Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
7 May 2015

Minutes – item no. 1

Centre 0276 (Reproductive Medicine Clinic, Bristol) – Renewal Inspection Report

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Nick Jones Director of Compliance & Information Ian Peacock Analyst Programmer
Members of the Executive in attendance:	Sam Hartley Head of Governance & Licensing Dee Knoyle Committee Secretary

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:

- HFEA protocol for the conduct of meetings of the 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 the 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 the publication of Authority and committee papers

Consideration of application

1. The panel considered the papers, which included an application form, inspection report and licensing minutes for the past three years.

2. The panel noted that this is a treatment only centre which provides intrauterine insemination (IUI). The panel noted that in relation to activity levels this is a small centre.

3. The panel noted that the centre has been licensed by the HFEA since 2007 and is on a four-year licence due to expire on 30 June 2015.

4. The panel noted that in 2013, the centre reported 66 cycles of partner insemination with 16 pregnancies. This was consistent with the national average. The panel noted that the centre reported one twin and one triplet pregnancy which equates to a 12.5% multiple clinical pregnancy rate.

5. The panel noted that at the time of the inspection on 20 January 2015, the Inspectorate identified three major and four other areas of non-compliance. The panel noted that since the inspection the Person Responsible (PR) has fully implemented two of the recommendations and has committed to fully implementing all of the recommendations within the prescribed timescales.

6. The panel noted that some improvement is required in order for the centre to demonstrate suitability of its practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use this to best effect to monitor and improve the service provided.

7. The panel noted that the Inspectorate recommends the renewal of the centre's treatment licence for a period of four years without additional conditions.

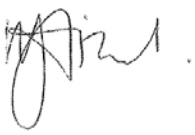
Decision

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 licenced activities, and the PR has discharged their duty under section 17 of the HF&E Act 1990 (as amended).

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

11. The panel endorsed the Inspectorate's recommendation to renew the centre's treatment licence for a period of four years without additional conditions.



Signed: Date: 12 May 2015
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: 20 January 2015

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: Karen Conyers (lead), Susan Jolliffe

Date of Executive Licensing Panel: 7 May 2015

Centre name	Reproductive Medicine Clinic, Bristol
Centre number	0276
Licence number	L/0276/3/b
Centre address	Level D, St Michael's Hospital, Southwell Street, Bristol, BS2 8EG,
Person Responsible	Dr David Cahill
Licence Holder	Dr Jacqui Cornish
Date licence issued	01 July 2011
Licence expiry date	30 June 2015
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Reproductive Medicine Clinic Bristol is located within St. Michael's Hospital, which is part of University Hospital Bristol, NHS Foundation Trust and has held a 'Treatment (Insemination using partner sperm)' licence with the HFEA since 2007.

The centre provides partner intrauterine insemination treatment (IUI) only. The centre does not have facilities on site for the analysis or preparation of semen for use in treatment and this service is provided by the Bristol Centre for Reproductive Medicine (HFEA licensed centre 0295) nearby. The male partner attends centre 0295 to produce a sample of gametes and following preparation for insemination, the sample is transported back to the Reproductive Medicine Clinic by the patient(s) where the insemination is performed.

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

Since the inspection visit the Person Responsible (PR) has submitted an application for a change of Licence Holder (LH) to the person whom he has named on the licence renewal application form. The application for change of LH was submitted to ELP on 27 March 2015.

Pregnancy outcomes

In 2013, the centre reported 66 cycles of partner insemination with 16 pregnancies. This equates to a clinical pregnancy rate of 24% which is consistent with the national average. The centre reported 1 twin and 1 triplet pregnancy which equates to a 12.5% multiple clinical pregnancy rate. Centres providing IUI treatment only are not subject to the requirements of the HFEA General Direction 003 concerning multiple births. However the PR is committed to minimising the multiple birth rates and keeps these rates under review as part of the centre's quality objectives.

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 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 three major and four 'other' areas of non-compliance.

Since the inspection visit, the following recommendations have been fully implemented:

Major areas of non compliance:

- The PR should conduct a review of the efficacy of the centre's quality management system (QMS) with regard to the process of auditing.

'Other' areas that requires improvement:

- The PR should ensure that standard operating procedures (SOPs) are in place to fully describe all current practices.

Since the inspection the PR has given a commitment to fully implement all the following recommendations in the prescribed timescales:

Major areas of non compliance:

- The PR should ensure that all diagnostic tests are carried out by laboratories which are accredited by Clinical Pathology Accreditation (UK) (CPA) or another body accrediting to an equivalent standard.
- The PR should ensure that relevant data about all items coming into contact with gametes is traceable.

'Other' areas that requires improvement:

- The PR should review current practice to ensure that the disposal of sperm is documented for traceability purposes.
- The PR should audit the centre's compliance with regulatory requirements, approved protocols and quality indicators.

