HFEA Licence Committee Meeting

10 July 2014

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

Minutes – Item 5

Centre 0094 (Barts and the London Centre for Reproductive Medicine) – Treatment and Storage Renewal Licence

Members of the Committee:	Legal Adviser:
Andy Greenfield (lay) (Chair) David Archard (lay) Debbie Barber (professional) Jane Dibblin (lay)	Tom Rider, Fieldfisher Committee Secretary: Lauren Crawford

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

The following papers were considered by the Committee:

- Inspection report including PR response
- Application form (2014/005985)
- Previous Licence Committee minutes for the past three years:
    - 2014/000909: interim inspection (9 January 2014) update
    - 2013/016568: interim inspection (19 September 2013)
    - 2012/017628: change of LH
    - 2012/009802: change of PR
    - 2012/000359: interim inspection (20 December 2011) update
    - 2011/045266: interim inspection (23 September 2011)
- HFEA's additional licensing report (for Item 5a)
- Independent review report (for Item 5a)

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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); and
- 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 Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. Barts and the London Centre for Reproductive Medicine has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services, including storage of gametes and embryos. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

2. The centre provided 1,084 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to February 2014. In relation to activity levels this is a large centre.

3. Following an interim inspection in June 2013 serious concerns were raised regarding non-compliances at the centre and whether the Person Responsible (PR) had discharged her duty under Section 17 of the HF&E Act 1990 (as amended). Subsequent to that inspection, the centre team attended the HFEA for a management review meeting and submitted an action plan to address the non-compliances. The interim report and action plan were presented to Licence Committee (LC) in September 2013.

4. The LC agreed to adjourn their decision until January 2014 to allow the centre to demonstrate improvement following the implementation of the action plan and corrective actions. An executive update was presented to LC in January 2014 and the Committee agreed to the continuation of the centre's licence with no additional conditions. The LC urged the PR to continue to conduct and submit monthly audit reports and requested that the next renewal inspection report should be considered by the LC in due course.

5. The PR subsequently worked closely with the inspector for the centre and has performed extensive audits of patient records to identify areas of concern. The audit results have been reported monthly to the HFEA. Corrective actions have been implemented and staff training has been reported as being maintained.

Discussion

6. The Legal Adviser advised that the Committee could take into account in considering this licence renewal application the documents for Item 5a for the Committee Meeting, namely the HFEA's additional licensing report and the

Independent review report, which related to a Whistle-blower communication in connection with this centre. The Committee considered these two reports first and reached its decision upon them, as set out in the Minutes for Item 5a, before proceeding to discuss the papers for the licence renewal application.

7. The Committee noted that at the time of the inspection (15 and 16 April 2014), the Inspectorate reported that there were a number of areas of practice that required improvement, including fifteen 'other' areas of non-compliance or poor practice.

'Other' areas of non-compliance:

- the PR should ensure that witnessing records are fully completed at the time that the witnessing occurs;
- the PR should ensure that procedures are established to identify when additional screening tests for patients, partners and donors are required;
- the PR should ensure that individuals providing gametes for partner treatment or donation are screened in accordance with the timeframes specified by the Authority;
- the PR should ensure that all diagnostic tests are carried out by laboratories which are appropriately accredited;
- the PR should ensure that the documented procedures are audited against HFEA CoP requirements;
- the PR should ensure that a standard operating procedure (SOP) is produced documenting the practices by which patient confidentiality and privacy is maintained;
- the PR should ensure that corrective actions and timescale for implementation are documented for all audits performed at the centre;
- the PR should ensure that all third party agreements are compliant with the relevant standard licence condition (SLC) requirements;
- the PR should ensure the water bath (which is used to warm the work area in the air flow cabinet) is validated;
- the PR should ensure that all medical devices and other consumables used within the laboratory are CE marked;
- the PR should ensure that the assessment of competence of staff to perform designated tasks is evaluated and documented;
- the PR should ensure that patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms;
- the PR should ensure that patient files contain records of all clinical and laboratory data and the results of any tests carried out;
- the PR should ensure effective document control measures are in place and that only current versions of documents are in use;
- the PR should ensure that all licenced treatment activity is reported to the Authority within the timeframe required by Direction 0005.

8. The Committee noted that since the inspection the PR has given a commitment to fully implement these areas of practice that require improvement within the prescribed timescales.

