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
27 February 2015

Minutes – item no. 2

Centre 0327 (Boston Place) – Renewal Inspection Report

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Paula Robinson Head of Business Planning Ian Peacock Analyst Programmer
Members of the Executive in attendance:	Sam Hartley Head of Governance & Licensing Dee Knoyle Committee Secretary

Declarations of interest: The Chair declared that she had recently visited the clinic with another member of the executive in order to see the laboratory and the centre's paperless system. This visit was not related to the inspection process, or renewal application. The Panel had regard to the Authority's Guidance on Conflicts of Interest and judged that the fact that the Chair had recently visited the clinic on an unrelated matter did not constitute a conflict of interests.

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 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 including embryo testing. 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 May 2013 and is on a two-year licence due to expire on 23 May 2015.

4. The panel noted that in the 12 months to 30 September 2014, the centre provided 364 cycles of treatment (excluding partner intrauterine insemination).

5. The panel noted that for IVF and ICSI, HFEA-held register data for the period July 2013 to June 2014 showed the centre's success rates were in line with national averages.

6. The panel noted that in 2013, the centre reported nine cycles of partner insemination with no pregnancies. This was consistent with the national average.

7. Between July 2013 and June 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 18%. This represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

8. The panel noted that at the time of the inspection on 11 and 12 November 2014, the Inspectorate identified seven major and eight other areas of non-compliance. The panel noted that since the inspection the PR had provided assurance that some of the recommendations had been implemented and some were in progress. The panel noted that the PR had committed to fully implementing all of the outstanding recommendations within the prescribed timescales with the exception of one relating to screening.

9. The panel noted that the information provided by the PR in responding to this report demonstrated that the centre will continue to screen egg donors within a 12-week period prior to egg collection. It is a requirement that blood samples are taken from donors and screened 'at the time of each donation'. However, the PR had not provided satisfactory evidence to demonstrate why she had considered a 12-week timeframe is consistent with this requirement. The risks associated with not screening egg donors at the time of donation are small but could have a very serious impact on the recipients and/or donor conceived child. The HFEA has not further defined 'time of donation' and it was acknowledged that in the absence of this there is some flexibility.

10. The panel noted the conclusion of the management review meeting held with the PR, that further evidence was required to demonstrate compliance and the Inspectorate would request this evidence from the PR.

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

12. The panel noted that the Inspectorate recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales. The Inspectorate would continue to liaise with the centre closely with respect to the outstanding recommendations. Failure to fully implement the recommendation relating to screening would result in the submission of a further report to a licensing committee with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement policy.

Decision

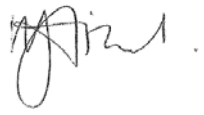
13. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

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 the PR has discharged their 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 continue to monitor the centre's performance. The panel urged the PR to fully engage with the Inspectorate and complete the recommendations. It emphasised that failure to implement the recommendations, in particular the recommendation relating to screening, within the prescribed timescales may result in the submission of a further report to a licensing committee, with the recommendation that appropriate regulatory action should be taken in accordance with the Authority's Compliance and Enforcement Policy.

17. The panel endorsed the Inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years without additional conditions.



Signed: Date: 13 March 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: 11 and 12 November 2014

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) and Storage

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

Inspectors: Parvez Qureshi, Karen Conyers, Gill Walsh, Chris Hall and Zakia Ezzouyar

Date of Executive Licensing Panel: 27 February 2015

Centre name	Boston Place
Centre number	0327
Licence number	L/0327/1/b
Centre address	16-20 Boston Place, London, NW1 6ER, UK
Person Responsible	Dr Anna Carby
Licence Holder	Mr Stuart Lavery
Date licence issued	24/05/2013
Licence expiry date	23/05/2015
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Boston Place has been licensed by the HFEA for treatment and storage since May 2013 and provides treatment to self-funded patients. A variation of the centre's licence to add embryo testing and change the licence to Treatment (including embryo testing) and Storage was granted by an ELP on 14 January 2014. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The premises have not undergone any major changes since the initial licence was granted.

The centre offers a full range of licensed treatments and provided 364 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2014. In relation to activity levels this is a medium-sized centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period July 2013 to June 2014 show the centre's success rates are in line with national averages.

In 2013, the centre reported nine cycles of partner insemination with no pregnancies. This is consistent with the national average.

Multiple births[2]

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

Between July 2013 and June 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 18%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

[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%.

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable with the exception noted within this report;
- the centre's practices are considered likely to be suitable subject to the implementation of corrective actions as recommended in this report;
- 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, seven major and eight 'other' areas of non-compliance.

Since the inspection, the PR has provided assurance that the following recommendations have been implemented:

Major areas of non-compliance:

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

'Other' areas that requires improvement:

- The PR should review the process by which she is assured that donor compensation and benefits in kind are made to all donors (including those recruited by satellite providers) in accordance with General Direction 0001.
- The PR should conduct a review of the centre's quality management system and ensure that;
    - the donor recruitment, assessment and screening standard operating procedure (SOP) is revised to ensure information regarding the outcome of genetic screening is noted and acted upon;
    - there is an effective mechanism in place for document control which ensures that only the current version of any document is in use;
    - all required corrective actions identified in the course of the audit of donor recruitment, assessment and screening are implemented.
- The PR should ensure that staff are able to demonstrate competence in the tasks they perform.
- The PR should review the centre's patient and donor information to ensure that;
    - proper information about legal parenthood is provided to patients giving consent to treatment;

- the written information for egg donors states that expenses are limited to as prescribed in General Direction 0001.

