# HFEA Executive Licensing Panel Meeting

**18 October 2013**

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

## Minutes – Item 1

**Centre 0170 – (Gateshead Fertility Unit) – Renewal Treatment & Storage Inspection Report**

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| **Members of the Panel:**<br>Juliet Tizzard – Head of Policy & Communications (Chair)<br>Joanne Anton – Policy Manager<br>Hannah Verdin – Senior Policy Manager | **Committee Secretary:**<br>Dee Knoyle<br>**Observing:**<br>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 considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a treatment and storage centre which provides a full range of licensed treatments. The Panel noted that in relation to activity levels this is a medium-sized centre.

3. The Panel noted that the centre has been licensed by the HFEA since 1996. The Panel noted that the centre is on a five-year licence, issued on 14 January 2009 and due to expire on 31 December 2013.

4. The Panel noted that the premises have not undergone any changes since the last interim inspection in July 2011, and there have been no changes to the licence since it was last issued.

5. The Panel noted that the centre reported 575 cycles of treatment in the 12 months to 30 June 2013. For the period April 2012 to March 2013, HFEA-held register data shows that the centre's success rates are in line with national averages, except for the centre's clinical pregnancy rates following ICSI in patients aged less than 38 years. In these patients, pregnancy rates are lower than the national average at a statistically significant level. Between 31 March 2013 and 31 July 2013, the centre's clinical pregnancy rates following IVF in patients aged less than 38 are consistent with the national average.

6. For 2012, the centre reported 82 cycles of partner insemination with five pregnancies. This equates to a six per cent clinical pregnancy rate which is consistent with the national average.

7. Between 1 April 2010 and 31 March 2011, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 23%. This represented performance that was not likely to be statistically different from the 20% maximum multiple birth rate target for this period.

8. Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 19%. This represented performance that was not likely to be statistically different from the 15% maximum multiple live birth rate target for this period.

9. The Panel noted that at the time of the inspection on 24 and 25 July 2013, the Inspectorate identified a number of areas of practice that required improvement, including three major and six other areas of non-compliance. The Panel noted that, since the inspection, the centre has provided evidence that some of the recommendations for improvements have been fully implemented subject to the submission of the audit reports at a later date.

10. The Panel noted the PR's commitment to implement the outstanding recommendations within the set timescales.

11. The Panel noted the Inspectorate's recommendation that some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides. The Panel, in particular, noted the non-compliances relating to record keeping and data submission.

12. The Panel noted the Inspectorate recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

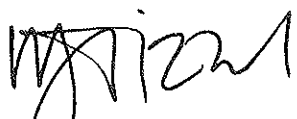
**Decision**

13. 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.

14. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and that he has discharged his duty under section 17 of the HF&E Act 1990 (as amended).

15. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

16. The Panel endorsed the Inspectorate's recommendation to renew the centre's Treatment and Storage licence for four years, without additional conditions, subject to compliance with the recommendations made in this renewal inspection report being implemented within the prescribed timescales.

Signed:  Date: 1 November 2013

Juliet Tizzard (Chair)

# 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 and donors. 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:** 24 and 25 July 2013
**Purpose of inspection:** Renewal of a licence to carry out 'Treatment and Storage'

## 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:** 18 October 2013

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| **Centre name** | The Gateshead Fertility Unit |
| **Centre number** | 0170 |
| **Licence number** | L/0170/10/c |
| **Centre address** | Gateshead Health NHS Foundation Trust<br>Queen Elizabeth Hospital<br>Sheriff Hill<br>Gateshead Tyne & Wear<br>NE9 6SX |
| **Person Responsible** | Mr Ian Aird |
| **Licence Holder** | Gateshead Health NHS Foundation Trust |
| **Date licence issued** | 14 January 2009 |
| **Licence expiry date** | 31 December 2013 |
| **Additional conditions applied to this licence** | None |

# Contents

# Section 1: Summary report

**Brief description of the centre and its licensing history:**
The Gateshead Fertility Unit has held a licence with the HFEA since 1996 and provides a full range of fertility services.

The centre provided 575 cycles of treatment in the 12 months to 30 June 2013. In relation to activity levels this is a medium sized centre.