9. The Committee noted the Inspectorate's recommendation to renew the centre's 'Treatment and Storage' licence for a period of four years without additional conditions subject to the recommendations made in the renewal inspection report being implemented within the prescribed timescales.

Discussion

10. The Committee had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and noted that the executive had received the supporting information required by General Direction 0008.

11. The Committee noted that the PR holds academic qualifications in the field of biological sciences. The proposed PR also has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii). She has successfully completed the HFEA PR Entry Programme.

12. The Committee noted the PR is suitable and will discharge her duty under section 17 of the HF&E Act 1990 (as amended).

13. The Committee was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

14. The Committee was satisfied that the premises (including those of relevant third parties) to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report.

15. The Committee referred to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states [The Licence Committee] will normally only grant a renewal licence for treatments/ storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

Decision

16. The Committee agreed to renew the centre's licence for a period of four years without any additional conditions

17. The Committee urged the centre to complete the outstanding recommendations within the prescribed timescales. The Committee noted that the inspector will continue to monitor the centre's performance. Failure to implement the recommendations may result in the submission of a further report to the Executive Licensing Panel with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

Signed: Date: 23/07/2014

Andy Greenfield (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 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 Licence Committee (LC) 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: 15 and 16 April 2014

Purpose of inspection: Renewal of a licence to carry out Treatment and Storage

The centre has applied to add the following activities: None

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

Inspectors: Janet Kirkland, Gill Walsh, Andrew Leonard, Karen Conyers, Heidi Birch (external), Sheila Pike (external), Chris Hall, Zakia Ezzouyar

Date of Licence Committee: 10 July 2014

Centre name	Barts and The London Centre for Reproductive Medicine
Centre number	0094
Licence number	L/0094/14/d
Centre address	Barts and the London NHS Trust, 2nd Floor, Kenton and Lucas Wing, St Bartholomew's Hospital, Little Britain, London, EC1A 7BE, UK
Person Responsible	Ms Bonnie Collins
Licence Holder	Mr Steve Ryan
Date licence issued	1 October 2009
Licence expiry date	30 September 2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Barts and the London Centre for Reproductive Medicine has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services, including storage of gametes and embryos. 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 centre provided 1,084 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2014. In relation to activity levels this is a large centre.

The current licence was varied in 2012 to reflect the following changes: change of Person Responsible (PR) and Licence Holder (LH).

Following an interim inspection in June 2013 serious concerns were raised regarding non-compliances at the centre and whether the PR had discharged her duty under Section 17 of the HF&E Act 1990 (as amended). Subsequent to that inspection, the centre team attended the HFEA for a management review meeting and submitted an action plan to address the non-compliances. The interim report and action plan were presented to Licence Committee (LC) in September 2013.

The LC agreed to adjourn their decision until January 2014 to allow the centre to demonstrate improvement following the implementation of the action plan and corrective actions. An executive update was presented to LC in January 2014 and the Committee agreed to the continuation of the centre's licence with no additional conditions. The LC urged the PR to continue to conduct and submit monthly audit reports and requested that the next renewal inspection report should be considered by the LC in due course.

The PR subsequently worked closely with the inspector for the centre and has performed extensive audits of patient records to identify areas of concern. The audit results have been reported monthly to the HFEA. Corrective actions have been implemented and staff training has been reported as being maintained.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 December 2012 to 30 November 2013 show that the centre's success rates are in line with the national averages.

In 2013, the centre reported 241 cycles of partner insemination with 28 pregnancies. This equates to 12% clinical pregnancy rate which is consistent with the national average pregnancy rate.

Multiple births[2]

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

Between 1 January 2013 and 31 December 2013 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%: 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;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The LC is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including fifteen 'other' areas of non-compliance.

