Executive Licensing Panel - minutes

Centre 0328 (GCRM Belfast)

Interim Inspection Report

Friday, 25 August 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Hannah Verdin (Chair) Anna Coundley Howard Ryan	Head of Regulatory Policy Information Access and Policy Manager Report Developer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

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:

- 8th 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 GCRM Belfast has held a treatment and storage licence with the HFEA since 2013. The centre provides a full range of fertility services.

1.2. The panel noted that in the 12 months to 28 February 2017, the centre had provided 502 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a small to medium sized centre.

1.3. The panel noted that the corporate body owning GCRM Belfast has recently purchased the business of Origin Fertility Care (centre 0200). The premises of centre 0200 will not be used and the licence will be voluntarily revoked. At the time of the inspection, embryos and gametes in storage had not yet been transferred from centre 0200 to the premises of centre 0328.

1.4. The panel noted that the inspection took place on 6 June 2017.

1.5. The panel noted that at the time of the inspection on 6 June 2017, three major areas of non-compliance or poor practice were identified concerning patients travel history, the oxygen cylinder and satellite centre agreements. The panel noted that since the inspection, the Person Responsible (PR) had complied with the recommendations concerning patient travel history and daily checks of the emergency equipment, including ensuring the oxygen cylinder is within the expiry date and suitable for use. The PR had agreed to comply with the recommendation to ensure that the HFEA is informed of all satellite agreements established by the centre, that all such agreements are compliant with General Direction 0010 and that satellite service providers are audited for compliance with HFEA requirements at least every two years.

1.6. The panel noted that for the year ending November 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%: this represents performance that is not likely to be statistically different than the 10% multiple live birth rate target.

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

2. Decision

2.1. The panel noted the non-compliances and the PR's engagement in addressing them.

2.2. The panel particularly noted the non-compliance concerning satellite centre agreements, identifying that the recommendation made in the report was due for completion by 7 December 2017.

2.3. The panel was satisfied the centre was fit to have its centre's 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

Hannah Verdin

Date

5 September 2017

Interim Licensing Report

Centre name: GCRM - Belfast
Centre number: 0328
Date licence issued: 25/11/2015
Licence expiry date: 24/11/2019
Additional conditions applied to this licence: none
Date of inspection: 06/06/2017
Inspectors: Janet Kirkland MacHattie, Andrew Leonard
Date of Executive Licensing Panel: 25/08/2017

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. For 2015-2017 the focus of an interim inspection is:

- **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

The inspection team recommends the continuation of the centre's licence.

The ELP is asked to note that there are three recommendations for improvement in relation to three major areas of non-compliance.

Since the inspection, the PR has confirmed that he has complied with the following recommendations.

'Major' areas of non-compliance:

- the PR should ensure that all patients and donors are asked about recent travel history with regards to the risks of Zika or Ebola viruses, prior to planning a treatment cycle, and that patient information regarding the risks is up to date and relevant;
- the PR should ensure that daily checks of the emergency equipment include a check that the oxygen cylinder is within its expiry date and is suitable to use.

The PR has agreed to comply with the following recommendation.

- the PR should ensure that the HFEA is informed of all satellite agreements established by the centre, that all such agreements are compliant with General Direction 0010 and that satellite service providers are audited for compliance with HFEA requirements at least every two years.

Information about the centre

The GCRM Belfast has held a licence with the HFEA since November 2013.

The centre provides a full range of fertility services.

The centre provided 502 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2017. In relation to activity levels this is a small to medium sized centre.

The corporate body owning GCRM Belfast has recently purchased the business of Origin Fertility Care (centre 0200). The premises of centre 0200 will not be used and the licence will be voluntarily revoked. At the time of the inspection, embryos and gametes in storage had not yet been transferred from centre 0200 to the premises of centre 0328.

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 November 2015 to December 2016 show the centre's success rates are in line with national averages.