The centre has one transport centre, Hexham General Hospital centre 0277.

The current licence was granted in January 2009 for a period of four years. The premises have not undergone any changes in the time since the last interim inspection in July 2011, and there have been no changes to the licence since it was last issued.

**Activities of the centre:**

| Type of treatment | Number of treatment cycles for the period 01/07/12 – 30/06/13 |
|---|---|
| In vitro fertilisation (IVF) | 250 |
| Intracytoplasmic sperm injection (ICSI) | 171 |
| Frozen embryo transfer (FET) | 143 |
| Donor insemination (DI) | 11 |
| Egg donation (non egg share) | 2 |
| | **Number of treatment cycles for calendar year 2012** |
| Partner insemination | 82 |

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

## Outcomes*

For IVF and ICSI, HFEA held register data for the period April 2012 – March 2013 show the centre's success rates are in line with national averages, except for the centre's clinical pregnancy rates following ICSI in patients aged less than 38 which are lower than the national average at a statistically significant level. Between 31 March 2013 and 31 July 2013 the centre's clinical pregnancy rates following IVF in patients aged less than 38 are consistent with the national average.

In 2012, the centre reported 82 cycles of partner insemination with five pregnancies. This equates to a six per cent clinical pregnancy rate which is consistent with the national average.

Between 1 April 2010 and 31 March 2011, the centre's multiple clinical pregnancy rate** for all IVF, ICSI and FET cycles for all age groups was 23%: this represented performance that was not likely to be statistically different from the no greater than 20% multiple live birth rate target for this period.

Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy** rates for all IVF, ICSI and FET cycles for all age groups was 19%: this represented performance that was not likely to be statistically different from the no greater than 15% multiple live birth rate target for this period.

*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 $P \leq 0.002$.

**[2]The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

## 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 three major, and six 'other' areas of non-compliance or poor practice.

Since the inspection visit the PR has confirmed that the following recommendations have been implemented, subject to the submission of the audit reports at a later date.

**Major areas of non compliance:**

- The PR should ensure that corrective actions have been documented and implemented following an audit of the centre's activities.

- The PR should ensure that Welfare of the Child (WoC) forms are correctly completed in the patient records.

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

- The PR should ensure that the centre carries out additional testing depending on the patient's travel history and known disease exposure.

- The PR should review systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms.

- The PR should ensure that donor goodwill messages and pen portraits are submitted to the HFEA in accordance with form guidance.

- The PR should ensure that all licenced treatment activity is reported to the Authority within the timeframe required by Direction 0005.

The PR has given a commitment to fully implement the following recommendations:

**Major areas of non compliance:**

- The PR should ensure that whenever possible only CE marked medical devices are used.

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

- The PR should ensure that the centre has a procedure that defines the responsibilities and actions required when cryopreserved material has to be recalled.

- The PR should ensure that all staff at the centre participate in an annual staff appraisal with their line manager, where the opportunity to discuss relevant professional development is provided.

## Recommendation to the Executive Licensing Panel

Some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides. The inspection team is

however satisfied that activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The inspection team recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to compliance with 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 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) |
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| What the centre does well.<br><br>The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos. |
| What the centre could do better.<br><br>Nothing noted on inspection. |

| ▶ **Patient and donor selection criteria and laboratory tests**<br>• Screening of patient and / or donors prior to procuring, processing and / or transporting gametes and embryos (Guidance notes 11 and 15)<br>• Payments for donors (Guidance note 13)<br>• Donor assisted conception (Guidance note 20) |
|---|
| What the centre does well.<br>**Screening of patients and / or donors**<br>The centre's procedures for screening patients and donors are broadly compliant with HFEA requirements. It is important that gamete providers are appropriately screened to |

minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

**Payments for donors**
Payments to donors are fully in line with the requirements of the HFEA. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

**Donor assisted conception**
People born as a result of donation are entitled to request and receive their donor's name and last known address, once they reach the age of 18. Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre is compliant with the requirements of the HFEA to ensure the donor conceived will be able to receive this information.

What the centre could do better.
**Screening of patients and / or donors**
The centre does not carry out additional testing depending on the patient's travel history and known disease exposure. (e.g., Rh D, Malaria, T.cruzi). Standard Licence Condition (SLC). T50(d) See recommendation 4.