The PR is in the progress of implementing, or has provided commitment to implement the following recommendations:

Major areas of non-compliance:

- The PR should take immediate action to review donor recruitment procedures to ensure that donors are selected on the basis of their age, health and medical history and that this assessment is documented.
- The PR should take immediate action to ensure that all relevant data about anything coming into contact with gametes or embryos is traceable.
- The PR should conduct a review of all medical devices currently in use to identify where products are not CE marked and take action to source alternatives.
- The PR should ensure that access to areas where confidential identifying information can be seen or obtained is restricted to people authorised by the PR.
- The PR should review the centre's procedures for record keeping to ensure that medical records contain all relevant documents and information.

'Other' areas that requires improvement:

- The PR should take immediate action to ensure that all manual witnessing steps undertaken are documented appropriately and that records of witnessing are retained for each patient / donor.
- The PR should ensure that medical gases are stored in accordance with guidance and that areas of restricted access are only used for their intended purpose.
- The PR should ensure that all third party agreements are reviewed to ensure compliance with requirements.
- The PR should review systems and processes to ensure that, completed patient and partner consent to disclosure of information is retained and is readily available for reference purposes and to enable the accuracy of the data supplied to the Authority to be confirmed

The PR has not given a commitment to fully implement the following recommendation:

Major areas of non-compliance:

- The PR should ensure that prior to the use and/or storage of patients'/donors' gametes and/or embryos created with patients'/donors' gametes, screening is performed within the timeframes set by the Authority and testing requirements are complied with as follows:
  - screening tests are conducted by a suitably accredited laboratory, CPA or an equivalent accrediting body;

Recommendation to the Executive Licensing Panel

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

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy rates meet or are below the target. Some improvement is required however, in order for the centre to demonstrate suitability of their practices.

The information provided by the PR in responding to this report demonstrates that the centre will continue to screen egg donors within a 12 week period prior to egg collection. It is a requirement that blood samples are taken from donors and screened 'at the time of each donation'. The HFEA has not further defined 'time of donation' and it is acknowledged that in the absence of this there is some flexibility. However, the PR has not provided satisfactory evidence to demonstrate why she considers a 12 week timeframe is consistent with this requirement. The risks associated with not screening egg donors at the time of donation are small but could have a very serious impact on the recipients and/or donor conceived child.

In consideration of the PR's failure to provide this evidence, a management review meeting was held on 6 February 2015 in accordance with paragraph 4.6 of the HFEA's compliance and enforcement policy. The conclusion of the management review was that further evidence was required to demonstrate compliance. In accordance with paragraph 4.2 of the HFEA's compliance and enforcement policy it was agreed that informal action was warranted in the first instance and the centre's inspector will request further information from the PR.

The inspection team recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales. The centre's inspector will continue to liaise with the centre closely with respect to the outstanding recommendation described above. If this is not resolved to the Executive's satisfaction, this will result in the submission of a further report to the Licence Committee/ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement policy.

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

What the centre could do better
The centre uses an electronic witnessing system and a manual system for steps not covered by the electronic checks however, records of electronic witnessing could not be reviewed on inspection due to a data storage failure which resulted in the loss of these records. The centre reported this to the HFEA as an incident and has provided regular updates regarding the investigation of this event and actions taken to ensure this does not recur.

The centre's own parallel testing / audit of the electronic witnessing system included a step at the end of each cycle where staff checked the electronic witnessing record and signed to confirm that the record was complete or noted where there were any non-conformities. Following the data failure the centre reviewed the parallel audit records of the relevant 318 records where the electronic witnessing records were lost and concluded that a manual 'witnessing complete' check was recorded in 316 cases. In two instances no manual check of the electronic record is documented.

The centre does not therefore have a record of electronic witnessing checks. The inspection team does however consider that the centre's practice of manually auditing the electronic witnessing records at the end of each episode provides a high level of assurance that appropriate electronic witnessing was conducted in these cases. No further recommendation is made in relation to this as documented above, the clinic has already implemented corrective action to minimise the risk of recurrence.

In four of six witnessing records of manual witnessing that were available for review on inspection it was noted that a number of steps (the time that witnessing took place when discarding gametes or placing them in storage and clearance of flow hood) were not recorded (SLC T71 (see recommendation 8)).

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

Screening of donors (Guidance note 11)
The centre's procedures for recruitment and screening of donors are partially compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; Directions 0001)
The centre's procedures are broadly compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. 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 (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Screening of donors (Guidance note 11)
The centre has recruited a very small number of egg donors thus far. A review of donor records on inspection and the centre's own donor audit showed that egg donors are not consistently screened in accordance with current professional body guidance.

Staff were able to describe that donors are selected on the basis of their age, health and medical history but two donor records reviewed on inspection contained no record that the health and medical history of the donor had been assessed prior to their donation being accepted.

In one instance it was noted that the results of genetic screening of a known egg donor had indicated possible genetic abnormalities. There was no evidence in either the donor or recipient's record to demonstrate this information was acted on. The donor's gametes

went on to be used in treatment. Embryos created were used in treatment but did not result in an ongoing pregnancy or live birth. Surplus embryos were cryopreserved (SLC T52a see recommendation 1).

In cases where testing is initiated by the centre, blood testing is conducted by a suitably accredited laboratory. However, where screening is initiated outside of the centre by another organisation the PR could not confirm whether these tests had been conducted by a laboratory accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard).

In two donor records reviewed screening had not been performed within the timescales specified by the Authority (SLC T53a and b (see recommendation 2)).

