HFEA Executive Licensing Panel Meeting

27 June 2014

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

Minutes – Item 2

Centre 0070 – (The Bridge Centre) – Interim Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair) Joanne Anton – Policy Manager Ian Peacock – Analyst Programmer	Sam Hartley – Head of Governance & Licensing

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 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 The Bridge Centre has held a licence with the HFEA since 1992. The centre provides a full range of fertility services, including embryo testing, and has a network of satellite and transport centres.

2. The Panel noted that the centre is currently on a four-year licence, due to expire on 30 September 2016. The licence was last varied in March 2013, to change the Person Responsible (PR).

3. The Panel noted that the inspection took place on 9 April 2014.

4. The Panel noted that in the 12 months to February 2014 the centre provided 1,730 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

5. The Panel noted that, for IVF and ICSI, HFEA register held data for the period ending November 2013 showed that the centre's success rates are in line with national averages, except for:
    - clinical pregnancy rates following IVF in patients aged 16-37 years, which are lower than average at a statistically significant level; and
    - clinical pregnancy rates following ICSI in patients aged more than 38 years, which are lower than average at a statistically significant level.

6. The Panel noted that for the year 2013 the centre reported 71 cycles of partner insemination with seven pregnancies. This equates to a 10% pregnancy rate. However, the centre failed to report data for intrauterine partner insemination cycles for 2012, which means that no statistical evaluation of the success rates was carried out.

7. The Panel noted that between 1 February 2013 and 31 January 2014, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%; this represented performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

8. The Panel noted that at the time of inspection recommendations were made regarding one 'critical', one 'major' and three 'other' areas of non-compliance. Since the inspection, the PR has fully implemented one recommendation in relation to an 'other' area of compliance, and has taken action and given full commitment to implement all other recommendations within the prescribed timescales.

9. The Panel noted in particular that the centre has not yet fully addressed the storage of embryos and gametes beyond the consented period, and that this has been identified as a critical non-compliance at the last two inspections. While the Panel acknowledged the action taken and progress that the PR has made since her appointment, it still had significant concerns in relation to this non-compliance, and urged the Inspectorate to continue to monitor progress against the recommended action in relation to this issue.

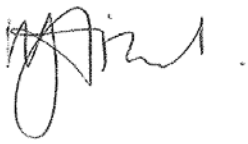
10. The Panel further noted that 13 of the 21 patients who gave feedback since the last inspection had given negative feedback, and acknowledged the steps taken by the PR in addressing the issues raised by the patients.

11. The Panel noted that the Inspectorate recommends the continuation of the centre's licence.

Decision

12. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its Treatment and Storage (with embryo testing) licence continued, and approved the Inspectorate's recommendation to continue the centre's licence with no additional conditions.

13. The Panel noted the PR's engagement and commitment to address the outstanding areas of non-compliance, and urged the centre to adhere to the recommendations and timescales set out by the Inspectorate. The Panel endorsed the Inspector's undertaking to monitor closely the centre's progress, and to refer any future delays in the implementation of recommendations to a licensing committee.



Signed: Date: 30 June 2014
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: The Bridge Centre
Centre number: 0070
Date licence issued: 1 October 2012
Licence expiry date: 30 September 2016
Additional conditions applied to this licence: None
Date of inspection: 9 April 2014
Inspectors: Lisa Beaumont (Lead) and Sara Parlett
Date of Executive Licensing Panel: 27 June 2014

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

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

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that the report makes recommendations for improvement in relation to one 'critical', one 'major' and three 'other' areas of non-compliance. Since the inspection, the Person Responsible (PR) has provided evidence that the following recommendation has been fully implemented:

'Other' areas of practice that require improvement:

- The PR should ensure that data is submitted to the HFEA for cycles of partner insemination within the specified timeframe.