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

'Other' areas that require improvement:

1. the PR should ensure that witnessing records are fully completed at the time that the witnessing occurs;
2. the PR should ensure that procedures are established to identify when additional screening tests for patients, partners and donors are required;
3. the PR should ensure that individuals providing gametes for partner treatment or donation are screened in accordance with the timeframes specified by the Authority;
4. the PR should ensure that all diagnostic tests are carried out by laboratories which are appropriately accredited;
5. the PR should ensure that the documented procedures are audited against HFEA CoP requirements;
6. the PR should ensure that a standard operating procedure (SOP) is produced documenting the practices by which patient confidentiality and privacy is maintained;
7. the PR should ensure that corrective actions and timescale for implementation are documented for all audits performed at the centre;
8. the PR should ensure that all third party agreements are compliant with the relevant standard licence condition (SLC) requirements;
9. the PR should ensure the water bath (which is used to warm the work area in the air flow cabinet) is validated;
10. the PR should ensure that all medical devices and other consumables used within the laboratory are CE marked;
11. the PR should ensure that the assessment of competence of staff to perform designated tasks is evaluated and documented;
12. the PR should ensure that patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms;

13. the PR should ensure that patient files contain records of all clinical and laboratory data and the results of any tests carried out;
14. the PR should ensure effective document control measures are in place and that that only current versions of documents are in use.
15. the PR should ensure that all licenced treatment activity is reported to the Authority within the timeframe required by Direction 0005.

Recommendation to the Licence Committee.

The inspection team notes that the centre's success rates are consistent with the national averages and that their multiple clinical pregnancy rate indicates the centre is likely to meet the 10% live birth rate target for treatments in 2013. The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

The inspection team recommends the renewal of the centre's Treatment and Storage licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

The inspector will continue to monitor the centre's performance. Failure to implement the recommendations of this report within the prescribed timescales will result in the submission of a further report to the LC 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. The centre uses a manual witnessing system which was observed during various laboratory activities. Effective witnessing ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better

Witnessing (Guidance note 18)

- During an audit of a sample of 10 sets of witnessing records it was found that one signature (of the operator) and one time of procedure was not recorded (SLC T71). See recommendation 1.

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 screening donors are broadly 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 compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes. 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 non-identifying information regarding the 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's SOP for screening patient's, partners and donors does not include the requirement to perform additional testing dependant on the patient, partner or donor's history and/or the characteristics of the gametes donated (SLCT50d and T52 h). See recommendation 2.
- Prior to the processing of patient gametes or embryos intended for use in treatment or storage, the centre does not consider the need to carry out additional HTLV-1 antibody testing, based on an assessment of whether a patient or patient's parents live in or originated from high incidence areas or if the patient has or has had sexual partners originating from those areas (SLC T50c). See recommendation 2.
- Blood samples for screening of individuals providing gametes for partner treatment or donation are not being obtained within the time frame specified by the Authority. (SLC T53b and T51b). See recommendation 3.

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 suitable. This is important to ensure that all licensed activities are conducted in an 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 does not have any active satellite/transport agreements so this area was not reviewed during this inspection.

The centre is compliant with HFEA requirements to processes 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 which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are partially compliant with HFEA requirements for accreditation by the United Kingdom Accreditation Service (UKAS) or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre 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, 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 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 and that
- 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 note15)
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 have enough information to permit them to 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 imports and exports of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are 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;
- 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 broadly 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.

Transport and satellite agreements (Guidance note 24; Directions 0010)
The centre does not currently have any active transport or satellite IVF agreements.

Equipment and materials (Guidance note 26)

The centre uses equipment and materials that are broadly compliant with HFEA requirements.

- All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.
- The centre is broadly 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 is 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 adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Laboratory accreditation (Guidance note 25)

- It was discussed on inspection that diagnostic test results are communicated to the centre in a referral letter from the patient's referring clinician. As the centre does not have copies of the actual test results the PR was not able to verify that these tests had been performed in a suitably accredited laboratory (SLC T51a and T53a). The communication of results in this manner also risks transcription errors impacting on the patient's treatment pathway. See recommendation 4

Quality management system (QMS) (Guidance note 23)

- It was apparent on inspection that the SOP's for surrogacy, additional screening and some laboratory SOP's had not been audited against the HFEA CoP to ensure compliance with current requirements (SLC T36). See recommendation 5.
- The PR could not provide evidence of a SOP documenting the practices by which patient confidentiality and privacy are maintained (SLC T33b). See recommendation 6.
- Whilst the centre could provide evidence of regular audits of licensed activities it was difficult to ascertain in some instances if corrective actions had been implemented and the impact of the corrective actions had subsequently been reviewed (SLCT36).See recommendation 7.