Payments for donors (Guidance note 13; Directions 0001)
Where a satellite patient was treated with the gametes of a known egg donor, the centre could not confirm whether compensation was provided to the donor by the satellite centre and/or whether the payment was in accordance with Direction 0001 (see recommendation 9).

One donor record reviewed included a disclaimer that suggested the donor understood that she could claim £750 in compensation for her donation and expenses. Although no excess payment of additional claim for expenses was made, this information is not compliant with General Direction 0001 (see recommendation 14).

Suitable premises and suitable practices

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

What the centre does well

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

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

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories (excluding those which conduct screening initiated outside of the centre by another organisation) which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are broadly 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 has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; Directions 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

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

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history (with the exceptions detailed within the report) 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; Directions 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or

embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified; (label seen on shipper covered all requirements except did not specify 'do not freeze'. This was corrected immediately during the inspection).
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that 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 treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Directions 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

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 and embryos during any step from procurement to use for human application or disposal,
- to identify the donor and recipient of particular gametes or embryos,
- to identify any person who has carried out any activity in relation to particular gametes or embryos, and
- 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 (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 broadly compliant with HFEA requirements.

Satellite agreements (Guidance note 24; Directions 0010)
The centre has systems in place to manage satellite activities that are broadly compliant with HFEA requirements with the exception noted regarding compensation of known egg donors donating via a satellite clinic (see recommendation 9). This is important to ensure that activities performed by satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA

requirements.

The centre is compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. 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

Safety and suitability of premises and facilities (Guidance note 25)
A tour of the centre's premises showed that the cylinders in the medical gas store were not stored securely. Also the electrical control cupboard which the estate manager confirmed had restricted access contained cleaners' buckets, mops and standing water indicating that access is not controlled: the storage of cleaning implements in standing water may also represent an infection control risk and may compromise electrical safety (SLC T2 and T17 see recommendation 11)

Infection control
The centre does not have a process in place to manage pre-employment occupational health screening for staff. The centre's infection control lead was not able to confirm the immunisation status of staff currently employed at the centre (SLC T2 see recommendation 11).

Traceability (Guidance note 19)
Traceability of consumables, in one of five records reviewed the lot numbers for two items identified as coming into contact with gametes or embryos were not traceable (SLC T99 see recommendation 3).

Quality management system (QMS) (Guidance note 23)
The donor recruitment, assessment and screening SOP does not direct activity to ensure that, the outcome of genetic and other screening found to be of significance to the donor and/or potential recipient(s) is acted upon (SLC T33(b)).

The centre has not implemented all required corrective actions identified in the course of the centre's own audit of donor recruitment, assessment and screening (SLC T36 see recommendation 10).

Third party agreements (Guidance note 24)
The content of a third-party agreement reviewed in the course of the inspection did not

include a description of how any diagnostic test results should be relayed to the commissioning centre including sign off and confirmation that the results apply to the correct sample (SLC T114 see recommendation 13).

Equipment and materials (Guidance note 26)
The following medical devices used by the centre are not CE marked: culture media supplement, vitrification kit, Pasteur pipette droppers and egg collection tubes.

The addition of a non-CE marked supplement to a CE marked culture media product was discussed with the laboratory manager both during and after the inspection – it is noted that the addition of this product invalidates the CE mark status of the culture medium. The laboratory manager provided a review of evidence and documents she had used to justify selection of these products but it remains the case that the use of the medium is non compliant with requirements of SLC T30 which requires the use of CE marked medical devices where possible. In a Clinic Focus article provided in April 2013 clinics were advised that in the absence of any prospect that non CE marked products would meet the requirements of licence conditions, they should implement a plan of action to ensure compliance within the following year (see recommendation 4).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1220/8).

Staff (Guidance note 2)
The centre is broadly compliant with HFEA requirements. The centre has 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
Relevant staff were not able to provide documented evidence of their competence in selecting and recruiting donors (SLC T12 and SLC T15a see recommendation 12).

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

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

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 we spoke to two patients who provided feedback on their experiences. A further 32 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with 17 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

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

What the centre does well

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

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

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; Direction 0001)
The centre does not provide treatment involving egg and sperm sharing arrangements therefore 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. This is important to protect the surrogate and any children born as a result of the treatment.

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 partially 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

Confidentiality and privacy (Guidance note 30)
In the recovery area patient information was viewable on a computer screen and it was considered that this posed a risk to confidentiality: although there was no evidence that there have been known breaches of confidentiality it is noted that identifying information is clearly visible and this was a concern raised at the time the centre's licence was issued (HF&E Act section 33(1)) (see recommendation 5).

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and / or donors are broadly 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

Information (Guidance note 4; CH(11)02)
The written patient information regarding legal parenthood appeared unclear and confusing as it made reference to both legal parenthood and parental responsibility but the information did not clearly explain the difference between them. This puts the centre at risk of failing to provide proper information to patients giving consent to treatment (CoP guidance 6.2, see recommendation 14).

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5)
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.

Legal Parenthood (Guidance note 6)
The partners of women treated with donated gametes or embryos, where the couple are neither married nor in a civil partnership, must give their consent in order to become the legal parent of any child born. If this consent is not properly taken, it can have serious consequences, such as the partner having to adopt any child born in order to become the legal parent. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. On this inspection we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and that actions had been taken in response to the audit findings.

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
In two instances the audit team were unable to find patient/partner disclosure consents on the clinics IT system to confirm that the consent information supplied to the HFEA is accurate (Chair's Letter CH(10)05 ,Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007 see recommendation 15).

