Executive Licensing Panel - minutes

Centre 0294 (Craigavon Area Hospital) Renewal

Friday, 17 June 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Joanne Anton Howard Ryan	Director of Strategy & Corporate Affairs Head of Regulatory Policy Technical Report Developer
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
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 considered the papers, which included a completed application form, inspection report, and licensing minutes for the last three years.

1.2. The panel noted that Craigavon Area Hospital, centre 0294 is located in Portadown. The centre provides basic fertility treatment (insemination using partner sperm). In relation to activity levels this is a small centre.

1.3. The panel noted that the centre has been licensed by the HFEA since 2007.

1.4. The panel noted that in 2015 the centre reported 99 cycles of partner insemination with nine pregnancies which equates to a 9% clinical pregnancy rate. This is likely to be consistent with the national average.

1.5. The panel noted that at the time of the renewal inspection on 6 April 2016, one major and two other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has committed to fully implementing the recommendations.

1.6. The panel noted that some improvement is required in order for the centre to demonstrate suitability of their practices.

1.7. The panel noted that the centre has a Quality Management System in place and the PR is encouraged to use it to best effect to monitor and improve the service provided.

1.8. The panel noted that the inspectorate recommends the renewal of the centre's treatment (insemination using partner sperm) licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (insemination using partner sperm) licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

30 June 2016

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 6 April 2016

Purpose of inspection: Renewal of a licence to carry out Treatment (Insemination using partner sperm).

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Shanaz Pasha (Lead), Lesley Brown.

Date of Executive Licensing Panel: 16 June 2016

Centre name	Craigavon Area Hospital
Centre number	0294
Licence number	L/0294/3/b
Centre address	Lurgan Road, Portadown, Craigavon, BT63 5QQ
Person Responsible	Dr Timothy McCormick
Licence Holder	None
Date licence issued	1 September 2012
Licence expiry date	31 August 2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Craigavon Area Hospital has held a Treatment (Intrauterine insemination using partner sperm) licence with the HFEA since 2007 and provides basic fertility services.

The centre provided 99 cycles of partner intrauterine insemination in 2015. In relation to activity levels this is a small centre.

The centre relocated premises within Craigavon Area Hospital, away from the maternity and gynaecological outpatient area. The current licence was varied to reflect the change of premises in August 2015.

Pregnancy outcomes[1]
In 2015 the centre reported 99 cycles of partner insemination with nine pregnancies. This equates to a nine percent clinical pregnancy rate. National data for this year had not been analysed as yet however this is likely to be consistent with the national average.

Summary for licensing decision.

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one major and two 'other' areas of non compliance which have resulted in the following recommendations:

Major area of non compliance:

- The PR should ensure that all medical devices used are CE marked.

'Other' areas that require improvement:

- The PR should review practices related to the management of medicines.
- The PR should ensure that all activities carried out by the centre are audited against regulatory requirements, and the quality management system includes documented standard operating procedures for all activities.

Recommendation to the Executive Licensing Panel.

The centre has no critical areas of concern but does have one major of area of concern.

The inspection team notes that the success rates are consistent with the national average.

Some improvement is required in order for the centre to demonstrate suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

The inspector will continue to monitor the centre's performance. The inspection team recommends the renewal of the centre's Treatment (Intrauterine insemination partner sperm) licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm) at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and the patient to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well
The centre does not undertake treatment with donor gametes therefore this area of practice is not applicable to this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The centre is compliant with HFEA requirements to process gametes in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The third party laboratories which undertake the diagnosis and investigation of patients, patients' partners, or their gametes are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre does not perform surgical procedures as part of its licensed activities therefore this area of practice is not applicable to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre provides insemination with partner sperm. In the last year the centre has reported no multiple pregnancies.

Procurement of gametes (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre does not distribute gametes or embryos therefore this area of practice is not applicable to this inspection.

Receipt of gametes and embryos (Guidance note15)
The centre does not receive distributed gametes and embryos therefore this area of practice is not applicable to this inspection.

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import or export gametes therefore this area of practice is not applicable to this inspection.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability:

- to identify and locate gametes during any step from procurement to use for human application or disposal;
- to identify any person who has carried out any activity in relation to particular gametes; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have transport and satellite treatment links therefore this area of practice is not applicable to this inspection.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. Some of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Medicines management
Nurses routinely dispense fertility drugs to patients. NMC guidance states "registrants may in exceptional circumstances label from stock and supply a clinically appropriate medicine to a patient against a written prescription." The centre does not have an SOP for dispensing fertility drugs (SLC T2, Standards for Medicines Management, NMC, 2007). See recommendation 2.

Quality management system (QMS) (Guidance note 23)
In the last two years the centre has not conducted an audit of consent to treatment.
It is acknowledged that centre staff monitor the temperature of the drugs fridge and clinic incubator daily, however the centre does not have SOPs for actions to be taken by clinic staff if the temperatures fall out of range of the required parameters (SLC T33, SLC T36). See recommendation 3.

Equipment and materials (Guidance note 26)
The following medical devices used by the centre are not CE marked for assisted reproductive therapy (ART) use: 14ml round bottom tubes, 5ml round bottom tubes, positive displacement pipette tips, 3ml sterile disposable plastic pipettes, specimen pots and Puresperm reagent (SLC T30,Clinic Focus April 2013). See recommendation 1.

Staff engaged in licensed activity

Person Responsible (PR)

Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better
Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA requirements.

Safeguarding
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better
Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well
The centre does not perform embryo testing therefore this area of practice is not applicable to this inspection.