Since the inspection, the PR has taken action and given a commitment to complete the remaining actions to implement the following recommendations within the specified timescales:

Critical areas of practice that require improvement:

- **the Person Responsible (PR) should ensure that embryos and gametes are not stored beyond their consented storage period and that all consents are complete. This was an issue at the previous two inspections.**

Major areas of practice that require improvement:

- the PR should ensure that patient/partner consents to disclosure of identifying information to researchers are reported accurately to the HFEA.

'Other' areas of practice that require improvement:

- the PR should ensure that witnessing checks are completed and recorded at the time the relevant laboratory process takes place.
- the PR should ensure that a low oxygen monitor is installed in the embryology laboratory.

In consideration that the PR gave a commitment to implement recommendations from this, and the previous renewal inspection, and also in consideration of the serious implications of the centre being unable to ensure gametes and embryos are stored within the terms of the consent given by the gamete providers, the Executive will undertake to monitor the centre's progress closely. Any delays in implementing the recommendations will be referred to a licensing committee.

The Executive acknowledges that the PR has only been in post for just over a year, and has been proactive in addressing inherited legacy issues, including the management of cryo-preserved material. However, the storage of embryos and gametes beyond their consented storage period was cited as a non-compliance in this and the two previous inspection reports. If, during the next inspection, the same non-compliance is identified, the Executive may conclude that the PR has not discharged her duty as PR, and will consider whether regulatory sanctions are warranted.

Information about the centre

The Bridge Centre is located in central London close to London Bridge and has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services including embryo testing. The centre offers a UK based egg sharing programme offering treatment using donated eggs. The centre also has a network of satellite and transport centres.

The centre provided 1730 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to February 2014. In relation to activity levels this is a large centre.

A change of Licence Holder (LH) to Dr Kamal Ahuja was approved by the ELP in November 2012. A change of PR to Ms Janine Elson was approved by the ELP in March 2013.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period ending November 2013 show that the centre's success rates are in line with the national averages except for:

- clinical pregnancy rates following IVF in patients aged 16-37 years which are lower than average at a statistically significant level.
- clinical pregnancy rates following ICSI in patients aged more that 38 years which are lower than average at a statistically significant level.

Please refer to page seven of this report for further details.

In 2013, the centre reported 71 cycles of intrauterine partner insemination with seven pregnancies. This equates to a 10% clinical pregnancy rate. However the centre failed to report data for intrauterine partner insemination cycles for 2012 (see recommendation 5) which means that no statistical evaluation of the success rates was carried out.

Multiple births[22]

[1] 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. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2] The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

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

Between 1 February 2013 and 31 January 2014, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The inspection team was able to review records that were present in five sets of patient notes and concluded that records of witnessing are accurately maintained.

The following laboratory activities were observed in the course of the inspection: transfer of eggs collected at transport centres from tubes to dishes; disposal of unfertilised eggs; embryo cryopreservation; sperm preparation and embryo transfer. All of the procedures observed were witnessed in accordance with HFEA requirements using a combination of electronic and manual witnessing, with one exception detailed below.

It was observed that during embryo cryopreservation, whilst the embryos were still in the process of being frozen, the manual witness step for cross-checking the location of the embryos in the dewar had already been recorded as being completed on the laboratory worksheet by the practitioner. Therefore, a witness step had been recorded before the procedure had occurred (see recommendation 3).

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 14 patients were reviewed in the course of the inspection. Six discrepancies were found between completed patient / partner disclosure consents in patient files and the related consent data submitted for inclusion in the HFEA register (see recommendation 2).

Consent: To the storage of cryopreserved material

The PR provided a summary of the findings of a recent review of the centre's cryopreserved material. Embryos for three patients, oocytes for four patients and partner sperm for 18 patients are currently being stored beyond the consented period. A further 57 sperm samples frozen for fertility preservation are either being stored beyond the consented period or the consents are missing or have been completed incorrectly. Storage of cryopreserved material without written effective consent was cited as an area for improvement at the last two inspections.

The PR explained that it was recognised that the centre's management of cryopreserved

material had again become an issue and that, since January 2014, the centre had employed a full time dedicated member of staff to manage this.