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 and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

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 partially 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.

Storage of gametes and embryos (Guidance note 17)
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. 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.

What the centre could do better

Screening of patients (Guidance note 17)

In cases where testing is initiated by the centre, blood testing is conducted by a suitably accredited laboratory. However, where screening is initiated outside of the centre by another organisation, the PR could not confirm whether these tests had been conducted by a qualified laboratory, which has suitable accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. Review of a sample number of patient records showed that screening had not been performed within the timescales specified by the Authority (SLC T51a and b see recommendation 2).

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'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.

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 partially 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. (As detailed within the report, the centre will not be able to fully meet this requirement due to a recent significant server failure resulting in loss of some records).

Obligations and reporting requirements (Guidance note 32 ; Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are partially compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better

Record keeping and document control (Guidance note 31)
No version control was evident on some documents reviewed on the centre's data base (SLC T34 see recommendation 10).

In two records reviewed there was no medical history or indication for treatment recorded SLC T46 (see recommendation 6).

Obligations and reporting requirements (Guidance note 32 ; Direction 0005)
A sample audit of patient and donor records held at the centre showed the following:

- in one record, information submitted to the HFEA register records that the patient had treatment with her partner's gametes. The patient record held at the centre recorded that the patient had treatment with donor gametes;
- in one record a donor already registered with the HFEA by the centre at which he donated was registered again by the centre thus creating a duplicate record.
- five of seven DI treatments undertaken in a 12 month sample period had not been reported to the HFEA at the time of inspection as required by General Direction 0005.
- 24% of the IVF treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005).

A small number of other minor errors and omissions were also identified at the time of inspection (SLC T9(e) / T41 General Direction 0005 see recommendation 7).

Section 3: Monitoring of the centre's performance

Following the initial licence inspection in 2013, recommendations for improvement were made in relation to one area of major non-compliance and eight 'other' area of non-compliance. There were no critical non-compliances noted.

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

On-going monitoring of centre success rates

Over the last year the centre has not been asked to review any procedures for the provision of any treatment.

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. **Donor recruitment, assessment and screening** The centre has recruited a very small number of egg donors thus far. A review of donor records on inspection and the centre's own donor audit showed that egg donors are not consistently screened in accordance with current professional body guidance. Staff were able to describe that donors are selected on the basis of their age, health and medical history but two	The PR should take immediate action to review donor recruitment procedures to ensure that donors are selected on the basis of their age, health and medical history and that this assessment is documented. The HFEA should be advised of the findings of the review including any corrective measures taken to when responding to this report. Three months after implementing corrective actions, the PR should audit screening and assessment of donors recruited after the implementation of corrective actions to assess their effectiveness. A summary report of the audit findings should be provided to the HFEA.	The Donor Medical Questionnaire has been updated, providing donors with clear instructions to provide details about their medical history and their family medical history. An additional section has been added requiring clinicians to review any medical condition or family medical history disclosed before the donor screening blood tests are taken. Clinicians are required to document their decision. Between September 2013 and January 1st 2015 Boston Place has completed 9 egg donation cycles. A full audit of their records has been completed	The Executive acknowledges the PR's response to this recommendation. The PR has provided a response and detail of subsequent actions relating to the donor chromosomal screening and any implications for the known donor and recipient separate to this report. In addition, the PR has assessed the potential impact of the other non-compliances found

donor records reviewed on inspection contained no record that the health and medical history of the donor had been assessed prior to their donation being accepted. In one instance it was noted that the results of genetic screening of a known egg donor had indicated possible genetic abnormalities. There was no evidence in either the donor or recipient's record to demonstrate this information was acted on. The donor's gametes went on to be used in treatment. Embryos created were used in treatment but did not result in an ongoing pregnancy or live birth. Surplus embryos were cryopreserved. SLC T52a	The PR should also conduct a retrospective audit of the records of all donors to determine whether an appropriate assessment has been made. Where non-compliances are found and the donor gametes have been used in treatment, the PR should assess the potential impact of this on the recipients or any off spring born. The PR should provide detail of this audit and actions taken in response to the findings by when responding to this report.	and showed several nonconformities with the Code of Practice. The nonconformities included: • 1 instance where a chromosomal abnormality was not detected until after egg collection and embryo transfer • 1 instance where the chlamydia and gonorrhea was not tested by the Nucleic Acid Technique • 1 instance where a patient should have been screened for Malaria and was not • 3 instances where some of the blood tests were done outside the 12 week screening window • 2 instances where screening tests were done at an overseas clinic and therefore unable to verify if the laboratory was CPA accredited The chromosomal nonconformity is addressed in the same document **Re-Audit of new protocol** An audit date has been set for	in their retrospective audit. However, further clarification is required regarding screening of egg donors which should be conducted at the time of donation and not within three months of donation. The risks associated with not screening egg donors at the time of donation (or close to it) are small but these could have a very serious impact on the recipients. From the centre's own egg donation audit where screening had been undertaken a significant amount of time before donation the PR should contact a virologist /microbiologist to seek advice whether any additional tests need to be conducted to ensure that the recipients have

		March 2015	not been infected. In response to this report, the PR provided additional information for the centre's rationale for having a 12 week screening timeframe. However the Executive does not consider this information explains why the PR considers that 12 weeks fits the requirement of screening at the 'time of each donation' and will seek further clarification from the PR. The PR should provide a summary report of the audit and any actions resulting from it to the centre's inspector by 12 May 2015. Further action is required.