What the centre could do better
Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well
During the inspection visit the inspector spoke to one patient who provided feedback on her experiences. A further five patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with three of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they 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;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better
Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF& E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing

a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre provides basic partner treatment services only and therefore is not subject to the counselling requirements of schedule 3. It is noted however that counselling is available to all patients and their partners.

Egg [and sperm] sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not provide egg or sperm sharing arrangements therefore this area of practice is not applicable to this inspection

Surrogacy (Guidance note 14)
The centre does not provide surrogacy treatments therefore this area of practice is not applicable to this inspection

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients.

What the centre could do better
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients are compliant HFEA requirements. This ensures that the centre gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better
Nothing identified at this inspection.

Consent and Disclosure of information, held on the HFEA Register, for use in research
What the centre does well **Consent (Guidance note 5;6)** The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients have provided all relevant consents before carrying out any licensed activity. **Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)** Consent to disclosure to researchers requirements are not relevant to basic partner IUI services and therefore this area of practice is not relevant to this inspection. .
What the centre could do better Nothing identified at this inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo
What the centre does well The centre does not create embryos therefore this area of practice is not applicable to this inspection.
What the centre could do better Nothing identified at this inspection.

Screening of patients Storage of gametes and embryos
What the centre does well **Screening of patients (Guidance note 17)** The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened. **Storage of gametes and embryos (Guidance note 17)** The centre does not store gametes or embryos therefore this area of practice is not applicable to this inspection.
What the centre could do better Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre does not create or store embryos therefore this area of practice is not applicable to this inspection.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping **Obligations and reporting requirements**
What the centre does well **Record keeping and document control (Guidance note 31)** The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care. **Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)** The centre provided an annual return for IUI treatments undertaken in 2015 within the required timeframe (General Direction 0005).
What the centre could do better Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2014, a recommendation for improvement was made in relation to one 'other' area of non-compliance.

The PR provided information and evidence that the recommendation was fully implemented within the prescribed timescale.

On-going monitoring of centre success rates

As this centre provides partner IUI treatment only, the centre's success rates are not subject to on-going monitoring through the HFEA risk tool.

Areas of practice requiring action

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, General Direction 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 area 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 or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. 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	Executive Review
None identified at this inspection.			

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 to a 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
- 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	Executive Review
1.CE marking The following medical devices used by the centre are not CE marked for ART use: 14ml round bottom tubes, 5ml round bottom tubes, positive displacement pipette tips, 3ml sterile disposable plastic pipettes, specimen pots and Puresperm reagent. All medical devices should be appropriately CE marked where available. SLC T30. Clinic Focus April 2013.	The PR should ensure that CE marked devices are used where available. We would not recommend the implementation of precipitous changes that might impact on quality of treatment that is provided to patients. The PR should conduct a review of all medical devices currently in use to identify where products are not CE marked and take action to source alternatives. It is expected that all medical devices should be CE marked by 6 October 2016.		The Executive acknowledges the PR's response in the table below and his commitment to fully implementing this recommendation. Further action is required

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Medicines Management Nurses routinely dispense fertility drugs to patients. NMC guidance states "registrants may in exceptional circumstances label from stock and supply a clinically appropriate medicine to a patient against a written prescription." The centre does not have an SOP for dispensing fertility drugs. SLC T2 and Standards for Medicines Management, NMC, 2007.	The PR should review practices related to the management of medicines. The PR should organise a review of dispensing practices by a registered pharmacist. A copy of the report should be sent to the centre's inspector by 6 July 2016.		The Executive acknowledges the PR's response in the table below and his commitment to fully implementing this recommendation. The Executive would like to thank the PR for providing a copy of an SOP for dispensing fertility drugs. Further action is required.
3. QMS In the last two years the centre has not conducted an audit of consent to treatment.	The PR should ensure that an audit of consent to treatment is carried out. A summary report should be sent to the centre's inspector by 6 July 2016 The PR should ensure that the		The Executive acknowledges the PR's response in the table below and his commitment to fully implementing this recommendation.

It is acknowledged that centre staff monitor the temperature of the drugs fridge and incubator daily, however the centre does not have SOPs for actions to be taken by staff if the temperatures fall out of range of the required parameters. SLC T36 and SLC T33.	centre has documented procedures for staff to follow if the drugs fridge and incubator malfunction or fail. The PR should submit copies of the SOPs to the centre's inspector by 6 July 2016.		The Executive would like to thank the PR for providing copies of SOPs for actions to be taken in the event that the incubator and drugs fridge malfunction. Further action is required.

Reponses from the Person Responsible to this inspection report
The PR and staff at Centre 0294 thank the HFEA and their inspection staff for their recent inspection and associated inspection report. The team at CAH have taken action to engage with HFEA and the Southern Trust HSCNI in correcting those clinic processes that require improvement and change. We will comply with the requirement to provide full evidence of implimentation by July 2016. For your consideration we attach draft SOPs relating to Medictions dispensing and safety, temperature sensitive equipment e.g. (refridgerator) and assocaited trouble-shooting and also consent for invasive procedures associated with licensed treatment. We have already implimented consent procedures and will be audinting compliance in the near future. We also acknowledge the need to make the process of audit and Quality Mangement more robust and repeatable. We will consequently engage with the Trust Audit Department to establish a clearly defined protocol for the audit and review process. This will involve clear doccumentation of the HFEA auditable standards, a definition of the audit process used, comparison with the standards, clearly doccumented audit findings, any process of change required and a set timescale for implimentation and reaudit to complete the audit cycle. The PR and andrology team in CAH will undertake to review all equipment and reagents used in processing partner semen preparations for licensed treatments and ensure that all are compliant with HFEA regulations within the alloted timeframe. Details of any changes required will be forwarded to the review team.