## Good clinical practice

**What the centre does well.**

**Multiple births (Guidance note 7)**
The single biggest risk of fertility treatment is a multiple pregnancy.

The progress in reducing the clinical multiple pregnancy rates suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target.

**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 or embryos clinically ineffective or harmful to the recipient.

**Traceability (Guidance note 19)**
The centre's procedures are compliant with HFEA requirements to ensure it has the ability -
(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
(b) to identify the donor and recipient of particular gametes or embryos,

(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and
(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

**Quality management system (Guidance note 23)**
The centre has a quality management system in place that is partially 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 an agreement in place which covers the:
(a) procurement, testing or processing of gametes or embryos on behalf of the licensed centre, or
(b) supply of any goods or services (including distribution services) to the licensed centre which may affect the quality or safety of gametes and embryos.

**Satellite and transport centre management (Guidance note 24)**
The centre has one transport agreement with Hexham General Hospital (centre 0277) which is compliant with HFEA requirements. The centre has no satellite arrangements.

**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/or staff, with the 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.

**Quality management system (Guidance note 23)**
Corrective actions have not been documented and implemented following audit of the following activities (SLC T36);
Consent to treatment.
Welfare of the child.
Procedures for the submission of data to the HFEA.
Audit in all the above areas had been completed in the last two years, but the corrective actions had still to be addressed, this was an oversight by the centre.

Audit of the following area had not been undertaken in the last two years.
Procurement and processing procedures.
See recommendation 1.

**Equipment and materials (Guidance note 26)**
The ICSI dishes and the pipettes used by the centre are not CE marked, where available CE marked products should be used. 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/1085/7).

**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.
**Staff (Guidance Note 2)**
Not all staff at the centre participate in an annual staff appraisal with their line manager. This is important to determine that the relevant professional development is provided. SLC T15 (CoP 2.1). See recommendation 6.

## 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

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| 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.<br>An audit of 10 patient records conducted on inspection showed that in four instances the WoC assessment form was incomplete or incorrectly completed; no form gave rise to WoC concerns. SLC T46(e) See recommendation 3. |

## 2. The experience of patients

### Patient feedback

What the centre does well.

During the inspection visit the inspectors spoke to three patients who provided feedback on their experiences. A further 33 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 31 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;
- provides a friendly and professional service.

What the centre could do better.

Nothing noted on inspection.

### Treating patients fairly

What the centre does well.

**Gamete 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's procedures for treatment involving surrogacy are compliant with HFEA requirements to ensure that the arrangement is legal and protects the rights of the surrogate and the commissioning couple. Patients providing gametes in surrogacy arrangements are screened as donors in order to safeguard the health of the surrogate.

**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 and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

**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 and donors.

**Counselling (Guidance note 3)**
The centre's counselling staff and procedures are compliant with HFEA requirements, ensuring that counselling support is available to patients before and during the consenting process and treatment.

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 and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

**Provision of a costed treatment plan (Guidance note 4)**
The centre provides an individual costed treatment plan to its self funded patients. This ensures that patients know the full cost of their proposed treatment before deciding on whether to proceed or not.

What the centre could do better.
Nothing noted on inspection

## Consent

What the centre does well.

**Consent**
Compliant consent procedures ensure that patients and donors have provided all relevant consents before carrying out any licensed activity.
The centre's procedures for obtaining consent are compliant with HFEA requirements.

**Disclosure of information, held on the HFEA Register, for use in research**
The Register started operating in August 1991 and is a rich source of information about assisted reproductive technologies (ART), its outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA is permitted to disclose non-identifying information to researchers it can only

provide identifying information with the consent of patients. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA. The centre's procedures for doing this do not ensure that the HFEA holds an accurate record of the patients consent, so that it only releases the patients identifying information, to researchers, with their consent.

What the centre could do better.

**Disclosure of information, held on the HFEA Register, for use in research**
Discrepancies were found between three of 20 patient and partner disclosure consents found on the patient files and related data submitted by the centre for inclusion on the register. At the time of the inspection feedback session staff confirmed that they took the consent data from the handwritten patient and partner registration forms rather than the signed Disclosure Consent forms on file. In these circumstances, where the former differ from the latter there will also be a discrepancy between the disclosure consent and the data submitted to the register.
Chair's Letter CH(10)05. Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007.
See recommendation 7.

