Executive Licensing Panel - minutes

Centre 0294 (Craigavon Area Hospital)

Interim Inspection Report

Friday, 22 June 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Lisa Whiting Niamh Marren	Director of Strategy and Corporate Affairs Data and Insights Analyst Regulatory Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Karen Conyers	Inspector

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 Craigavon Area Hospital is located in the county of Armagh, Northern Ireland and has held a licence with the HFEA since 2007. The centre provides basic partner services.

1.2. The panel noted that, for the year January to December 2017, the centre reported 116 cycles of partner insemination with eight pregnancies. This equates to a 7% clinical pregnancy rate which is consistent with the national average.

1.3. The panel noted that in 2017, one of the eight pregnancies resulting from partner insemination treatment was a multiple pregnancy.

1.4. The panel noted that the inspection took place on 17 April 2018.

1.5. The panel noted that at the time of the inspection, one major area of non-compliance was identified concerning the Quality Management System (QMS). There were also two 'other' areas of non-compliance regarding screening of patients and consent. Since the inspection, the Person Responsible (PR) has given a commitment to fully implementing the recommendations made in the report

1.6. The panel noted that the inspectorate recommends the continuation of the centre's treatment (insemination using partner sperm) licence, particularly noting the positive feedback provided by patients.

2. Decision

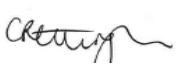
2.1. The panel expressed particular concern regarding the non-compliance surrounding consent, noting the audit report is due for submission in October 2018. The panel also noted that audit reports on the non-compliances, concerning the QMS and screening patients are due for receipt in July 2018.

2.2. The panel was satisfied the centre was fit to have its treatment (insemination using partner sperm) 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

26 June 2018

Interim licensing report

Centre name: Craigavon Area Hospital
Centre number: 0294
Date licence issued: 1 September 2016
Licence expiry date: 31 August 2020
Additional conditions applied to this licence: None
Date of inspection: 17 April 2018
Inspectors: Shanaz Pasha (lead); Andrew Leonard
Date of Executive Licensing Panel: 22 June 2018

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. We license 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 before a licence being granted or renewed assesses a centre's compliance with the law and our Code of Practice (CoP) and standard licence conditions (SLC).

This is a report of a short notice 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 focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

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 our 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. In particular we note the positive feedback provided by patients.

The ELP is asked to note that there are recommendations for improvement in relation to one major and two 'other' areas of non compliance or poor practice.

Since the inspection visit, the PR has given a commitment to fully implementing the following recommendations:

Major areas of non compliance:

- The PR should ensure that the quality management system and auditing processes are effective.

'Other' areas of practice that require improvement:

- The PR should ensure with immediate effect that patients and their partners are assessed for possible past or present Zika and Ebola virus exposure or infection. The PR should ensure that the risk assessment form relating to HIV and hepatitis B and C, is signed by a responsible clinician or nurse.
- The PR should ensure that consent obtaining processes are robust.

Information about the centre

The Craigavon Area Hospital is located in the county of Armagh, Northern Ireland and has held a licence with the HFEA since 2007.

The centre provides basic partner services.

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

For the year January to December 2017 the centre reported 116 cycles of partner insemination with eight pregnancies. This equates to a 7% clinical pregnancy rate which is consistent with the national average.

Multiple births

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

In 2017, one of the eight pregnancies resulting from partner insemination treatment was a multiple pregnancy.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of sperm and that identification errors do not occur. Witnessing was discussed with the laboratory team and sperm preparation was observed in the laboratory in the course of the inspection. The

procedure observed was witnessed in accordance with HFEA requirements using a manual system.

The inspection team was able to review records that were present in the laboratory and concluded that records of manual witnessing are maintained.

Consent: to the storage of cryopreserved material

The centre has a treatment only licence and therefore no gametes or embryos are stored at this clinic.

Staffing

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

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients 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: witnessing, consent and infection control.

The centre's procedures for auditing are partially compliant with requirements because the centre does not document the annual review of the QMS and the centre has not undertaken an audit of the third-party laboratory. See recommendation 1.