Third party agreements (Guidance note 24)

- The content of a sample of third-party agreements reviewed in the course of the inspection indicated that they were generic and did not meet SLC requirements (SLC T114 &T116). See recommendation 8.

Equipment and materials (Guidance note 26)

- The water bath (which is used to warm the work area in the air flow cabinet) has not been validated (SLC T24). See recommendation 9.
- The PR could not confirm that all medical devices and other consumables used within the laboratory were CE marked (SLC T30). See recommendation 10.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (T/1215/8).

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

Staff (Guidance note 2)

- The PR could not provide documentation of the assessment of competencies for relevant staff involved in donor assessment and screening and in maintaining traceability (SLC T12, T15a and b). See recommendation 11.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. This is important 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.

Safeguarding
The centre's procedures are compliant with safeguarding requirements. This ensures that the centre patients and staff are protected from harm where possible.

What the centre could do better

Nothing identified at this inspection.

Embryo testing

Pre-implantation genetic screening
Embryo testing and sex selection

What the centre does well

Pre-implantation genetic screening (Guidance note 9)
The centre does not carry out pre-implantation genetic screening.

Embryo testing and sex selection (Guidance note 10)
The centre does not carry out embryo testing.

What the centre could do better

Not applicable

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspection team spoke to four patients and their partners who provided feedback on their experiences. A further 20 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive; of the 17 individuals providing written feedback to the HFEA, 12 commented that they had 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; Directions 0001)
The PR advised the inspector that they do not provide any egg or sperm sharing

arrangements to patients.

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are broadly 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 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

Surrogacy (Guidance note 14)

- The SOP for surrogacy was last reviewed in 2011 and did not include reference to most recent CoP updates (SLC T36). 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 compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Nothing identified at this inspection

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

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research (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 of 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)

- Four discrepancies were found between completed patient/partner/donor disclosure consents on patient files and the related consent data submitted for inclusion on the register. A total of 16 consents were examined. See recommendation 12

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 broadly compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

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)

- The centre's SOP for screening patients, partners and donors does not include the requirement to perform additional testing dependant on the patient, partner or donor's history and/or the characteristics of the gametes donated (SLC T50d and T52h). See recommendation 2;
- Prior to the processing of gametes or embryos intended for use in treatment or storage the centre does not consider the need to carry out additional HTLV-1 antibody testing, based on an assessment of whether a patient or patient's parents live in or originated from high incidence areas or if the patient has or has had sexual partners originating from those areas (SLC T50c). See recommendation 3;
- Blood samples for screening of individuals providing gametes for partner treatment or donation are not being obtained within a time frame specified by the Authority. (SLC T53b and T51b). See recommendation 3.

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 broadly compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32 ; Directions 0005)
The centre's procedures for submitting information about licensed activities to the Authority broadly 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.

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Record keeping and document control (Guidance note 31)

- The centre has been using patients and partners diagnostic test results transcribed onto a checklist provided by external referrers as evidence of their viral status. The inspection team considers that this may introduce an element of risk of transcription error and that this practice should be reviewed (SLC T46g). See recommendation 13.
- In one set of notes reviewed during the audits, the Welfare of the Child forms used were not the current version (SLC T34). See recommendation 14.

Obligations and reporting requirements (Guidance note 32)

- Our review of patient and donor records against data submitted by the centre to the HFEA's Register identified a small number of minor errors. One of the 54 DI treatments reviewed at inspection had not been reported to the HFEA as required by Direction 0005. See recommendation 15.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2013, recommendations for improvement were made in relation to five areas of critical non-compliance, five areas of major non-compliance and three 'other' areas of non-compliance.

The PR provided information and evidence that all but one 'critical' recommendation were completed within the prescribed timescales.

The following recommendation has not been fully implemented:

- The PR should ensure that provision of information to patients prior to giving consent to the use of gametes/embryos after death and to posthumous birth registration is clear. The implications of such consents must be discussed and it should be ensured that the consents documented, are consistent and accurately reflect the patient's wishes.
  The PR should perform an audit of all records where patients may have completed this consent and seek advice from the Trusts' legal team as to actions that may need to be taken.
  The PR should provide the HFEA with a summary of the legal advice obtained by the centre and, if relevant, the outcome of the audit of patient consents and an action plan documenting the anticipated timescale for contacting any affected patients.