In 2016 the centre reported 10 cycles of partner insemination with no 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.

For the year ending November 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%: this represents performance that is not likely to be statistically different 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. Two oocyte collections were observed in the course of the inspection. The procedures observed were witnessed using both manual and electronic witnessing systems in accordance with HFEA requirements.

[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: 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 and consent records were reviewed, the 'bring-forward' system was discussed with staff and storage records were reviewed. 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 centre's rolling audits of all aspects of compliance, including witnessing, consent, welfare of the child, medicines management, in the treatment of six patients per month, as well as the centre's non conformance log. 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:

- the centre's arrangements for reviewing storage and legal parenthood consents;
- the use of CE marked medical devices;
- the content of the centre's website;
- the use of the most recently issued HFEA consent form versions;
- HFEA Clinic Focus articles regarding Zika and Ebola viruses.

The centre is broadly effective in implementing learning from their audits and guidance from the HFEA, because the staff interviewed on the day of the inspection were not aware of the current information from the HFEA issued in a clinic focus article with reference to Zika or

Ebola viruses and the information for patients does not reflect the most current information from the HFEA regarding these viruses (see recommendation 1).

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.

The centre was subject to a pharmacy inspection in February 2016 which did not identify any issues and therefore medicines management was not a focus on this inspection visit.

Prescription of intralipid 'off label'

Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The SOP for administering and monitoring patients during intralipid infusion was reviewed by the inspection team and was considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

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 the following medical devices was reviewed in the course of the inspection: media, EmbryoGlue®, cultures dishes and vitrification kits. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, there were no patients available to speak with the inspectors about their experiences at the centre. Seven patients provided feedback directly to the HFEA in the time since the last inspection (the last response was received in November 2016). Feedback was generally positive with two of the individuals providing written feedback giving compliments about the care received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- maintains an effective system for responding to patient phone calls.

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 in two additional areas:

- the oxygen cylinder on the centre's emergency trolley had passed the expiry date stated on the cylinder (recommendation 2). The oxygen cylinder was replaced immediately by centre staff.
- the PR has not informed the HFEA of two satellite centre arrangements and a satellite agreement has not been documented for one of these centres. One satellite agreement was present but did not include all of the information required by General Direction 0010. In addition, neither of the two satellite centres have been audited or reviewed by the PR in the last two years, to ensure the services they provide comply with HFEA requirements (see recommendation 3).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2015, recommendations for improvement were made in relation to five 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.

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 register team at the HFEA reported that the centre provides information to the register in a compliant manner.

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.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The audit report showed that no couples were affected by legal parenthood consent anomalies. At the inspection in July 2015 we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

During the inspection visit we reviewed three patient records for consent to legal parenthood and no discrepancies were identified.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this center to be compliant with HFEA requirements.

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 carried out.

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 area of non compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Centre staff interviewed on the day of the inspection were unaware if patients or donors are asked about recent travel history prior to embarking on treatment, with reference to the risks from Zika virus and/ or Ebola virus. The patient information leaflet about Zika virus also did not reflect current information from the HFEA regarding these viruses. Clinic focus April 2017 SLC T50(d).	The PR should ensure that all patients and donors are asked about recent travel history with regards to the risks of Zika or Ebola prior to planning a treatment cycle. The PR should review the centre's SOPs to ensure that recent travel history is taken into account when preparing patients for treatment, and that the SOPs reflect current professional guidelines and guidance from the HFEA. The PR should ensure that patient information regarding risks from Zika and Ebola is up to date and reflects current professional guidelines and	We have introduced into the patient details and history a question regarding the patient's travel history. It has also been added to a check list which is completed at the treatment planning appointment. We now display in our waiting room a notice asking patients to inform staff of travel to any zika or ebola areas. The relevant SOPs have been reviewed. A leaflet containing information on Ebola and Zika virus is now added to an information park given to all patients. The information reflects HFEA guidance and current guidelines	The PR’s response is acknowledged. The centre’s inspector requests that the PR inform the HFEA of the result of the risk assessment. By 6 December 2017.