The circumstances under which material was stored past the consented period were discussed on inspection. These include situations where verbal confirmation of the patient(s) wishes to extend the storage period is received but written confirmation is not then forthcoming. In these situations the centre makes further attempts to communicate with the patients as required before taking necessary action (see recommendation 1).

Staffing

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

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit the inspection team spoke to three patients who provided feedback on their experiences, and observed interactions between centre staff and patients. A further 21 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was mixed. Eight of the individuals providing written feedback to the HFEA commented that they have compliments about the care that they received. However, 13 patients reported negative feedback which included:

- a lack of drug information given (including side effects), and conflicting information from nurses on drug administration;
- difficulty in contacting the centre out of hours;
- a lack of privacy and dignity; and
- staff attitude - a lack of empathy.

The inspection team discussed in detail with the PR the issues surrounding this feedback, and the complaints the centre receives directly. The centre fully acknowledges the issues and has been proactive in taking steps to address them. Some of the action taken includes:

- introduction of team nursing since January 2014, to provide better continuity of care;
- introduction of a ‘reproductive health appointment’ to improve the administration process and ensure patients are booked in for the correct appointment and
- a commitment to review and improve how patients are able to contact the centre out of hours.

The inspection team considers that the PR is being proactive in addressing the issues raised by patients and does not consider a recommendation is proportionate; however, the centre’s inspector will liaise closely with the centre to monitor patient feedback going forward.

On the basis of this feedback, observations made and discussions with the PR in the course of the inspection it was possible to assess that the centre:

- is now able to provide better continuity of care since introducing team nursing and
- is proactive in addressing the issues patient complaints have raised.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, no additional non compliances were identified.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2012, recommendations for improvement were made in relation to one area of critical non-compliance, 10 areas of major non-compliance and six 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented with the following exceptions:

- One dewar, situated in the centre's main laboratory, did not appear to be in close proximity to a low oxygen sensor. Post inspection, the PR confirmed that an oxygen monitor had been fitted, but this was not present on this visit to the centre, see recommendation 4.
- In one of the 12 consent to disclosure registration forms audited on inspection, a discrepancy was noted where a patient had consented for research, but this consent decision was incorrectly submitted for inclusion on the HFEA register. The PR should ensure that, in future, all data submitted regarding consent to disclosure of identifying information from the HFEA register is entered accurately and is supported by the patient record. On this visit, six discrepancies were found out of 14 records reviewed, see recommendation 2.
- The centre maintains records to be able to provide donors with information regarding the number, sex and year of birth of persons born as a result of their donation. However, the PR explained that it was not clear if these records could provide accurate information. The inspection team is aware that the majority of the donor bank records have been relocated to centre 0011, along with the samples. This non-compliance is no longer the sole responsibility of this centre's PR.
- Whilst there is no legal requirement for a good will message and personal description to be provided, the HF&E (Disclosure of Donor Information) Regulations 2004, Section 2 (2)(g)(h) clearly envisage that the type of information that may be contained in such descriptions should be disclosed to the donor-conceived, where available. Some donors are not being asked to provide this information, which undermines the HFEA's ability to discharge its statutory responsibilities towards the donor-conceived. The centre is required to ensure that:

- prospectively, all donors are given the opportunity to provide a good will message and personal description.
- a plan for retrospectively contacting donors who were not given the opportunity to provide a good will message and personal description is provided to the Executive.

The centre has taken the following action to address the above issues:

- The centre acknowledged that whilst a low oxygen sensor had been fitted following the renewal inspection in 2012, it was not present on the day of this inspection and the PR committed to replace it with immediate effect.
- The error noted for one consent to disclosure registration form was corrected and a sample audit undertaken. Staff were provided with update training on EDI.
- An audit of outcomes following treatment with donor sperm was provided during this inspection; however the audit documented anomalies in relation to treatment of eight patients. Review of the audit findings against HFEA register information suggests that these eight patients received treatment with the gametes of donors not registered with HFEA. The centre has been dealing with legacy issues relating to donor treatment outcomes and is taking appropriate action. Given the scale of the task, the inspection team feel the centre should be given more time to address these eight anomalies and therefore feel it is not proportionate to cite this as a non-compliance again. This will continue to be reviewed by the Executive through the on-going monitoring system.
- The centre has written to all eligible donors retrospectively to offer them the option of writing a goodwill message. All egg donors are offered the option of a goodwill message, and all sperm donors are recruited and managed by centre 0011. No further action required.