## 3. The protection of gametes and embryos

### Respect for the special status of the embryo

What the centre does well.

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- Licensed activities only take place on licensed premises.
- Only permitted embryos are used in the provision of treatment services.
- Embryos are not selected for use in treatment for social reasons.
- Embryos are not created by embryo splitting.
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman.
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

The centre has stated on their application form that they are intending to start freezing blastocysts, and had considered the additional staff training required. The centre currently performs vitrification of the embryo and will adopt a similar process.

What the centre could do better.

Nothing noted on inspection.

### Storage of gametes and embryos

What the centre does well.

The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers.

What the centre could do better.

Nothing noted on inspection.

### Distribution and / or receipt of gametes and embryos

What the centre does well.

The centre's procedures for distributing and / or receiving gametes and embryos are broadly compliant with HFEA requirements. This ensures that all gametes / embryos sent to other licensed centres within or outside the UK are appropriately labelled and relevant information is sent to the other centre to ensure the continued quality and safety of the gametes and embryos. The centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in a way that does not comprise their quality and safety.

What the centre could do better.

The centre does not have a procedure that defines the responsibilities and actions required when cryopreserved material has to be recalled. SLC T33(b). CoP interpretation of mandatory requirements 15C. See recommendation 5.

**Use of embryos for training staff** (Guidance note 22)

What the centre does well.

The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

The centre uses embryos to train staff in the following activities:

- Cryopreservation and thawing techniques
- Vitrification
- Embryo handling and manipulation
- Assessment of embryos

All of these activities have been authorised by the Authority.

What the centre could do better.

Nothing noted on inspection.

## 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)**
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a result of their donation. In order to maintain this Register, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities, to the Authority are broadly compliant with HFEA requirements and ensure the HFEA can supply accurate information to a donor-conceived person and their parents.

What the centre could do better.

**Obligations and reporting requirements (Guidance note 32)**
A review of donor files identified three instances where goodwill messages and pen portraits had not been submitted to the HFEA in accordance with form guidance. SLC T9(e) / T41Direction 0005. See recommendation 8.

**Timelines of treatment reporting**
In the audit sample reviewed on inspection, it was found that 21% of IVF and 18% of DI treatments in the audit sample were reported outside the five working day period required by Direction 0005.
SLC T9(e) / T41. See recommendation 9.

## Section 3: Monitoring of the centre's performance

Following the interim inspection in 2011, recommendations for improvement were made in relation to four 'other' areas of non-compliance. The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

### On-going monitoring of success rates

In the last year, the centre has received no alerts from the HFEA Risk Tool regarding its treatment success rates.

For IVF and ICSI, HFEA held register data for the period April 2012 – March 2013 show the centre's success rates are in line with national averages, except for the centre's clinical pregnancy rates following ICSI in patients aged less than 38 are lower than the national average at a statistically significant level. There was a notable dip in the clinical pregnancy rate in this area alone, in February 2012. The centre reviewed their practice and found no cause for concern, but noted it had been an unusually busy month and the increased activity may have caused the results.
Between 31 March 2013 and 31 July 2013 the centre's clinical pregnancy rates following IVF in patients aged less than 38 are consistent with the national average.

## 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.Quality management system**<br>Corrective actions have not been documented and implemented following audit of the following activities;<br>• Consent to treatment.<br>• Welfare of the child.<br>• Procedures for the submission of data to the HFEA.<br>An audit had not been completed in the previous two year period for;<br>• Procurement and processing procedures. | The PR should document corrective actions from the three audits, and identify an implementation plan.<br><br>A summary report of actions taken by the PR should be provided to the lead inspector by 25 October 2013.<br><br>Procurement and Processing Audit to be conducted by November 2013. | All audits will now include a corrective action section to be completed as necessary.<br>The audits identified have now had corrective actions implemented (please see attached).<br>Procurement and Processing Audit had not been conducted at the time of the inspection. this is to be completed by November 2013. | The PR has taken action to ensure that all audits now have a corrective action section in the summary of the audit report, and that the corrective actions are implemented by the centre.<br><br>There is one outstanding audit to be completed and sent to the lead inspector by 25 November 2013. |

