

1. Consideration of application

1.1. The panel noted that King's Fertility has held a licence with the HFEA since July 1992. The centre provides a full range of fertility services and has two transport centres; Epsom and St Helier NHS Trust (0259) and Kingston Hospital Assisted Conception Unit (0270).

1.2. The panel noted that, in the 12 months to 31 March 2019, the centre had provided 1,396 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre.

1.3. The panel noted that, for IVF and ICSI, HFEA register data, for the period January 2018 to December 2018, show the centre's success rates are in line with the national averages with the following exception:

- The clinical pregnancy rate following ICSI in women aged under 38 years old are lower than average at a statistically significant level.

1.4. The panel noted that, in 2018, the centre reported 27 cycles of partner insemination with two pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

1.5. The panel noted that, HFEA register data, between January 2018 and December 2018, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4%. This represents performance that is likely to be statistically lower to the 10% multiple live birth rate target for this period.

1.6. The panel noted that the inspection took place on 10 April 2019.

1.7. The panel noted that at the time of inspection there were two major areas of non-compliance concerning pregnancy success rates and consent to treatment. There was also one 'other' area of non-compliance regarding medicines management. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement all the recommendations made in the report, and has committed, where required, to audit the effectiveness of those actions within the required timescales.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment and storage licence, particularly commending the centre in achieving and maintaining a significantly low multiple birth rate.

2. Decision

2.1. The panel congratulated the centre on the significantly low multiple birth rate.

2.2. The panel was satisfied the centre was fit to have its treatment and storage licence continued.

3. Chair's signature

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

Signature

Name

Richard Sydee

Date

11 June 2019

Interim Licensing Report

Centre name: King's Fertility
Centre number: 0109
Date licence issued: 1 October 2017
Licence expiry date: 30 September 2021
Date of inspection: 10 April 2019
Inspectors: Louise Winstone, Nicola Lawrence and Janet Kirkland-MacHattie
Date of Executive Licensing Panel: 4 June 2019

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 (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. 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 commend the centre in achieving and maintaining a significantly low multiple birth rate.

The ELP is asked to note that this report makes recommendations for improvement in relation to two major and one 'other' area of non compliance or poor practice.

The PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales.

Major areas of non compliance:

- The PR should seek to improve the pregnancy success rates for ICSI treatments involving fresh embryos in women under 38 years old.
- The PR should ensure that correct consent forms are used so that effective consent to treatment is obtained.

'Other' areas of practice that require improvement:

- The PR should ensure medicines management practice is compliant with regulatory and best practice guidance.

Information about the centre

King's Fertility has held a licence with the HFEA since July 1992.

The centre provides a full range of fertility services and has two transport centres, Epsom and St Helier NHS Trust (0259) and Kingston Hospital Assisted Conception Unit (0270).

The centre provided 1,396 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2019. In relation to activity levels this is a large centre.

The centre's licence was varied in October 2017 to reflect a change of Person Responsible and a change of centre name, in November 2017 to reflect a change of Licence Holder and in February 2019 to reflect a change of premises.

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 period January 2018 to December 2018 show the centre's success rates are in line with national averages with the following exception:

- The clinical pregnancy rate following ICSI in women aged under 38 years are lower than average at a statistically significant level. See recommendation 1.

In 2018, the centre reported 27 cycles of partner insemination with two pregnancies, which is in line with the national average.

Multiple births[2]

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

Between January 2018 and December 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4%. This represents performance that is likely to be statistically lower than 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. During the inspection, the receipt of transport eggs into the laboratory and a sperm preparation were observed. The procedures were witnessed using an electronic witnessing system, along with manual witnessing steps, in accordance with HFEA requirements. The centre's own audits were also discussed with

[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 multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 10% MLBR target is calculated as equivalent to a MCPR of 13%.

staff. 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.

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs 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 appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

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; consent to storage and the quality management system.

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
- counselling
- screening
- imports of gametes and embryos from outside the EU/EEA
- the use of the Single European Code

- the use of CE marked medical devices
- HFEA Clinic Focus articles regarding the mix up of laboratory gases and equipment failures.

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.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be broadly compliant with guidance because: the carry-over of stock in the controlled drugs register is not witnessed. See recommendation 3.

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.

During the inspection, we reviewed infection control practices and found them to be 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'.

