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: 23 May 2013
Purpose of inspection: Renewal of a licence to carry out 'Treatment' only.

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.

Date of Executive Licensing Panel: 16 August 2013

Centre name	Ayrshire Fertility Unit, Crosshouse Hospital
Centre number	0287
Licence number	L/0287/2/e
Centre address	Crosshouse, Kilmarnock, Ayshire, Scotland KA2 0BE
Person Responsible	Dr Santanu Acharya
Licence Holder	Dr David Rae
Date licence issued	1 December 2009
Licence expiry date	30 November 2013
Additional conditions applied to this licence	None

Doc name: Centre 0287 Renewal report – treatment only
Doc reference: CT-29
TRIM reference: 2013/011419

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This section provides a summary of findings, with key recommendations for improvement. **3**

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This section sets out the areas of practice that require the attention of the Person Responsible (PR) and the PR's response. Some of the requirements will have been met from the time of inspection to the publication of this report as shown in the summary, Section 1. **15**

Section 1: Summary report

Brief description of the centre and its licensing history:
The Ayrshire Fertility Unit, Crosshouse Hospital, has held a licence with the HFEA since 2007. The centre provides basic partner services (intra uterine insemination (IUI)) to National Health Service (NHS) patients.

The centre provided 114 cycles of treatment in 2012, which makes this a small centre in terms of activity.

The current licence was issued in December 2009 and expires in November 2013. The premises have not undergone any changes in the time since the last interim inspection in October 2011.

The following variations to the centre's licence have been approved by the ELP:

- 3 June 2010 - change of PR to Dr Santanu Acharya
- 12 August 2011 - change of Licence Holder (LH) to Dr David Rae

Activities of the centre:

Type of treatment	Number of treatment cycles for the period 01/01/2012 – 31/12/2012
Intra uterine insemination (partner)	114

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	N/A
Storage of sperm	N/A
Storage of embryos	N/A

Outcomes*
In 2012, the centre reported 114 cycles of partner insemination with seven pregnancies. This equates to a six percent clinical pregnancy rate which is consistent with the national average.

*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. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of P ≤ 0.002.

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 PR is suitable and he has discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with 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 four major and two 'other' areas of non-compliance or poor practice.

Since the inspection visit the PR has provided evidence that the following recommendations have been fully implemented:

Major areas of non compliance

1. The PR should ensure that whenever possible only CE marked medical devices are used.
2. The PR should ensure that witnessing is recorded in the patients' record at all critical points of the clinical and laboratory process.

'Other' areas of non-compliance or poor practice that require improvement

3. The PR should ensure that the witnessing standard operating procedure (SOP) includes the witness step at the time of insemination.
4. Where a sperm sample is produced at home, this must be recorded in the gamete provider's records.

The ELP is asked to note that there are two areas of practice where progress has been made, that still require full implementation:

Major areas of non compliance

1. The PR should ensure that the centre has established a written agreement with those third parties who provide goods that influence the quality and safety of gametes.

2. The PR should ensure that the welfare of the child (WoC) assessment is appropriately recorded by centre staff and that actions resulting from the centre's own audit of these processes are implemented.

Recommendation to the Executive Licensing Panel

The centre needs to make some improvements in order to ensure that the quality and effectiveness of the service it provides is in line with good practice. The inspection team is however satisfied that activities carried out at the centre are necessary in order to provide licensed treatment services.

The inspection team recommends the renewal of the centre's 'treatment' only licence for a period of four years without additional conditions subject to compliance with the recommendations made in this report being implemented within the agreed 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 and eggs) and embryos 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 (Guidance note 18)

What the centre does well.

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

What the centre could do better.

It is important to record that the patient and partner's sample are positively identified prior to the procedure. Discussion with staff and a review of patient records did confirm that a check of the patient and sample does take place at the time of insemination. However, the centre's witnessing SOP does not include the requirement to document the witnessing step at the time of insemination with partner sperm prepared in the laboratory. Standard Licence Condition (SLC) T33b. See recommendation 6.

An audit of 10 witnessing records conducted on inspection showed that in one instance the record of witnessing steps was incomplete. The signature of the witness at the time of insemination was missing. SLC T71. See recommendation 4.