On-going monitoring of centre success

The centre received three risk tool alerts during the last year relating to success rates, and the centre responded appropriately to these.

The centre's success rates are statistically below average for IVF under 37 years and ICSI above 38 years. Data analysis demonstrates that these poor success rates are historic in nature and that the issues have since been resolved. The centre's success rates will continue to be closely monitored by the centre's inspector.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

The centre has resolved historic issues related to submission of treatment information to the HFEA and has much improved its response in addressing data submission errors. The centre is considered to be broadly compliant with regulatory requirements but the following issues are noted:

- a small number of unregistered donors and late submission of pregnancy outcome data discrepancies remain outstanding. These are not significant enough in number to require a recommendation to be made;

- discrepancies were found in six out of 14 consent to disclosure registration forms, see recommendation 2;
- the centre failed to submit partner intrauterine insemination data for year ending 2012. The 2013 data was submitted within the required timeframe, see recommendation 5.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

‘Critical’ 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 child who may be born as a result of treatment services. A ‘critical’ area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Embryos for three patients, oocytes for four patients and partner sperm for 18 patients are currently being stored beyond the consented period. A further 57 sperm samples frozen for fertility preservation are either being stored beyond the consented period, or the consents are missing or have	The PR has provided a summary report of the number of patients for whom embryos and gametes remain in store without effective consent. The PR is required to; • review the bring forward system, with the aim of ensuring sufficient notice is given to patients to ensure that gametes and embryos are not stored beyond the consented period. • review those patients whereby consent is missing / incorrect and provide a	An interim summary report is attached. As of 29/5/2014, there is only one set of embryos stored beyond their consented period. We are awaiting a copy of the husbands death certificate. There are no eggs stored beyond their consented period. There are 5 expired partner sperm samples stored .There are 29	The centre has submitted a summary report of all cryo-preserved material in storage. The Executive acknowledges the action taken by the PR. The PR has committed to complete the remaining actions to implement this recommendation within the required timeframe. The

been completed incorrectly. Storage of cryopreserved material without written effective consent. **This was cited as an area for improvement at the last two inspections**. (Schedule 3, 8(1) and (2) HF&E Act)	summary report of the review to the HFEA. A summary report of the findings of the reviews, including any corrective actions and the timescale for their implementation should be submitted to the HFEA by 9 July 2014. By the time the PR responds to this report, where gametes and embryos remain in store without effective consent, a plan should be submitted to the HFEA documenting the centre's intended actions and the anticipated timescale for their implementation. The PR should provide monthly updates to the HFEA on progress in implementing the proposed actions. Within three months of the implementation of corrective actions, the centre should conduct an audit of consent to storage and a summary report of the findings of the audit should be provided to the HFEA. The PR is reminded of guidance issued by the HFEA in CH(03)03 (http://www.hfea.gov.uk/2687.html)	patients with frozen sperm still without CD forms -all have been contacted. The Bring forward system is in place and there is now a permanent Frozen Assets manager in post to ensure that the SOP is carried out.. A further summary will be sent by 9th July.	completion of these actions will be reviewed by the Executive through the on-going monitoring system.