- The PR should ensure that the assessment of competence of staff to perform their designated tasks is evaluated and documented.

Recommendation to the Executive Licensing Panel

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

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

The inspection team 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.

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

What the centre does well

Witnessing (Guidance note 18)
It is important that the centre has procedures to ensure patients receive treatment using the correct gametes. The centre has procedures for double checking the identification of gametes and the patient to whom they relate, and these are compliant with HFEA requirements.

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 provide treatment with donor gametes therefore this area of practice is not applicable to this inspection.

What the centre could do better

Nothing identified at 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
Procurement of gametes
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.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients or their partners, or their gametes or any material removed from them, are partially 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 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)
Centres providing IUI treatment only are not subject to the requirements of the HFEA General Direction 003 concerning multiple births.

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's processes for the receipt of the prepared sperm samples from 0295 are compliant with the relevant HFEA requirements.

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

Traceability (Guidance note 19)
The centre's procedures are partially 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 the donor and recipient of particular gametes,
- 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 partially 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 does not have any critical equipment that requires validation, servicing or monitoring therefore this area of practice is not applicable to this inspection.

Process validation (Guidance note 15)
The centre does not perform any critical processing procedures therefore this area of practice is not applicable to this inspection.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. 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

Laboratory accreditation (Guidance note 25)
The PR had not evaluated the accreditation status of all the laboratories which are used for diagnostic semen analyses, blood screening tests or for test results provided by external referrers (SLC T51a; see recommendation 1). During the inspection the PR was able to provide evidence that one of the laboratories used to perform blood screening tests was accredited by the CPA.

Traceability (Guidance note 19)
The laboratory sheet documenting information about equipment and consumables used during sperm processing for traceability purposes is provided to the centre with the sperm sample, but in two of five records audited there was no record of the centrifuge (one record) or products (one record) that had been used during the sample preparation procedure. This means that the centre has not ensured that relevant data about all items identified as coming into contact with gametes is traceable (SLC T99; see recommendation 2).

The centre was unable to provide evidence that in all cases gametes are traceable from procurement of gametes to patient treatment or disposal and vice versa. In two of five records audited there was no record of the disposal of sperm (SLC T99; see recommendation 4).

Quality management system (QMS) (Guidance note 23)
The centre does have a quality management system but corrective actions resulting from audits are not always clearly identified and documented, and in one case there was no record of the implementation of any corrective actions (SLC T36; see recommendation 3).

In the last two years the centre has not effectively audited their compliance against regulatory requirements and their own approved protocols and quality indicators (SLC T36; see recommendation 5).

There is no SOP for the screening of patients and their partners, and the SOPs in place for traceability and witnessing did not fully describe current practices (SLC T33b; see recommendation 6).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has largely complied with HFEA requirements.

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 (T/1123/7).

Staff (Guidance note 2)
The centre is broadly 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

Staff (Guidance note 2)
The PR could not provide documentation of the assessment of competence for relevant staff involved in welfare of the child assessment and in maintaining traceability (SLC T12 and T15a; see recommendation 7).

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 inspectors were unable to speak to any patients as none were in the centre on the day of the inspection. Since the last inspection seven patients provided feedback directly to the HFEA. Four of the individuals provided written feedback with compliments about the staff and the care that they received.

The centre does encourage patient feedback, and was able to provide a copy of their own patient questionnaire completed by 24 patients in 2014. This report also contained positive feedback from patients.

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 only basic partner treatment services and is not therefore subject to the counselling requirements of schedule 3: therefore this area of practice is not

applicable to this inspection.

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 and donors.

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients 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.

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 and donors 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)
The HFEA does not hold any information about patient's IUI treatments therefore this area of practice is not applicable 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 to minimise the risks of cross infection during treatment and processing of gametes.

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 treatments undertaken in 2013 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 2013, 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, although it is noted in this report that the centre is again non-compliant in relation to documentation of corrective actions following audits.

On-going monitoring of centre success rates

As this centre only provides IUI partner treatment, their 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, 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 identified		Nil to add	

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. The PR had not evaluated the accreditation status of all the laboratories which are used for diagnostic semen analyses, blood screening tests or for test results provided by external referrers. During the inspection the PR was able to provide evidence that one of the laboratories used to perform blood screening tests was accredited by the CPA. SLC T51a.	The PR should ensure that all diagnostic tests are carried out by laboratories which are appropriately accredited. The PR should review the accreditation status of all laboratories which provide test results either directly or through the referral pathway. A summary of the findings of this review, any corrective actions identified and timescales for implementation should be provided to the centre's inspector by 20 April 2015.	This was partly addressed during the visit and is part of my action pklan to address issues raised at the visit. It will be addressed in writing by April 20th.	The PR provided the findings of the review of the laboratory used for patient's virology screening testing together with evidence of the laboratory's CPA accreditation status. The PR is reminded that the recommendation also included a review of the accreditation status of laboratories used for diagnostic semen analyses and/or for test results provided by external referral pathways. The findings of this review should be submitted to the HFEA by 20 May 2015.