The CE mark status of all medical devices in use in the laboratory was reviewed in the course of the inspection. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

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 14 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. The majority of patients confirmed that they had paid what they expected to. For the system to work well, it's important that every patient knows about the rating system. The PR was asked to consider ways to promote the use of this facility and to encourage patients to provide feedback directly to the HFEA. The PR confirmed that this information is be added to all patient information and has now placed posters in all of the waiting areas directing and inviting patients to log onto the HFEA website and provide feedback. Improvement in this area will be followed up at the next inspection.

The centre do however, actively collect their own patient feedback and the most recent patient survey responses were reviewed. Between January 2019 and March 2019, 86 patients completed the patient survey. Feedback was positive with 89% of patients giving a 5 out 5 rating with the remaining 11% of patients giving a 4 out of 5 rating.

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

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 non-compliant with the following HFEA requirement:

- During a review of patient records, it was noted that in one record, an ED consent form (your consent to donating embryos) had been completed by a patient donating eggs to her partner. The patient should have completed a WD (your consent to donating eggs) consent form instead. In another record, a married patient couple receiving IUI treatment with donor sperm had completed a PBR form (your consent to being registered as the legal parent in the event of your death). This form is used for patients creating embryos and undergoing IVF treatment. Completing this form unnecessarily is not considered a risk, however, the inspectors were concerned that staff taking this consent may not have an understanding of the purpose of this form.

The centre had not identified these anomalies at the time of treatment or through their own audits. See recommendation 2.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to one critical, seven major and six 'other' areas 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 April 2017, the centre has received five risk tool alerts related to performance, to which the PR has responded appropriately. However, clinical pregnancy rates following ICSI in patients aged less than 38 years remain lower than average at a statistically significant level. This was discussed with the PR during and following the inspection. The success rate does appear to be improving and the centre has not received a further risk tool alert this month. The PR has provided a commitment to keep success rates in this group of patients under regular review and to provide regular updates to the centre's inspector. See recommendation 1.

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 that inspection in 2017, 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. Three 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. 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, with the exception noted in 'Compliance with HFEA standard licence conditions' section. See recommendation 2.

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	Inspection team's response to the PR's statement
None		N/A	

‘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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Pregnancy success rates The centre’s success rates for ICSI treatments involving fresh embryos in women under 38 years old are lower than the national average at a statistically significant level.	The PR should seek to improve the pregnancy success rates for ICSI treatments involving fresh embryos in women under 38 years old. The PR should provide the centre’s inspector with a review of the centre’s success rates for the groups of patients identified above when responding to the report. Following this, the PR should provide the centre’s inspector quarterly updates on the actions taken to address the	We have provided to our inspector a detailed report, a summary of which follows below. We have done a deep-dive into the data, as there are several statistics and metrics one can apply to a data set. This particular group in our centre has a number of confounding factors. As this is not a finding seen in any of the other age groups, treatment groups or metrics, we have ascertained that it is not a technical, training, process or equipment issue. In the main,	The Executive acknowledges the PR’s response and commitment to keep success rates in this group of patients under review. The PR has committed to provide quarterly updates to the centre’s inspector. Further action is required.

	success rates, with a goal of improving the success rates by 10 October 2019.	two (and potentially three) reasons emerge after interrogation of the data. In the past 6 months we have expanded our expert andrology service with the addition of two consultant andrologists to our team, as we are now a tertiary, regional, referral centre for men with severe sperm problems. This group is mainly diagnosed and over represented in our younger age cohort and all require ICSI. This leads to a skewing of success rates as it inherently has a significantly lower chance of success. This is supported by a breadth of international data, pointing to a fundamental issue with the sperm used for treatment derived from men with severe cases of OATS and/or NOA. In addition, in the last 12 months we have adopted a rigorous OHSS minimisation programme. We routinely employ segregation of treatment in high risk cases, with elective freeze-all	

		followed by a frozen-thawed cycle. In our younger age group, this accounts for 12-15% of our cycles started. They also represent an inherently better prognosis cohort, leaving those having a fresh transfer artificially skewed towards a poorer prognosis cohort. However, the outcome for the subgroup where segregation of treatment is employed, has an over than 50% clinical pregnancy success rate with a 0% OHSS rate. As minimisation, if not elimination, of OHSS whilst keeping a high success rate from cycle started and embryo transferred is an ultimate aim of our clinic, and the Authority as a whole, we do not believe that our clinical management should be altered by the requirement to chase a singular headline statistical metric. Finally, all EDI treatment submissions have also been checked for all 'freeze all' patients (FAE) under 38 years	