2. Screening In cases where testing is initiated by the centre, blood testing is conducted by a suitably accredited laboratory. However, where screening is initiated outside of the centre by another organisation, the PR could not confirm whether these tests had been conducted by a qualified laboratory, which has suitable accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. A review of patients'/donors' notes indicated that screening was not being performed within the timescales specified by the Authority. SLC T51a and b, & T53a and b	The PR should ensure that prior to the use and/or storage of patients'/donors' gametes and/or embryos created with patients'/donors' gametes, screening is performed within the timeframes set by the Authority and testing requirements are complied with as follows: ◦ screening tests are conducted by a suitably accredited laboratory, CPA or an equivalent accrediting body; The PR should review the regulatory requirements and the clinic's process for screening. A summary of this review and of any corrective actions implemented as a result of this review should be provided to the centre's inspector by 12 February 2015. Three months after the implementation of corrective actions, the centre should perform an audit of patient and donor screening to determine whether the corrective actions are effective.	As a result of IVFH-BP-QM-HFEA AUDIT-001 EGG DONATION Boston Place reviewed its programme to ensure all donation cycles adhered to T50, T51a and b & T53a and b. This involved updating several documents. **Patient Information** The patient information did not contain detailed information of the length of time it takes to process certain tests such as Cystic Fibrosis and Karyotype (4 weeks) and how long blood tests are valid (12 weeks). The lack of clear information meant patients had unrealistic expectations in terms of completing their screening tests and then delaying treatment to suit their personal schedules. This is now clearly stated The patient information did not stipulate that all blood tests must be done at a CPA accredited or equivalent lab. This is now clearly stated.	The Executive acknowledges the PR's response to this recommendation. The PR should provide information to demonstrate that screening of patients is performed within the timeframe specified by the authority The PR should ensure that the centre's SOPs and information for egg donors accurately reflects screening requirements, in particular that screening is required at time of donation. Refer to Executive Review comments for recommendation 1. The PR should provide a summary report of the audit and any actions resulting from it to the centre's

	This audit should be provided to the centre's inspector by 12 May 2015.	**Review of Standard Operating Procedures** After a review of the programme it was decided to create a new step in the process to provide nurses with adequate time to collect information regarding the medical history and screening requirements of a prospective donor. Donors are now required to attend a screening appointment after their consultation with a doctor and a counselor. Once their results are reviewed by a clinician they will then be seen for a Coordination appointment. Previously, coordination was done at the time of screening. **Donation Checklist** The screening checklist in use at the time was not robust enough and at times not completed by nurses. A new checklist has been created that clearly identifies all HFEA required blood tests, including parameters for travel or ethnicity related screening tests. This will ensure all patients are appropriately, and fully,	inspector by 12 May 2015. Further action is required.

		screening in accordance with the Code of Practice. The screening checklist also clearly stipulates that blood tests must be from a CPA accredited (or equivalent) laboratory. After the audit it was decided that a doctor should review and sign off on all of the screening blood tests prior to the start of stimulation. Once a doctor has signed off on the blood tests a Coordination Appointment will be arranged for the nurses to go over the medication details, injection instructions and treatment protocol. **Re-Audit of new protocol** An Audit has been set for April 2015	
3. Traceability Traceability of consumables, in one of five records reviewed the lot numbers for two items identified as coming into contact with gametes or embryos were not traceable.	The PR should take immediate action to ensure that all relevant data about anything coming into contact with gametes or embryos is traceable. The HFEA should be advised of the measures taken to ensure that this happens by the time the PR responds to this report.	**Full Audit** Two traceability audits were undertaken in the past 12 months. The corrective actions identified in the audits were completed prior to the inspection and audit reports shared with the inspectors. Since that time we have	The Executive acknowledges the PR's response and actions regarding the implementation of this recommendation. The PR should provide a summary report of

SLC T99	Within three months of the implementation of corrective actions, the centre should conduct an audit of traceability and a summary report of the findings of the audit should be provided to the centre's inspector by April 2015.	instigated a new system of a traceability list to be checked weekly along with checklist in every electronic record to ensure traceability list is added to each electronic record where applicable. Newer batches of consumables will be kept separate from batches in use using a sticker system. A further audit will be carried out by April to ensure the new system is compliant.	the traceability audit and any actions resulting from it to the centre's inspector by 12 May 2015. Further action is required.
4. Equipment and Materials The following medical devices used by the centre are not CE marked: culture media supplement, vitrification kit, Pasteur pipette droppers and egg collection tubes. The addition of a non-CE marked supplement to a CE marked culture media product was discussed with the laboratory manager both during and after the inspection – it is noted that the addition of this product	The PR should conduct a review of all medical devices currently in use to identify where products are not CE marked and take action to source alternatives. The PR should provide the centre's inspector with a list of all medical devices including disposables, equipment, and culture medium indicating the CE mark status of these products. Where devices are not CE marked then the PR should indicate what the timescale for sourcing alternatives by 12 February 2015. It is expected that all medical devices should be CE approved by 12 May 2015.	**Full Audit** A full list of medical devices is supplied with CE mark status **Audit Findings** A review of consumables used in the lab identified the following items not being CE marked: • Kitazato Vitrification System • Plasticware • Media culture Boston Place has sourced an alternative Kitazato Vitrification System which is CE Marked. It will be in use pending validation.	The Executive acknowledges the PR's response and commitment to the implementation of this recommendation. The Executive notes the PR's comments on their opinion on the culture media alternatives available to them. The PR should update the centre's inspector by 12 May 2015 as to the progress of the plans to meet the requirement that all medical devices