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 use of the most recently issued HFEA consent form versions;
- The use of CE medical devices;
- HFEA Clinic Focus articles regarding: assessment of Zika and Ebola virus risk and encouraging patients to provide feedback on their treatment experiences on the HFEA website.

The centre's procedures for implementing learning are broadly compliant with requirements because:

- The centre has not systematically implemented assessment of Zika and Ebola virus risk for all patients and partners. The risk assessment form relating to HIV and hepatitis B and C, states that a patient is suitable for treatment but the form is only

signed by the patients. Such an assessment has to be signed off by a responsible clinician or nurse;
- An audit of 10 patient records highlighted that the centre is not using the current version of the HFEA's welfare of the child assessment form;
- The centre does not specifically direct or encourage patients to provide feedback on the HFEA website regarding their treatment experiences. It is however acknowledged that the centre directs patients to the HFEA website for information.

See recommendations 1 and 2.

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 and disposal 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 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 are approved for the provision of fertility treatment, to ensure the safety of gametes and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of sperm pots, serological pipettes, 5ml tubes and media 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

During the inspection, we spoke to two patients about their experience at the centre. No patients have provided feedback directly to the HFEA in the time since the last inspection. The centre collects patient feedback through a questionnaire and feedback received for the last 12 months was reviewed on this inspection. The feedback was positive and patients complimented 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;
- gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- 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 fully compliant with HFEA requirements, with the exception of those areas identified elsewhere in this report and because:

- It was noted in an audit of 10 records that patients had completed section 5.1 of the MGI consent form, related to posthumous use of sperm samples. The centre has a treatment only licence and cannot store gametes, so cannot act on a consent for posthumous use. See recommendation 3.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2016, recommendations for improvement were made in relation to one major and two '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

The centre has not been asked to review procedures for the provision of treatment.

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

The centre does not provide treatment with donor gametes therefore requirements related to legal parenthood consent were not relevant at this inspection.

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 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. QMS Review of the QMS identified that: • the centre does not document the annual review of the QMS; • the centre has not undertaken an audit of the third party laboratory; • the centre has not implemented learning from recent HFEA updates; • the centre is not using the current version of the HFEA welfare of the child form. SLCs T32 and T36	The PR should ensure that the QMS and auditing processes are effective. The PR should review the centre’s processes for evaluating the QMS. A summary of the review should be sent to the centre’s inspector by 17 July 2018. The PR should ensure that an audit is undertaken of the third-party laboratory. A copy of the audit summary should be sent to the centre inspector by 17 July 2018. The PR should review the centre’s processes for implementing guidance from	The PR, the clinical team and quality manager will ensure that there is an annual review of all audits and quality improvement programmes performed with the unit to ensure that there is a systematic approach to both the performance of audit and the dissemination of findings to all relevant stakeholders. This review doccument will be maintained in the Unit's Quality Manual. We will comply with the HFEA instructions and forward the summary doccument by the 17/07/18. The PR and the clinical lead for Andrology will meet with the Laboratory Lead and	The Executive acknowledges the PR’s commitment to addressing this non compliance. We look forward to receiving the audit reports in July 2018.

	the HFEA into practice and ensure effective processes are implemented. A summary of the review and corrective actions should be sent to by 17 July 2018. The PR should ensure that up to date HFEA forms are used and are completed by patients. The PR should review the centre's processes for using the latest versions of HFEA forms. A summary of the review and corrective actions should be sent to the centre's inspector by 17 July 2018. Three months after implementing corrective actions, the PR should audit their effectiveness. A summary report of this audit should be provided to the centre's inspector 17 October 2018.	management team to determine the focus of an audit of Andrology Laboratory Performace. This will be performed and forward to the HFEA within the appropriate timescale. The PR acknowledges this audit will be an ongoing requirement. The laboratory will remain subject to perfomance assessment by other regulatory bodies outwith of the HFEA, in line with current practice and licensing requirements. The PR has already ensured that updates, newsletters and e-mails received electronically from the HFEA are immediately disseminated to all relevent stakeholders and clinical staff within the Unit. The PR will check to ensure that all relevent clincial staff can access the appropriate areas of the HFEA Portal on the HFEA website. Clinically relevant changes in HFEA guidance will be introduced to practice and	