During an audit of patient records performed on this renewal inspection, it was again observed that in some instances consent to the posthumous use of gametes/embryos had been documented in the absence of consent to storage. This was discussed at length with the PR who assured the lead inspector that staff did discuss the implications of consenting in this way with the patients.

In addition she informed the inspection team that all staff were currently undergoing further training in provision of information prior to obtaining consent. As this was identified as an issue in June 2013 with recommendations being confirmed and accepted in September 2013 the inspection team considered that this was being addressed and advised the PR to inform the inspector on the completion of the training.

The PR did perform an audit of patient files within the timescales required by the previous report .However she decided to extend the scope of the audit to include a comprehensive audit of in excess of 900 files. Upon completion the PR will review the findings and seek legal advice where indicated.

The PR was reminded to inform the HFEA of any legal advice obtained by the centre and actions taken to address any issues identified.

On-going monitoring of centre success rates

In 2013 the centre did not receive any performance related alerts regarding success rates.

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
None			

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
1. During an audit of a sample of 10 sets of witnessing records it was found that one signature (of the operator) and one time of procedure was not recorded (SLC T71).	The PR should ensure that witnessing records are fully completed at the time that the witnessing occurs. This recommendation should be implemented immediately and the PR should inform the inspector of the actions taken. Three months after changes are implemented, the PR should audit the completeness of witnessing records to ensure the actions taken have removed this non-compliant practice. A report of the audit should be provided to the centre's inspector by 16 October 2014.	Monthly audits of witnessing to be contined. Outcome of audits to be sent to fertility staff. Staff competency - to be assessed as part of appraisal preparation. Annual update will now include witnessing.All appraisals must be completed by July 2014. Staff who have not completed the witnessing as per CRM SOP to be reminded of the importance of its completion.	The inspector acknowledges the PR's response and looks forward to receiving a report of the audit by 16 October 2014. Further action required.
2. The centre's SOP for screening patient's, partners and donors does not include the requirement to perform additional testing dependant on their medical history	The PR should take immediate action to ensure that procedures are established to identify and carry out additional screening tests when required. The	Update all SOPs that refer to screening of patients, partners and donors. To ensure that additional testing is performed based on medical history.	The inspector acknowledges the PR's response and looks forward to receiving a report of the audit by 16 October 2014. Further action required.

and/or the characteristics of the gametes donated (SLC T50d and T52h). Prior to the processing of gametes or embryos intended for use in treatment or storage the centre does not consider the need to carry out additional HTLV-1 antibody testing of the gamete providers, based on an assessment of whether a patient or patient's parents live in or originated from high incidence areas or if the patient has or has had sexual partners originating from those areas (SLC T50c).	HFEA should be advised of the measures taken to implement this recommendation by 16 July 2014. Within three months of the implementation of procedures, or by 16 October 2014 at the latest, the centre should conduct an audit of screening and a summary report of the findings of the audit should be provided to the HFEA.	Patient registration, clinical history and checklist forms to be reviewed to ensure that this is addressed during the consultation and at intervals along patient pathway Undertake an audit of patients, egg donors, sperm donors and surrogacy couples.	
3. Blood samples for screening of individuals providing gametes for partner treatment or donation are not obtained within the time frame specified by the Authority (SLC T51b and T53b),	The PR should ensure that blood samples for screening of individuals providing gametes for partner treatment or donation are obtained within the time frame specified by the Authority. The HFEA should be advised of the measures taken to implement this recommendation by 16 July 2014.	Currently a monthly audit is undertaken of patients screened within 12 or 24 months of treatment. This will now be extended to include screening within 3 months of the first treatment cycle for IUI and IVF/ICSI treatments.	The inspector acknowledges the PR's response. The PR should ensure that staff are aware of the requirement for individuals to be screened within the time frame specified by the Authority. The HFEA should be advised of the measures taken to