‘Major’ area of non compliance

A ‘major’ area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
2. Six discrepancies were found out of 14 records, between completed patient / partner disclosure consents in patient files, and the related consent data submitted for inclusion in the HFEA register. (Chair’s letter CH (10)05 and supplementary guidance and General Directions 0005) **This was an issue at the last inspection.**	The PR is required to ensure that the data submissions identified as being incorrect are corrected immediately. The PR is required to review the systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the HFEA accurately reflects that given and recorded on completed disclosure consent forms. A report of this review should be submitted to the HFEA by 9 July 2014. An audit should be conducted three months after implementing	The discrepancies have been corrected. The transport centre that wasn't sending copies of the Consent to Disclosure forms but transcribing the data onto their summary sheets have been advised to send the original forms and are now doing so. Retraining has been given to the staff responsible. An audit will be carried out in August 2014 and the results submited to the HFEA.	The centre has corrected the six discrepancies. The Executive acknowledges the action taken by the PR. The PR has committed to complete the remaining actions to implement this recommendation within the required timeframe. The completion of these actions will be reviewed by the Executive through the on-going monitoring system.

	any changes, to confirm that any changes made to systems and processes are having the desired effect. A report of this audit should be provided to the HFEA by 9 October 2014.		

‘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	Inspection team’s response to the PR’s statement
3. It was observed that during embryo cryopreservation, whilst the embryos were still in the process of being frozen, the manual witness step for cross-checking the location of the embryos in the dewar had already been recorded as being completed on the laboratory worksheet by the practitioner. Therefore, a witness step had been recorded before the procedure had occurred. (SLC T71)	The PR should take immediate action to ensure that witnessing is completed and recorded contemporaneously 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. The PR should review witnessing procedures. A summary report of the review findings including corrective actions and the timescale for their implementation should be	The team member involved will complete a retraining exercise and an SOP review to ensure future compliance occurs. The point has discussed in the laboratory meeting to ensure the embryology team is aware of the issue.An audit of vitrification witnessing will be carried out for the next 10 events and a repeat audit of general witnessing will be completed for the deadline specified in the report.	The Executive acknowledges the action taken by the PR. The PR has committed to complete the remaining actions to implement this recommendation within the required timeframe. The completion of these actions will be reviewed by the Executive through the on-going monitoring system.

	submitted to the HFEA by 9 July 2014. The PR should provide monthly updates to the HFEA on progress in implementing corrective actions.		
4. There was no low oxygen monitor in the embryology laboratory where two dewars are kept. **This was an issue at the last inspection**, which the centre had reported as resolved - an oxygen monitor had been fitted, but had since been removed. (SLC T17 and SLC T23)	The PR is required to ensure a low oxygen alarm is fitted, in the embryology laboratory with immediate effect. The PR is required to provide evidence to the HFEA that this has been undertaken by 9 July 2014.	We are awaiting a professional response from Britannia monitoring systems, service due in the next two weeks so they wish to perform tests on site . Team members will use a personal low O2 monitor to ensure O2 levels are safe in the interim. The point discussed in a previous inspection, and assurance given that the two low O2 monitors in the area are suffficient for safe monitoring of O2 levels.	The Executive acknowledges the action taken by the PR. The PR has committed to complete the remaining actions to implement this recommendation within the required time scale. The completion of these actions will be reviewed by the Executive through the on-going monitoring system.
5. The centre did not submit data for partner insemination cycles to the HFEA for year ending 2012. (SLC T9(e))	The PR is required to submit partner insemination cycle data for year ending 2012 by 9 July 2014. The 2013 data was submitted within the required timeframe.	Thank you for bringing this to my attention. This wasn't discussed at inspection nor raised prior to this report. This had not been handed over by the previous PR. The data has now been	The centre has submitted data for partner insemination cycles for the year ending 2012. No further action.

		submitted.	

Additional information from the Person Responsible
Goodwill message and personal description. At the last insepction the Centre was advised that historical forms were outstanding for egg donors. All egg donors from 2008 to 2011 were contacted. On the 16/5/2014 the HFEA confirmed that blank forms needed to be submitted for those that had not replied. On the 19/5/2014 the HFEA provided a list of all sperm and egg donors where the Goodwill message and Personal description had not been submitted. All donors on this list have now either had a goodwill message and personal description submitted (blank where they have opted not to complete it) or have been sent a form to complete which will be submitted on receipt.