invalidates the CE mark status of the culture medium. The laboratory manager provided a review of evidence and documents she had used to justify selection of these products but it remains the case that the use of the medium is non compliant with requirements of SLC T30 which requires the use of CE marked medical devices where possible. In a Clinic Focus article provided in April 2013 clinics were advised that in the absence of any prospect that non CE marked products would meet the requirements of licence conditions, they should implement a plan of action to ensure compliance within the following year SLC T30 Clinic Focus April 2013		Boston Place has sourced alternative plasticware from Vitrolife which is CE marked. We attempted to order the alternatives in May 2014 but were informed by the company that there were stock issues. They have now informed us this is no longer the case and no further orders will be made for non CE marked plasticware. Boston Place is the only UK clinic offering 100% Embryoscope culture system. We believe single step media is the only alternative to maximise safety of embryos, and Global supplemented with LGPS is currently the only validated alternative single step media for use in the Embryoscope. We are currently in the process of validating alternative CE marked single step options commercially available. However, as these are new products on the market they will need extensive validation to ensure their efficacy and safety in our clinic setting. The May 2015 deadline may not allow us to complete a	will be CE marked. Further action is required.

		full safety and efficacy evaluation by this time.	
5. Confidentiality In the recovery area patient information was viewable on a computer screen and it was considered that this posed a risk to confidentiality: although there was no evidence that there have been known breaches of confidentiality it is noted that identifying information is clearly visible and this was a concern raised at the time the centre's licence was issued HF&E Act section 33(1)	The PR should ensure that access to areas where confidential identifying information can be seen or obtained is restricted to people authorised by the PR. The PR should review the centre's procedures for controlling access to confidential identifying information. A summary of this review should be provided to the centre's inspector when responding to this report. The PR should conduct an audit of access to confidential identifying information six months after the implementation of any actions to ensure that any changes are effective and a summary of this audit to be provided to the centre's inspector by 12 May 2015.	**Controlling Access to Confidential Identify Information** Boston Place is a paperless clinic and therefore all patient information is scanned onto the Patient Management System. Access to the Patient Management System is safeguarded by personal logins and passwords. Privacy and Confidentiality audits have found staff to be discreet when conversing with patients in public areas and all medical areas are accessible via a swipe pass. Privacy screens have been ordered for the staff computers in the recovery area to ensure patient confidentiality is protected. They will be fitted on January 9th. **Re-Audit** A date has been set for May 2015	The Executive acknowledges the PR's response to this recommendation. The PR has confirmed that privacy screens have been fitted to the computers in the recovery area. Following audit in May 2015 the PR should provide a summary report of the audit and any actions resulting from it to the centre's inspector by 12 June. Further action is required.

6. Record keeping and document control In two records reviewed there was no medical history or indication for treatment recorded SLC T46	The PR should review the centre's procedures for record keeping to ensure that medical records contain all relevant documents and information. A summary of the review and any actions implemented should be provided to the centre's inspector by 12 February 2015. Three months after the implementation of any changes the PR should conduct an audit of patient records to ensure that any actions have been effective. A summary of the audit findings and any further actions required is to be provided to the centre's inspector by 12 May 2015.	To be submitted by the February 12th deadline	The PR has provided a summary of the review of the centre's procedures for record keeping. The review also included a summary of the actions taken to ensure that medical records contain all relevant documents and information... The PR should provide a summary report of record keeping audit and any actions resulting from it to the centre's inspector by 12 May 2015. Further action is required.
7. Obligations and reporting requirements A sample audit of patient and donor records held at the centre showed the following: • in one record, information submitted to	The PR must ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The systems and processes used for licensed treatment data submission should be reviewed to enable the	**Review of licensed treatment data submission** The interface between the HFEA EDI programme and Boston Place's IDEAS programme has not been operational since opening in September 2013. The Centre	The PR has provided a summary report confirming that the centre has conducted a review of their processes and has implemented appropriate corrective

the HFEA register records that the patient had treatment with her partner's gametes. The patient record held at the centre recorded that the patient had treatment with donor gametes; • in one record a donor already registered with the HFEA by the centre at which he donated was registered again by the centre thus creating a duplicate record. • five of seven DI treatments undertaken in a 12 month sample period had not been reported to the HFEA at the time of inspection as required by General Direction 0005. • 24% of the IVF treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005).	reasons for non-reporting and delayed submissions to be identified and addressed. This recommendation should be implemented by 12 January 2015. The reporting of the DI treatment cycles identified as outstanding at the time of inspection should be reported immediately. It is possible that DI cycles undertaken outside the sample period could be similarly affected and the PR should undertake an audit of DI cycles to identify any other cycles that have not been reported to the Authority by 12 February 2015 and implement corrective actions where necessary. The reason(s) for misreporting the IVF treatment in which donor gametes were used should be investigated and the corrective actions to prevent recurrence identified and implemented by 12 February 2015. All other IVF cycles in which donor gametes have been used should also be audited to ensure they have been accurately reported by 12 February 2015 and corrective actions implemented where necessary.	did not get standalone EDI until approximately April 2014; unfortunately this ceased to function after the IT issue reported to the HFEA in September 2014. Since then there have been several interactions between our IT personnel, IDEAS personnel and HFEA IT Support we have not been able to resolve why either of these systems are not functional. Without an operational EDI system it is difficult for our Centre to comply with regulations and we would welcome an on-site meeting with HFEA IT and our local IT department to give us access to EDI on-site. We have been reliant on intermittent reports kindly generated by Zakia since September 2014. Since the inspection we have reviewed the current Error Report which contains approximately 70 errors. We have divided the error report by discipline and identified trends in the report. As a result of these trends we have updated our EDI	actions. No further action is required.