	Within three months of the implementation of corrective actions and by 16 October 2014 at the latest, the centre should conduct an audit of the timing of screening tests and a summary report of the findings of the audit should be provided to the HFEA.		implement this recommendation by 16 July 2014. The inspector looks forward to receiving a report of the audit by 16 October 2014. Further action required.
4. Diagnostic test results are communicated to the centre by the patient's referring clinician without documented evidence of the relevant laboratory test results. The PR was therefore not able to verify that tests had been performed in a suitably accredited laboratory (SLC T51a and T53a)	The PR should ensure that all diagnostic tests are carried out by laboratories which are appropriately accredited, that evidence of this is collected and that appropriate records of diagnostic tests are maintained in the patient records. This recommendation should be implemented by 16 July 2014 and the HFEA advised of the actions taken. Within three months of the changes to procedures, or by 16 October 2014 at the latest, the centre should conduct an audit of the evidence collected regarding the accreditation of the laboratories providing	Referrals and funding team to audit and confirm the referral pathways where transcipted results are provided or where the accreditation of the laboratory performing the tests is not clear from the copy provided. PR to clarify whether BH Trust laboratories are accredited for virology and biochemistry screens. Referrers will be asked to provide copies of blood test results and confirm accreditation. Audit to be undertaken.	The Inspector acknowledges the PR's response and request that she update the inspector as to the accreditation status of the laboratories used to perform diagnostic tests by 16 July 2014. The inspector looks forward to receiving the report of the audit by 16 October 2014. Further action required.

	diagnostic testing services. A summary report of the findings of the audit should be provided to the HFEA.		
5. The SOP for surrogacy, additional screening and some laboratory SOP's have not been audited against the HFEA CoP to ensure compliance with current requirements (SLC T36).	The PR should ensure that the documented procedures are audited against HFEA CoP requirements. A plan for these compliance audits should be provided to the HFEA by 16 July 2014 which should ensure that all documented procedures are audited and the required corrective actions are completed by 16 April 2015. A final report of the audits with the required corrective actions should be provided to the HFEA by 16 April 2015.	All CRM SOPs will be audited against CoP requirements before 16 April 2015. Master index to be used to track progress of this audit.	The inspector acknowledges the PR's response. The inspector looks forward receiving the report of the audits by 16 April 2015. Further actions required.
6. On inspection the PR could not provide evidence of an SOP documenting the practices by which patient confidentiality and privacy are maintained (SLC T33b).	The PR should ensure that a SOP is produced documenting the practices by which patient confidentiality and privacy are maintained. The PR should provide the inspector with a copy of the SOP and evidence of staff training by 16 July 2014.	PR to write an SOP to state practices by which patient confidentiality and privacy are maintained.SOP to include reference to BH Trust policy Confidentiality CoP (COR/POL/022/2012-001)and Information Governance.	The inspector expects to receive a copy of the SOP in addition to evidence of staff training in practices by which patient confidentiality and privacy are maintained by 16 July 2014. Further action required.

7. Whilst the centre could provide evidence of regular audits of licensed activities it was difficult to ascertain in some instances if corrective actions had been implemented and subsequent impact reviewed (SLCT36).	The PR should ensure that corrective actions with their timescale for implementation are documented for all audits performed at the centre. The PR should provide the inspector with evidence of a process by which corrective actions and timescales for implementation are documented by 16 July 2014.	The PR has confirmed that she will ensure that corrective actions with their timescale for implementation are documented for all audits performed at the centre. The PR will provide the inspector with evidence of a process by which corrective actions and timescales for implementation are documented within the required timescales.	The inspector looks forward to receiving evidence of these processes by 16 July 2014. Further action required.
8. The content of a sample of third-party agreements appeared to be generic and did not meet SLC requirements (SLC T114 & T116).	The PR should ensure that all third party agreements are reviewed to ensure compliance with SLC requirements. A summary report of the findings of the review, including a list of all third party agreements included in the review and the required corrective actions, should be provided to the HFEA by 16 July 2014	PR to review all TPA to ensure that they reflect the particular sections of CoP. New TPAs to be completed with all suppliers.	The inspector looks forward to receiving the summary report by 16 July 2014. Further action required.
9. The water bath (which is used to warm the work area in the air flow cabinet) has	The PR should ensure the water bath is validated by 16 July 2014.	Water bath to be validated asap	The inspector expects to receive confirmation of the validation of the waterbath by