		made subject to an audit of performance after 3 months. Key changes and the subsequent audits will documented in the Quality Manual. Previous editions (electronic and hard copies) of the WOC forms have been removed and superceded with the latest copies of the form from the HFEA portal. A review of all HFEA forms appropriate to our practice/license will be completed annually or after any notificaion of change by the HFEA, and this review will be formally doccumented and maintained in the Quality Manual. The PR will comply with HFEA timescales for a review of current form usage. The PR agrees that all changes required by the HFEA in this report will be subject to audit 3 months after implimentation, and these audit reports will be sent to	

		HFEA for evaluation within the required timescales.	

‘Other’ areas of practice that require 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
2. Screening patients Centre staff do not systematically consider and document possible past or present Zika and Ebola virus exposure or infection when assessing patients and their partners for treatment. SLC T50d The risk assessment form relating to HIV and hepatitis B and C, states that a patient is suitable for treatment but the form is only signed by the patients. Such an assessment has to be signed off by a responsible clinician or nurse. SLC T2	The PR should ensure with immediate effect that patients and their partners are assessed for possible past or present Zika and Ebola virus exposure or infection. The PR should ensure that patient information is available regarding the risks associated with the exposure to this virus. The PR should consider, with expert advice if necessary, if there is any risk to patients resulting from the past failure to perform Zika and Ebola assessment. If risk is present, appropriate risk control measures should be implemented. The PR should inform the centre’s inspector of the actions taken to implement this recommendation when	The Unit has already introduced patient information and consent documentation relating to both Zika and Ebola virus for all patients currently undergoing or commencing treatment. The information has links to reliable sources for up -to-date information on the prevalence and extent of these viral diseases. Testing for exposure will be performed in the Regional Virology Laboratory RVH, Belfast according to the risk of clinical exposure, and all statutory reporting requirements followed. Management will be implemented in conjunction with Clinical Virology advice. Treatment will be withheld until the consent process is fully completed and in affected individuals in accordance with current clinical advice from the	The Executive acknowledges the PR’s commitment to addressing this non-compliance. The PR confirmed via email that the risk assessment forms have been revised to include countersignature by clinician or nurse in charge. The PR has also committed to discussing whether there is any risk to patients resulting from past failures to screen for Zika and Ebola with a lead virologist. We look forward to receiving the audit report in July 2018.

	responding to this report. Three months after implementing corrective actions, the PR should audit their effectiveness. A summary report of this audit should be provided to the centre's inspector by 17 July 2018. The PR should review and revise the risk assessment form and ensure that it clearly documents a relevant staff member's risk assessment and decision re. treatment. A summary of the review and corrective actions should be sent to the centres inspector by 17 July 2018.	HFEA and WHO. These changes will be subject to audit and the report held in the Quality Manual. Copies of the new consent forms and the audit report will be forwarded to the HFEA within required timescales.	
3. Consent An audit of 10 patient records, highlighted that patients had completed section 5.1 of the MGI consent form related to posthumous use of sperm samples, however the centre has a treatment only licence and cannot store gametes for posthumous use.	The PR should ensure that consent obtaining processes are robust. The PR should review the processes by which patients complete consent forms and should ensure that patients only complete relevant sections of the MGI form. A	With regard to consent for the posthumous use of sperm, the PR confirms that this portion of the form was never appropriate for patients participating in licensed treatments with the Unit. Partners had been inadvertently completing this portion of the form along with	The Executive acknowledges the PR's commitment to addressing this non-compliance. We look forward to receiving the audit report in October 2018.

SLC T2	summary of the review and corrective actions should be provided when responding to this report. Three months after implementing corrective actions, the PR should audit their effectiveness. A summary report of this audit should be provided to the centre's inspector by 17 October 2018.	those portions of the consent process that were appropriate to their management. Clinical staff obtaining consent will inform patients and their partners that posthumous use of sperm samples will not be an option and direct them that this portion of the consent form should not consequently be completed.	

Additional information from the person responsible