		to see the percentage of freeze all and the reason behind it. It was noted that most EDI treatment forms had a certain option ticked on the intention to treat question. That was 'for immediate treatment' rather than 'for storing embryos' in almost all of them, even if the FAE was planned before the cycle was started. This could be a contributing factor skewing our statistics further. This question has been raised by our QM to our inspector and we are awaiting advice on what the other clinics do nationally. As it happens, the RBAT alert on which this non-compliance was based on has now ceased. In addition, since we moved to our new premises and new lab, our first KPIs have shown an increase across both our ICSI and IVF success rates. A fact which is reassuring to us, as the Authority still analyses and reports on data from our old premises and old lab.	

		We monitor our centre's KPI's monthly, and quarterly reports will be provided to the centre's inspector as requested.	
2. Consent to treatment In one record reviewed, an ED consent form (your consent to donating embryos) had been completed by a patient donating eggs to her partner. The patient should have completed a WD (your consent to donating eggs) consent form instead. In another record, a married patient couple receiving IUI treatment with donor sperm had completed a PBR form (your consent to being registered as the legal parent in the event of your death). This form is used for patients creating embryos and undergoing IVF treatment. SLC T2 and T57.	The PR should ensure that correct consent forms are used so that effective consent to treatment is obtained. The PR should undertake a full review of consenting processes, including staff training requirements and provide a summary of this review to the centre's inspector by 10 July 2019. The PR should also conduct a root cause analysis into the circumstances which led to the failings in the completion of the correct consents and why consent form checks failed to identify the anomaly. A copy of the root cause analysis including any preventative and corrective actions should be provided to the centre's inspector by 10 July 2019.	Ensuring that all consent forms used for treatment are correct is one of the top priorities of the centre's quality management system. A full review of the centre's consenting processes, including staff training requirements, has been undertaken. A summary of this review has been forwarded to the centre's inspector. A review of these cases has been conducted. A copy of this review, including the root cause analysis, the preventive actions and the corrective actions, has been forwarded to the centre's inspector.	The Executive acknowledges the PR's response. A review of consenting processes, including staff training requirements and a root cause analysis has been provided. The PR has committed to provide the follow up audit by 10 October 2019. Further action is required.

	Three months after the review, the PR should audit consenting processes to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre’s inspector by 10 October 2019.	In three months, we will audit the centre's consenting processes to ensure compliance. A summary report of this audit will be provided to the centre's inspector by 10 October 2019.	

‘Other’ areas of practice that require improvement

‘Other’ 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	Inspection team’s response to the PR’s statement
3. Medicines Management The carry-over of stock in the controlled drugs register is not witnessed. SLC T2. The Association of Anaesthetists of Great Britain & Ireland (AAGBI) ‘Controlled Drugs in Peri-operative Care’ (2018).	The PR should ensure medicines management practice is compliant with regulatory and best practice guidance. The PR should review medicines management practice and address the issue identified in this report. A summary report of this review including corrective actions taken, should be provided to the centre’s inspector by 10 July 2019. Three months after the review, the PR should audit medicines management practices to ensure that corrective actions implemented have been	When a page in the controlled drugs register comes to an end, the closing stock for that page is checked, recorded and double witnessed by two healthcare workers. When the new page starts, the carry-over stock (from the old page) is recorded, but this particular section on the new page is not double witnessed once more. We have reviewed the Association of Anaesthetists of Great Britain & Ireland (AABGI) 'Controlled Drugs in Perioperative Care' (2018) document, along with the preceding (2006) document and the NICE 2016 Controlled drugs: safe use and management (NG64)	The Executive acknowledges the PR’s response. A review of medicines management practice has been provided. The PR has committed to provide the follow up audit by 10 October 2019. Further action is required.

	effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre’s inspector by 10 October 2019.	guideline. Although this specific point is not included in the above documents, we agree that this is good practice, and we have therefore adopted this recommendation in the centre's controlled drugs register. We have reviewed our medicine's management practice following this inspection. A summary report of this review, including corrective actions, has been provided to the centre's inspector as requested. In three months, we will audit the centre's medicine management practise to ensure compliance. A summary report of this audit will be provided to the centre's inspector by 10 October 2019.	

Additional information from the Person Responsible