A small number of other minor errors and omissions were also identified at the time of inspection SLC T9(e) / T41 General Direction 0005		Submission SOP and provided detailed, step by step, instructions on how to input and send the data as well as how to identify and clear errors. We have not yet cleared the error report as we need to arrange training for all staff. This will be done and the current error report will be cleared by the February 12th submission deadline. **Reporting Donor Insemination Cycles** All of the donor insemination cycles identified at the inspection have been registered. A full audit of all donor insemination cycles since the clinic opened will be completed and any missing registrations will be completed. A report to identify the corrective actions needed has not yet been compiled and will be submitted by the February 12th deadline. **Misreporting of donation cycle report** Boston Place requests the name	

		of the patient who was registered as having treatment with her partner but actually had treatment with a donor to ensure that the donor registration takes place and to enable us to complete a full review. The review report will be submitted by the February 12 deadline. **Donation Registration** The EDI errors have been identified a full report will be completed by the February 12th submission deadline. All donors will be correctly registered by then.	

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
8. Witnessing In four of six witnessing records of manual witnessing that were available for review on	The PR should take immediate action to ensure that all manual witnessing steps undertaken are documented appropriately and that records of witnessing are retained for each	**Manual Witnessing review** Following the HFEA inspection, laboratory staff were reminded to complete time and date for witnessing to tick the clearance	The Executive acknowledges the PR's response to this recommendation.

inspection it was noted that a number of steps (the time that witnessing took place when discarding gametes or placing them in storage and clearance of flow hood) were not recorded SLC T71	patient / donor. The PR should conduct a review of witnessing practice. A summary of this review and actions taken should be provided to the centre's inspector by 12 February 2015. Three months after the implementation of any changes the PR should conduct an audit of witnessing records and a summary report of the findings of the audit should be provided to the centre's inspector by 12 May 2015.	of flow hood tickbox when checking the flow hood is clear On 7th January 2015 a re-audit was undertaken of the 42 egg collections since November 12th. The following nonconformities were identified: • 3 tick boxes were missed to record that the embryologist checked to ensure flow hood was clear • 2 cryolocation checks were missed • 1 time and date were missed. Embryologists discussed the importance of completing witness dates and tick boxes and identified the corrective action. The witness form has been redesigned to make it easier to notice when a witness information is missed. **Re Audit of Protocol** A witnessing audit has been scheduled for March 2015	Following audit in March 2015 the PR should provide a summary report of the audit and any actions resulting from it to the centre's inspector by 12 May 2015 Further action is required.
9. Payment of donors The centre has not paid	The PR should review the process by which she is assured that donor	**Patient Information & Consent** In IVFH-BP-INF-CLN-004 donor	The Executive acknowledges the PR's

compensation to donors to date but a satellite patient has been treated with eggs provided by a known egg donor, and the centre could not provide evidence of whether compensation was provided to the donor by the satellite centre or if any payment was in accordance with General Direction 0001	compensation and benefits in kind are made to all donors (including those recruited by satellite providers) in accordance with General Direction 0001. A summary of this review and actions implemented to ensure that compliance with General Direction 0001 can be demonstrated should be provided to the centre's inspector by 12 February 2015.	compensation is clarified. The same wording is used in the egg donation consent form. Satellite Centres are now required to fill out the donor compensation form and send it to Boston Place prior to every donor's egg collection.	response to this recommendation. No further action is required.
10. Quality Management system The donor recruitment, assessment and screening SOP does not direct activity to ensure that the outcome of genetic and other screening found to be of significance to the donor and/or potential recipient(s) is acted upon No version control was evident on some documents reviewed on the centre's data base The centre has not	The PR should conduct a review of the centre's quality management system and ensure that; ◦ the donor recruitment, assessment and screening SOP is revised to ensure information regarding the outcome of genetic screening is noted and acted upon; ◦ there is an effective mechanism in place for document control which ensures that only the current version of any document is in use; ◦ all required corrective actions identified in the course of the audit of donor recruitment, assessment and screening are implemented. The PR should provide a copy of the revised donor recruitment, assessment	**Donation SOP** As previously stated the Boston Place donation programme has been reviewed and corrective actions made. The SOP now clearly states what medical professionals should do to ensure that the outcome of genetic and other screening found to be of significance to the donor and/or potential recipient is acted upon **Version Control** The Quality Manager has completed the document revision and reclassification to ensure only the latest versions of documents are on the Shared Drive. Boston Place has a	The Executive acknowledges the PR's response to this recommendation. No further action is required.

implemented all required corrective actions identified in the centre's own audit of donor recruitment, assessment and screening. SLC T33 (b), SLC T34 and SLC T36.	and screening SOP to the centre's inspector by 12 February 2015. The PR should provide the centre's inspector with a summary report documenting all outstanding corrective actions including the anticipated timescale for their implementation when responding to this report.	clearly outlined document control protocol to ensure documents are reviewed yearly and out of date versions are archived. The Quality Manager has also restricted access to controlled documents such as Patient Information and Consents to herself, the Person Responsible and Head of Lab to ensure the system is followed. **Incomplete Corrective Actions** An audit of egg donors was completed on October 24, 2014 and recommended updating the patient information, donation SOP and checklist. The recommendations, fleshed out in this HFEA report, had not yet been implemented by the November 10th, 2014 inspection.	
11. Safety and suitability of premises and facilities A tour of the centre's premises showed that the cylinders in the medical gas store were not stored securely. Also the electrical	The PR should ensure that medical gases are stored in accordance with guidance and that areas of restricted access are only used for their intended purpose. The HFEA should be advised of the measures taken to ensure that this happens by the time the PR responds	**Medical Gas Storage** An additional small oxygen cylinder trolley has been ordered to accommodate excess cylinders and will arrive by end 16th Jan 2015. The larger unsecured cylinders have been secured with wall brackets.	The Executive acknowledges the PR's response to this recommendation. The PR has provided confirmation that a full review of electronic access has been