Patient and Donor selection criteria and laboratory tests

- Screening of patient and / or donors prior to procuring, processing and / or transporting gametes and embryos (Guidance notes 11 and 15)
- Payments for Donors (Guidance note 13)
- Donor assisted conception (Guidance note 20)

What the centre does well.

Screening of patients and / or donors

The centre's procedures for screening patients and patient partners are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment and the processing of gametes.

Payments for donors
The centre does not recruit donors and this area of practice is not applicable to this inspection.

Donor assisted conception
The centre does not provide treatment with donor gametes and this area of practice is not applicable to this inspection.

What the centre could do better.

Staff reported that on rare occasions, a partner may produce his sample at home; the sperm sample is then brought to the centre for preparation for insemination. This is not currently recorded in the patient / partner's medical record. SLC T68.
See recommendation 5.

Good clinical practice

What the centre does well.

Multiple births (Guidance note 7)
The centre does not provide treatment involving the transfer of embryos and this area of practice is not applicable to this inspection.

Process Validation (Guidance note 15)
The centre has fully validated all critical processing procedures to ensure that these procedures are effective and do not render the gametes clinically ineffective or harmful to the recipient.

Traceability (Guidance note 19)
The centre's traceability procedures are compliant with HFEA requirements and ensure that the centre can:

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

Quality management system (Guidance note 23)
The centre has a quality management system in place that is compliant with HFEA

requirements. The centre uses its quality management system to ensure optimum outcomes and improve the quality and safety of the treatment and services it provides to patients.

Third party agreements (Guidance note 24)
The centre has agreements in place which cover the supply of any goods and services which may affect the quality or safety of gametes, with the exception noted below.

Equipment and materials (Guidance note 26)
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 staff. With one exception noted below.

Premises (Guidance note 25)
The centre conducts all of the licensed activities in an appropriate environment, in line with good clinical practice. All diagnostic testing is carried out in a suitable accredited laboratory.

Adverse incidents (Guidance note 27)
The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all of the adverse incidents that have occurred and shares the lessons learned in order to continuously improve the services it offers.

What the centre could do better.

Third party agreements (Guidance note 24)
The centre has not established third party agreements (TPAs) with two suppliers of goods which may affect the quality or safety of gametes. SLC T111. See recommendation 1.

Equipment and materials (Guidance note 26)
The pipettes used by the centre are not CE marked. SLC T30. See recommendation 2.

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance note 1)
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

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 (PREP number T/1149/8).

Staff (Guidance Note 2)
The centre has suitably qualified and competent staff to carry out all of the licensed activities and associated services.

What the centre could do better.
Nothing noted at inspection.

Welfare of the Child (Guidance note 8)

What the centre does well.

The centre's procedures for taking into account the welfare of the child are partially compliant with HFEA requirements. The centre takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth.

What the centre could do better.

An audit of 10 patient records conducted on inspection showed that in one instance the patient had not signed the WoC assessment form to confirm an assessment had taken place. SLC T46e.
Incomplete WoC documentation had been identified during the centre's own record keeping audit, and corrective action had been identified but not yet implemented. SLC T36. See recommendation 3.

Embryo Testing

- Preimplantation genetic screening (Guidance note 9)
- Embryo testing and sex selection (Guidance note 10)

What the centre does well.

The centre does not undertake embryo testing and this area of practice is not applicable to this inspection.

What the centre could do better.
Nothing noted on inspection.

2. The experience of patients

Patient feedback

What the centre does well.

During the inspection visit the inspectors spoke with three patients who provided feedback on their experiences. A further 19 patients provided written feedback directly to the HFEA in the time since the last inspection. Feedback was very positive with all 19 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 a friendly and supportive service.

What the centre could do better.

Nothing noted on inspection.

Treating patients fairly

What the centre does well.

Egg sharing arrangements (Guidance note 12)

The centre does not undertake egg sharing and this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)

The centre does not undertake surrogacy and 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. The centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Treating patients fairly (Guidance note 29)

The centre treats prospective and current patients fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)

The provision of a counselling service is not mandatory for patients undergoing IUI, however the centre does offer counselling by qualified staff on request.