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| SLC T36 | | | |
| **2. Equipment and materials**<br>The ICSI dishes and 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 meeting.<br><br>The actions agreed should be implemented by 25 October 2013 and the centre's inspector should be informed that this has happened. | We are currently undertaking an inventory of all medical devices to ensure that, where possible, only CE marked equipment is used.<br>Where non CE marked equipment is identified an alternative CE marked product will be sought and costed. | The PR has taken action towards meeting the standard on CE marked equipment.<br>A further update will be requested, and full implementation is expected by 25 October 2013. |
| **3. Patient records- WoC.**<br>WoC forms were not correctly completed in patient records. An audit of 10 patient records conducted on inspection showed that in four instances the WoC assessment form was incomplete or incorrectly completed; no form gave rise to WoC concerns. SLC T46(e) | The PR should take immediate action to ensure that no treatments are provided before;<br>1. A WoC assessment form has been correctly completed.<br><br>The HFEA should be advised of the measures taken to ensure that this happens by the time this report is considered by a ELP.<br>The PR should undertake an audit of patient records to | All welfare of the child forms are now completed during the patients individual appointments and signed by clinical staff at that time.<br>All documentation is checked by nursing staff and then further reviewed by Laboratory staff prior to any treatment being conducted.An audit of patient consent forms is scheduled to be conducted at the beginning of October 2013 and the report submitted to the | To ensure that WoC forms are completed accurately, all patient records are checked twice prior to any treatment taking place.<br><br>An audit of WoC forms is planned, and the findings will be submitted to the lead inspector by 09 December 2013. |

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| | identify whether the inspection observations represent a systemic failure or a rare occurrence. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the lead inspector by 25 October 2013.<br><br>Within three months of the implementation of corrective actions, the centre should conduct an audit of WoC assessment procedures.<br>A summary report of the findings of the audit should be provided to the lead inspector. | Lead inspector<br><br>Welfare of the Child audit planned for November 2013 and report to be submitted to Lead Inspector by 09 December 2013 at the latest. | |

## 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 |
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| **4. Screening of patients and donors**<br>The centre does not carry out additional testing depending on the patient's travel history and disease exposure e.g, Rh D, Malaria, T.cruzi). SLC T50 (d) | The PR should take immediate action to ensure that procedures are established to identify when additional testing may be indicated and to develop procedures for carrying out additional testing. The HFEA should be advised of the measures taken to ensure that this happens by the time this report is considered by a ELP.<br>Within six months of the implementation of procedures, the centre should conduct an audit of screening and a summary report of the findings of the audit should be provided to the lead inspector, by 25 January 2014. | The current screening questionaire will be amended to include questions relating to recent foreign travel and disease exposure and where appropriate additional testing will be carried out. | The screening questionnaire has been amended.<br><br>The PR has been reminded that within six months of the implementation of procedures, the centre should conduct an audit of screening and a summary report of the findings of the audit should be provided to the lead inspector, by 25 January 2014. |
| **5. Recall procedure**<br>The centre does not have a procedure that defines the responsibilities and actions | It is acknowledged that recall is likely to be infrequent but in consideration that should a recall be necessary, staff | An appropriate SOP will be written to define the responsibilities and actions required when cryopreserved | The PR has agreed to send the SOP by 25 October 2013. |

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| required when cryopreserved material has to be recalled. SLC T33(b). CoP interpretation of mandatory requirements 15C. | should have clear instruction for how to proceed. The PR should ensure that a suitable procedure is established and a copy provided to the lead inspector by 25 October 2013. | material has to be recalled in line with the CoP mandatory requirements. This will be completed and forwarded to the lead inspector within the required time frame. | |
| **6. Staff appraisal.**<br>A group of staff had not had the opportunity to participate in an annual staff appraisal in the previous 12 months. SLC T15 (CoP 2.1) | The PR should ensure that all staff are able to participate in an annual appraisal with their line manager, to ensure that adequate opportunity for relevant professional development is provided.<br>An action plan for those staff that have not had an annual appraisal should be documented, and any corrective actions required to ensure compliance with the requirements and the timescale for the implementation.<br>A copy of the action plan should be provided to the lead inspector by 25 October 2013. | An action plan will be constructed to ensure that all staff are appraised at least annually. This particularly relates to laboratory staff and senior nursing staff.<br>The action plan will be forwarded to the lead inspector within the required time frame. | The PR has agreed to send the action plan for staff appraisal by 25 October 2013. |
| **7. Disclosure of information, held on the HFEA Register,** | The PR should review systems and processes to ensure that | Staff were entering details of disclosure consent from the | The PR has taken immediate action to address the |