control cupboard which the estate manager confirmed had restricted access was seen to contain cleaners buckets, mops and standing water. The centre does not have a process in place to manage pre employment occupational health screening for staff. The centre's infection control lead was not able to confirm the immunisation status of staff currently employed at the centre. SLC T2 and T17.	to this report The HFEA should be advised of the measures taken to ensure a process is in place to manage pre employment occupational health screening for staff by the time the PR responds to this report. .	**Occupational Health Screening** Boston Place has appointed Santia to undertake pre-employment screening and occupational health referrals – they are the UK's leading provider of integrated health and safety services. Santia will provide us with the services we require from 26 January 2015.	performed for all staff members in all areas. The electrical riser access is restricted to only senior management. The PR is asked to provide confirmation that cleaning equipment has been removed from the electrical control cupboard. Further action is required.
12. Staff Relevant staff were not able to provide documented evidence of their competence in selecting and recruiting donors SLC T12 and SLC T15a	The PR should ensure that staff are able to demonstrate competence in the tasks they perform. The PR should conduct a review of staff competence and how that is assessed and documented to ensure that staff are able to demonstrate competence as required.	At the time of the inspection the clinical competency regarding screening egg donors was in place for doctors, there was not a separate one in place for nurses. At the time of inspection the competency was in its third version and the same version is currently in use.	The Executive acknowledges the PR's response to this recommendation. No further action is required.

	A summary of this review and actions required, with a plan as to the timescales for this plan to be implemented should be provided to the centre's inspector by 12 February 2015.	As the protocol has been reviewed to ensure doctors sign off on the blood screening results and donor health questionnaire the competency does not need to be updated.	
13. Third party The content of a third-party agreement reviewed in the course of the inspection did not include a description of how any diagnostic test results should be relayed to the commissioning centre including sign off and confirmation that the results apply to the correct sample. SLC T114.	The PR should ensure that all TPAs are reviewed to ensure compliance with requirements. A summary report of the findings of the review including a list of all third party agreements included in the review should be provided to the centre's inspector by 12 April 2015. The report should also document any corrective actions required to ensure compliance and the anticipated timescales for the implementation of the corrective actions.	To be submitted by the April 12th deadline	The Executive acknowledges the PR's response to this recommendation. The PR to submit a summary report of the findings of the review together with any corrective actions to the centre's inspector by 12 April 2015 Further action is required.
14. Provision of information The written patient information regarding legal parenthood appeared unclear and confusing as it made	The PR should review the centre's patient and donor information to ensure that; ◦ proper information about legal parenthood is provided to patients giving consent to treatment;	**Legal Parenthood** As a result of the UK wide legal parenthood audit the Academic Reproductive Partnership, of which Boston Place is member of, took legal consultation and created new documents to	The Executive acknowledges the PR's response to this recommendation and has reviewed the updated patient information.

reference to both legal parenthood and parental responsibility but the information did not clearly explain the difference between them. This puts the centre at risk of failing to provide proper information to patients giving consent to treatment CoP guidance 6.2 One donor record reviewed included a disclaimer that suggested the donor understood that she could claim £750 in compensation for her donation and expenses. Although no excess payment of additional claim for expenses was made, this information is not compliant with General Direction 0001	° the written information for egg donors states that expenses are limited to as prescribed in General Direction 0001. The PR is to provide the centre's inspector with an updated copy of the legal parenthood and donor payment information by 12 February 2015.	address all aspects of legal parenthood. The documents were in use at the time of the inspection, however overviews of the concept of legal parenthood and parental responsibility had not been removed from other documents. This has now been done. **Donor Compensation** This information has been updated on IVFH-BP-INF-CLN-004.	No further action is required.
15. Disclosure of information, held on	The PR should review systems and processes to ensure that, completed	To be submitted by the February 12th deadline	The PR has provided a summary report

the HFEA Register, for use in research In two instances the audit team were unable to find patient/partner disclosure consents on the clinics IT system to confirm that the consent information supplied to the HFEA is accurate Chair's Letter CH(10)05, Guidance supplementary to Chair's Letter CH(10)05 and General Direction 0007	patient and partner consent to disclosure of information is retained and is readily available for reference purposes and to enable the accuracy of the data supplied to the Authority to be confirmed. The PR is to provide the centre's inspector with a summary of this review and any action taken by 12 February 2015. The PR should conduct an audit of records to ensure that, where consent to disclosure is present, this decision has been provided to the HFEA. Any omissions should be reported to the HFEA's register. Three months after the implementation of any changes the PR should conduct a further audit of patient/partner records to ensure that consent to disclosure decisions are recorded. A summary of the audit should be provided to the centre's inspector by 12 May 2015.		confirming that the centre has conducted a review of their processes and has implemented appropriate corrective actions. The PR should provide a summary report of consent to disclosure information audit to the centre's inspector by 12 May 2015. Further action is required.

*PR's responses were submitted in an email and extracts have been pasted in the report

Reponses from the Person Responsible to this inspection report