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 well being of prospective and current patients.

What the centre could do better.
Nothing noted on inspection.

Information

What the centre does well.

The centre's procedures for providing information to patients are compliant with 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.

Provision of costed treatment plans (Guidance note 4)
The centre provides NHS funded treatments only and this area of practice is not applicable to this inspection.

What the centre could do better.
Nothing noted on inspection.

Consent

What the centre does well.

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
The centre does not provide any patient identifying information to the HFEA register and this area of practice is not applicable to this inspection.

What the centre could do better.
Nothing noted on 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; this area of practice is not applicable to this inspection.

What the centre could do better.

Storage of gametes and embryos

What the centre does well.

The centre does not store gametes or embryos; this area of practice is not applicable to this inspection.

What the centre could do better.

Distribution and / or receipt of gametes and embryos

What the centre does well.

The centre does not distribute or receive gametes or embryos; this area of practice is not applicable to this inspection.

What the centre could do better.

Use of embryos for training staff

What the centre does well.

The centre does not create or store embryos and this area of practice is not applicable to this inspection.

What the centre could do better.

4. Information management

Record keeping and submitting information to the HFEA

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)
Centres providing basic partner treatment services only are only required to submit an annual return to the HFEA providing details of the number of treatments provided and the outcomes of those treatments. This enables the HFEA to satisfy their statutory reporting responsibilities and to provide information to patients via the HFEA website about centres' success rates.

The centre has submitted an annual return for treatments performed in 2012.

What the centre could do better.
Nothing noted in inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2011, recommendations for improvement were made in relation to three areas of major non-compliance and two 'other' areas of non-compliance.

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

Section 4: 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, 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 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, donor, embryo 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			

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 Third Party Agreements The centre has not established a TPA with two suppliers of goods that influence the quality and safety of gametes. SLC T111.	The PR should ensure that relevant TPAs are established with these suppliers by 23 November 2013. A copy of the TPAs may be requested by the centre's inspector after this date.	Contact has been made to the suppliers and TPA has been asked to be provided asap. A template has been sent for them to fill in and return.	Progress has been made by the centre in contacting the suppliers and sending a TPA to be signed, one supplier has acknowledged this, and agreed to return the signed document before August 2013. Further action required - Both TPAs need to be signed and returned to the centre.
2 Equipment and materials The pipettes used by the centre are not CE marked. SLC T30.	Wherever possible only CE marked medical devices should be used. The PR should respond with an action plan to address this before the report goes to the ELP	It has been discussed with the laboratory. The pipettes used do not have a CE mark but are good quality and has been used since the inception of the unit. This has not made any	The availability of CE marked pipettes has been discussed with the PR. No further action required.

	meeting. The actions agreed should be implemented by 23 November 2013 and the centre's inspector should be informed that this has happened.	impact on the results of the IUI procedures within the unit. The personnel are reasonably reassured that continued use of them will not in any way impact on the results. It was recognised that HFEA do not make it mandatory that CE marked pipettes has to be used. However, it will be looked into whether there is availability and if it is, every effort will be made to procure CE marked pipettes.	
3 WoC record keeping An audit of 10 patient records conducted on inspection showed that in one instance the patient had not signed the WoC assessment form. The centre's own audit identified an action required relating to documentation but this action had not been implemented. SLC T46e and SLC T36.	The PR should review the practice for ensuring that WoC assessments are documented, and an assessment is conducted in all cases prior to treatment being offered. The outcome of that review and confirmation that actions identified as a result of the centre's own WoC audit have been implemented should be provided to the centre's inspector. To determine whether this is a significant issue, and that corrective actions have been	The importance of WOC record keeping has been discussed with the team. Continued audit after every 10 completed IUI cases will identify if improvement in signing of WOC documents has been achieved. This will be fed-back to the team in the local bi-monthly meeting.	Staff at the centre have been made aware of the importance of welfare of the child documentation. An audit has been commenced, and outcomes will be shared with the centre's inspector later in the year. Further action required – to share the audit findings, including any corrective actions identified and implemented.