not been validated (SLC T24).			16 July 2014. Further action required.
10. The PR could not confirm that all medical devices and other consumables used within the laboratory were CE marked (SLC T30).	The PR should review the CE status of all medical devices and consumables currently in use. Where devices are not CE marked, the review should include the anticipated time by which a CE mark is expected to be obtained or the action that will be taken to ensure compliance within the next year. The review should be submitted to the HFEA by 16 July 2014.	CE mark status of all products now clear as added to traceability spreadsheet. Alternative suppliers being sought for non CE marked products.	The inspector looks forward to receiving the review as described by 16 July 2014. Further action required.
11. The PR could not provide documentation of the assessment of competencies for relevant staff involved in donor assessment and screening and in maintaining traceability (SLC T12, T15a and b).	The PR should, where noted in the report, ensure that the assessment of competence of staff to perform designated tasks is evaluated and documented. The PR should provide an update of these assessments to the inspector by 16 October 2014.	Competency for staff involved in donor screening to be written and relevant staff assessed as part of annual appraisal	The inspector looks forward to receiving a copy of the assessment of competencies by 16 October 2014. Further action required.
12. Four discrepancies were found between completed	The PR should:	A monthly audit of CD disclosures on EDI is being	The inspector acknowledges the PR's response and looks

patient/partner/donor disclosure consents on patient files and the related consent data submitted for inclusion on the register. A total of 16 consents were examined. Guidance Note 5 – Consent to treatment, storage, donation and disclosure of information Chair's Letter CH(10)05 Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007	• review systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure consent forms; • conduct an audit six months after implementing any changes to confirm that any changes made to systems and processes are having the desired effect; and • correct the submissions that have been identified as being incorrect.	undertaken and any errors corrected. The content of the CD and EDI CD is check at the point of ITT submission	forward to receiving the audit six months after the implementation of the changes. The PR to inform the inspector of the expected timescales for implementation of any corrective actions. Further action required.
13. The centre has been using patients and partners diagnostic test results transcribed onto a checklist provided by external referrers as evidence of their viral status. The inspection team considers that this may introduce an element of risk of transcription error and	The PR should review the procedure for accepting diagnostic test results from third parties. The PR should ensure that the results of all laboratory test and data which form part of the patient record, (hard copy or electronic) are	(see 4) Referrals and funding team to audit and confirm the referral pathways where transcripted results are provided or where the accreditation of the laboratory performing the tests is not clear from the copy provided. PR to clarify whether BH Trust	The inspector acknowledges the PR's response. The concerns raised in this non-compliance are with regard to the risks of transcription error. This would be addressed if the centre obtains copies of blood test results for their own records.

that this practice should be reviewed (SLC T46g).	accessible and are verified and traceable to the organisation providing the data. The PR should provide the inspector with a copy of this review by 16 July 2014.	laboratories are accredited for virology and biochemistry screens. Referrers will be asked to provide copies of blood test results and confirm accreditation. Audit to be undertaken.	The inspector requests the PR to inform her of the anticipated timescale for the implementation of the revised procedure for accepting diagnostic test results. Further action required.
14. In one set of notes reviewed during the audits, the Welfare of the Child forms used was not the current version (SLC T34).	The PR should ensure that only current versions of documents are used. The PR should confirm that this recommendation has been implemented by the 16 July 2014.	HFEA consents are now generated for each patient via ACUbase. This means that only current version should be used going forward.	The inspector acknowledges PR response. The PR should audit the consent forms generated from ACUbase to ensure that this system is effective. Further action required.
15. One of the 54 DI treatments reviewed at inspection had not been reported to the HFEA as required by Direction 0005 (SLC T9e and T41).	The PR must ensure that all licenced treatment activity is reported to the Authority within the timeframe required by Direction 0005. The treatment identified as unreported at the time of inspection should be reported immediately. The systems and processes used for licensed treatment data submission should be	The system currently in place is robust but fallible. The DI treatment has now been reported. Embryologists confirm that EDI data has been submitted in the red lab books. From now on audit of the submission of EDI Data will be included in the monthly audits of consents and treatments undertaken. A monthly audit of DI and FET treatments will be undertaken	The inspector is satisfied with the response. The submission of Data will continue to be monitored at the HFEA via the Risk Based Assessment Tool. No further action.

	reviewed to enable the reasons for non-reporting to be identified and addressed. This recommendation should be implemented within 1 month of the inspection date.	to ensure that all have been reported via EDI to the HFEA data register.	

Reponses from the Person Responsible to this inspection report