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| **for use in research**<br>Discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the HFEA register.<br>Chair's Letter CH(10)05 Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007 | going forward, the patient and partner disclosure consent information supplied to the HFEA, accurately reflects that given and recorded on completed disclosure consent forms;<br><br>Conduct an audit six months after implementing any changes to confirm that any changes made to systems and processes are having the desired effect; and<br><br>Correct the submissions that have been identified as being incorrect. | registration forms before the initial consultation had taken place . This practice has now ceased and staff visualise the disclosure consent forms after consultation when the implications of disclosure of information have been discussed. The form is then then completed in line with the couples wishes.<br>Audit to be conducted January 2014 | discrepancies between completed patient/ partner disclosure consents on the patient files and related consent data on the HFEA register.<br><br>An audit is planned for January 2014 to ensure that the changes have improved the accuracy of reporting.<br><br>Those submissions identified as being incorrect have been corrected. |
| **8. Obligations and reporting requirements**<br>A review of donor files identified three instances where goodwill messages and pen portraits had not been submitted to the HFEA in accordance with form guidance. SLC T9(e) / T41 Direction 0005. | The PR should ensure that donor goodwill messages and pen portraits are submitted to the HFEA in accordance with form guidance, by 25 October 2013<br><br>Three months after the implementation of corrective actions the centre should audit a random sample of 10 sets of | The appropriate standard operating procedures relating to gamete donors will be amended to ensure that relevant staff are aware that donor pen portraits and goodwill messages are submitted to the HFEA.<br><br>Audit will be carried out as requested but as the unit does | The quality manager has been working with the HFEA register team post inspection to ensure that licensed treatments are reported within the agreed timeframe.<br><br>The SOP relating to donor pen portraits has been updated and shared with staff at the centre. |

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| | donor records (i.e. relating to donor registrations within the three months following the implementation of corrective actions) to ensure that this issue has been effectively addressed.<br><br>The PR must ensure that all licenced treatment activity is reported to the Authority within the timeframe required by Direction 0005.<br><br>The systems and processes used for licensed treatment data submission should be reviewed to enable the reasons for delayed submissions to be identified and addressed. This recommendation should be implemented by 25 October 2013. | not perform a large number of cycles involving donor gametes it is unlikely that 10 donors will be registered in the time frame specified frame<br><br>We will ensure that the appropriate systems and processes are reviewed to facilitate timely reporting of licenced treatment activity. Audit will be carried out to ensure compliance. | An audit is planned to review the submission of donor pen portraits to the HFEA, by 25 January 2014. |
| **9. Timelines of treatment reporting**<br>In the audit sample reviewed on inspection, it was found that | The PR must ensure that all licenced treatment activity is reported to the Authority within the timeframe required by | The unit has a new process to submit forms via IDEAS database this should ensure that form's are submitted in a | The PR is aware of the timeframe for data submission; post inspection the centre has contacted the register team |

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| 21% of IVF and 18% of DI treatments were reported to the HFEA outside the five working day period required by Direction 0005.<br>SLC T9(e) / T41 | Direction 0005.<br><br>The systems and processes used for licensed treatment data submission should be reviewed to enable the reasons for delayed submissions to be identified and addressed. This recommendation should be implemented by 24 October 2013. | timely fashion .<br>HFEA portal will be used as a tool to ensure any missing forms are actioned as soon as possible. | and ensured that all missing data has now been submitted. |
| **Reponse from the Person Responsible to this inspection report** | | | |
| I am satisfied that the report reflects an accurate representation of the information discussed after the last inspection, thank you. | | | |