	guidance from the HFEA. The PR should ensure that communications from the HFEA such as clinic focus articles are disseminated to the centre team and are acted on where relevant. The PR should review the reason why information published in a clinic focus article was not acted on or disseminated to the centre team. The PR should consider in any cases where it is not clear that travel history was sought, and the risks of diseases such as Zika and Ebola were not assessed, whether there are any risks to patients and partners, donors and gametes and embryos in storage. The PR should confirm that he has addressed all aspects of this recommendation when responding to the report.	along with links to further information. It has always been my practice to forward relevant communications from the HFEA, such as the clinic focus, to the members of the clinics management team, and subsequently to all staff. The clinic focus is an agenda item on the management meeting under regulation, any actions required would be expected to be initiated from the management team. I will investigate the reasons why the information on zika/ebols was not acted upon. A risk assessment on patients already treated will be carried out. All issues raised in the report are being addressed.	
2. The oxygen cylinder on the centre's emergency trolley had passed the expiry date	The PR should ensure that daily checks of the emergency equipment include a check that	This is now included in the daily checks.	The PR's response is acknowledged.

stated on the cylinder. SLC T17.	the oxygen cylinder is within its expiry date and is suitable to use. Three months after the implementation of corrective actions, the PR should audit the records of the daily critical equipment checks, to ensure that a check that the oxygen cylinder is within its expiry date has been consistently performed. The PR should inform the centre's inspector of the result of the audit by 6 September 2017.	Within 3 months an audit of the daily checks will be forwarded to our inspector.	Audit to be received by 6 September 2017. Further action required.
3. The PR has not informed the HFEA of two satellite centre agreements nor has he audited or reviewed the compliance of these services with HFEA requirements in the last two years. In addition, the one satellite agreement seen on inspection did not include all required information.	The PR should review and audit the compliance of the satellite services. The PR should ensure that an agreement compliant with General Direction 0010 is in place with all satellite centres. The PR must submit a copy of each satellite agreement and the audit report for each satellite centre, to the HFEA by	We had not considered these external facilities to be true satellites of GCRM-Belfast. One of the clinics is located in Letterkenny General Hospital, in the Republic of Ireland and only conduct scans for patients during treatment. The other clinic which is within a private hospital, the Northwest Independent Hospital, also only conducts some monitoring scans during treatment. All	The PR's response is acknowledged. Whilst the centre's inspector appreciates that the PR has stated that these external facilities are only conducting some monitoring scans for patients during treatment she reminds the PR that these facilities are advertised as satellite centres on the clinics own website and described as

General Direction 0010.	06 September 2017.	results from both clinics are forwarded to GCRM-BELFAST where all decisions on treatment management are made and GCRM-Belfast communicates directly with the patients. As defined in General Direction 10.8 a satellite 'is where the assessment, drug therapy and monitoring take place'. In the facilities used by our patients only a monitoring scan takes place. This is similar to the service we provide to patients attending other UK licenced centres for treatment, yet no formal agreement exits with those centres. Following the inspection, if you agree these are not satellites as defined in general direction 10, I will review the agreements to ensure that they are compliant with Directions. If you still consider these to be 'satellites' we will audit the clinics and sign satellite agreements compatable with General Direction 10. I regret it will be impossible to have this achieved by the 06/09/17.	such. The PR therefore has to be assured among other things of the safety of the facilities, the competency of the individuals performing the scans, the validation of the scan machines and adherence of all staff at these facilities who have contact with the patients to standard licence conditions and the HFEA Code of Practice. Compliance with General Direction 10. provides documented evidence that the PR has considered these issues on behalf of his patients. The centre’s inspector had discussed this with the PR by telephone after the inspection event and expects this recommendation to be completed by 6 December 2017. Further action 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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

Additional information from the Person Responsible