	effective, the centre should audit a further set of 20 records and send the audit summary and any corrective action to the centre's inspector by 23 March 2014.		
4 Witnessing documentation An audit of 10 witnessing records conducted on inspection showed that in one instance the record of witnessing steps was incomplete. The signature of the witness at the time of insemination was missing. SLC T71.	The PR should take immediate action to ensure that witnessing is completed and recorded at all critical points of the clinical and laboratory process. The HFEA should be advised of the measures taken to ensure that this happens by the time this report is considered by the ELP. Immediately.	The existing SOP has been amended and will be implemented with immediate effect. Changed documentation has been sent to the HFEA inspector for her perusal. Continued audit policy has been instituted to inform the unit whether improvement in witnessing signing documentation has been achieved.	A copy of the amended witnessing SOP with the requested changes has been seen. The outcome of the next witnessing audit by the unit will determine any additional work required. No further action 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
5 Gamete provider Where sperm is produced at home the centre does not	The PR should ensure with immediate effect, in the rare event that where a partner	The existing SOP has been amended to inform where the sperm has been produced. A	A copy of the amended SOP and a copy of the disclaimer have been seen, and contain

record this in the gamete provider's records. SLC T68.	produces their sample for insemination at home, there is a mechanism in place which ensures this is recorded in the patient / partner record. The centre's inspector should be advised of the measures taken to ensure that this happens by the time this report is considered by the ELP. Immediately.	Disclaimer has also been introduced in this regard. Changed documentation has been sent to the HFEA inspector for perusal.	the requested changes. No further action required.
6 Witnessing SOP The witnessing SOP does not include the requirement to document the witness step at the time of insemination. SLC T33b.	The PR should ensure that the witnessing SOP reflects the requirement to witness the identity of the patient and her partner's gametes immediately prior to insemination. A copy of the revised SOP should be provided to the centre's inspector. By 23 August 2013.	The existing SOP has been amended and will be implemented with immediate effect. Changed documentation has been sent to the HFEA inspector for her perusal.	A copy of the amended SOP with the requested changes has been seen. No further action required.
Reponse from the Person Responsible to this inspection report			

All areas of non-compliance have been addressed and necessary documentation forwarded to the HFEA inspector. There is a policy of continuing audit that will be carried out independently by the clinical effectiveness team throughout the year. This will regularly feed-back the personnel in the local AFU meetings that are held every two months.

HFEA Executive Licensing Panel Meeting

16 August 2013

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 2

Centre 0287 – (Ayrshire Fertility Unit) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy and Communications (Chair)	Rebecca Loveys
Jasper Squire – Computer Programmer	Observing:
Matthew Watts – Regulatory Policy Manager	Sam Hartley – Head of Governance and Licensing

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this is a small centre which provides intrauterine insemination (IUI) and has been licensed since 2007.

2. The Panel noted that the centre is on a four year licence due to expire in November 2013 and that the renewal inspection took place on 23 May 2013.

3. The Panel noted that for 2012 the centre reported 114 cycles of partner insemination with seven pregnancies, and that this equates to a 6% clinical pregnancy rate that is consistent with the national average.

4. The Panel noted that, at the time of inspection, four major and two other areas of non-compliance were identified.

5. The Panel noted that, since the time of inspection, two major and two other areas of non-compliance have been addressed by the PR.

6. The Panel noted the major area of non-compliance concerning Welfare of the Child (WoC) assessments, and stressed the importance of addressing this.

7. The Panel noted that the Inspectorate recommends granting a four year licence with no additional conditions.

Decision

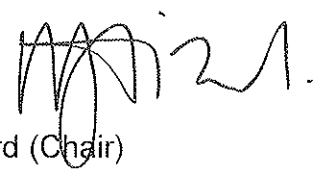
8. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

9. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities.

10. The Panel was satisfied that the licence renewal application concerns treatment or non-medical fertility services which relate to gametes intended for human application.

11. The Panel was satisfied that the premises to be licensed are suitable for the conduct of licensed activities based on the evidence in the report.

12. The Panel endorsed the Inspectorate's recommendations and timescales in the report. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions.

Signed:  Date: 21 August 2013

Juliet Tizzard (Chair)