			Further action is required.
2. The laboratory sheet documenting information about equipment and consumables used during sperm processing for traceability purposes is provided to the centre with the sperm sample, but in two of five records audited there was no record of the centrifuge (one record) or products (one record) that had been used during the sample preparation procedure. This means that the centre has not ensured that relevant data about all items identified as coming into contact with gametes is traceable. SLC T99.	The PR should ensure that relevant data about all items coming into contact with gametes is traceable. The centre's inspector should be advised of the measures taken to ensure that this happens by the time the PR responds to this report. Within three months of the implementation of corrective actions, the centre should conduct an audit of traceability of all equipment and consumables and a summary report of the findings of the audit should be provided to the centre's inspector by 20 July 2015.	Within 24 hours, I had written to BCRM to alert them to this. They have taken action to do so and we will audit this in May, and present the results to the team meeting in June and reply to you by July.	The Executive acknowledges the PR's response confirming that immediate actions were taken, and his commitment to fully implementing this recommendation. Further action is required in relation to completion of the audit due by 20 July 2015.
3. The centre does have a quality management system but corrective actions resulting from audits are not always	The PR should review the efficacy of the centre's QMS with regard to the process of auditing. In particular the review should consider the	We recognise this area and are addressing this. We will update you by April 20th	The PR provided the findings of the review of the efficacy of the centre's QMS including evaluation of all corrective actions from previous audits.

clearly identified and documented, and in one case there was no record of the implementation of any corrective actions. SLC T36. **This was identified as a non-compliance at the last inspection.**	recording of corrective actions to ensure that these are clearly documented and that systems are in place to ensure that timescales for implementation can be monitored and managed. The PR should also review the findings of the audits for which there was no documentation of corrective actions and ensure that any outstanding actions are documented and implemented. A summary of the findings of this review including any corrective actions identified and timescales for implementation should be provided to the centre's inspector by 20 April 2015.		The review included corrective actions and timescales for implementation. No 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
4. The centre was unable to provide evidence that in all cases gametes are traceable from procurement of gametes to patient treatment or disposal and vice versa. In two of five records audited there was no record of the disposal of sperm. SLC T99.	The PR should review current practice to ensure that the disposal of sperm is documented for traceability purposes. A summary of the findings of this review including any corrective actions identified timescales for implementation and staff training to be provided should be submitted to the centre's inspector by 20 April 2015. The PR should conduct an audit six months after the implementation of any changes to practices and forward a summary of the audit to the centre's inspector by 20 October 2015.	We will comply with this.	The PR provided a summary of the review of practices to ensure documentation of the disposal of sperm for traceability purposes including corrective actions taken. Further action is required in relation to the completion of the audit due by 20 October 2015.
5. In the last two years the centre has not effectively audited their compliance	The PR should audit the centre's compliance with regulatory requirements,	We will comply with this	The Executive acknowledges the PR's response and commitment to fully

against regulatory requirements and their own approved protocols and quality indicators. SLC T36.	approved protocols and quality indicators. A copy of the audit including any corrective actions identified and timescales for implementation should be provided to the centre's inspector by 20 July 2015.		implementing this recommendation. Further action is required in relation to the completion of the audit due by 20 July 2015.
6. There is no SOP for screening of patients and partners and those in place for traceability and witnessing did not fully describe current practices. SLC T33b.	The PR should ensure that SOPs are in place to fully describe all current practices. Copies of the updated SOPs and confirmation of provision of any required staff training should be provided to the centre's inspector by 20 April 2015.	We will comply with this.	The PR provided copies of the updated SOPs and confirmation of training provided to staff. No further action is required.
7. The PR could not provide documentation of the assessment of competence for relevant staff involved in welfare of the child assessment and in maintaining traceability. SLC T12 and T15a.	The PR should ensure that the assessment of competence of staff to perform their designated tasks is evaluated and documented. The PR should provide an update of the progress of these assessments to the inspector by 20 July 2015.	We will comply with this.	The Executive acknowledges the PR's response and commitment to fully implementing this recommendation. Further action is required in relation to providing an update on the progress in evaluating and documenting assessment of competence of staff due by

			20 July 2015.

Reponses from the Person Responsible to this inspection report
In each inspection, it appears that the inspectors come with somewhat different approaches to the inspection than we have previously had. This is useful, and ensures a comprehensive review of our processes. All the issues raised are capable of being addressed in a timely manner and will be.