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. 1

Centre 0325 (Bourn Hall (Norwich)) – 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: members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to Licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

Consideration of Application

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

2. The panel noted that this is a treatment and storage centre which provides a full range of licensed treatments. The panel noted that in relation to activity levels this is a small 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 30 April 2015.

4. The panel noted that in the 12 months to 31 October 2014, the centre provided 369 cycles of treatment (excluding partner intrauterine insemination).

5. The panel noted that for IVF and ICSI, HFEA-held register data for the period 1 August 2013 to 31 July 2014 showed that the centre's success rates were in line with national averages.

6. The panel noted that in 2013 the centre reported that no cycles of partner insemination treatments had been provided.

7. Between 1 August 2013 to 31 July 2014, the centre's clinical multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represented performance that was in line with the 10% maximum multiple live birth rate target for this period.

8. The panel noted that at the time of the inspection on 9 and 10 December 2014, the Inspectorate identified five major and three other areas of non-compliance. The panel noted in particular the major non-compliances. The panel noted that the Person Responsible (PR) had committed to fully implement all of the recommendations within the prescribed timescales. However the panel was concerned that the PR's initial response to the report did not provide assurances that these recommendations would be fully implemented. The panel noted that the Inspectorate would continue to monitor the centre's performance closely and failure to implement the recommendations in this report within the prescribed timescales may 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.

9. The panel noted that the success rates were consistent with the national average and the multiple clinical pregnancy rates met the HFEA target. However the PR is encouraged to continue to use the quality management system (QMS) to best effect to monitor and improve their success rates and to continually improve the quality of the service offered to patients.

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

11. The panel noted that following a management review, the PR revised the response to the recommendations made in the renewal inspection report. The Inspectorate was assured that the PR is engaged with the HFEA and the findings of this report, and that the PR had given a commitment to discharge her duty under section 17(1)(d) of the HF&E Act 1990 (as amended) in ensuring that the centre's practices are suitable.

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

Decision

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

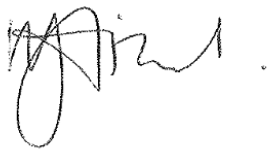
14. In light of the issues raised by the Inspectorate in its report, the panel had regard to its indicative applications guidance in relation to length of licence, in particular the history of compliance with statutory requirements and cooperation by the PR.

15. 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).

16. The panel noted that the premises to be licensed were suitable for the conduct of the licensed activities.

17. The panel noted the key dates for implementation of the recommendations and urged the centre to complete them within the prescribed timescales. The panel endorsed the Inspectorate's recommendation to continue to monitor the centre's performance. The Inspectorate is asked to provide the Executive Licensing Panel with an update report at the most appropriate time within the next 12 months.

18. The panel endorsed the Inspectorate's recommendation to renew the centre's treatment 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: 9 and 10 December 2014

Purpose of inspection: Renewal of a licence to carry out treatment and storage

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

Inspectors: Karen Conyers (lead), Janet Kirkland, Sara Parlett, Cathy Hodgson, Tarek Hussain

Date of Executive Licensing Panel: 27 February 2015

Centre name	Bourn Hall (Norwich) Limited
Centre number	0325
Licence number	L/0325/2/c
Centre address	Gateway 11, Unit 3, Farrier Close, Wymondham, Norwich, Norfolk, NR18 OWF, UK
Person Responsible	Mrs Frances Rose-Smith
Licence Holder	Dr Thomas Matthews
Date licence issued	1 May 2013
Licence expiry date	30 April 2015
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

Bourn Hall (Norwich) Limited has held a treatment and storage licence with the HFEA since May 2013 and provides a full range of fertility services. The centre provided 369 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2014. In relation to activity levels this is a small centre.

In June 2013 the ELP agreed to an application to a change of Person Responsible (PR) to Mrs Frances Rose-Smith.

The initial licence included an additional condition which stated: '*That no licensed activity should take place at the centre until the PR provides satisfactory evidence of compliance with the outstanding recommendations relating to the major areas of non-compliance detailed in the report and referenced in paragraph 5 of the Licence Committee minutes.*' In May 2013 the centre submitted an application to remove the condition imposed on the licence and the Licence Committee were not minded to remove the condition but instead modified it to state: *That no licensed activity should take place at the centre until the PR provides evidence that the Executive finds satisfactory of compliance with the outstanding recommendations relating to the major areas of non-compliance detailed in the report and referenced in paragraph 5 of the minutes of the Licence Committee meeting of 28 March 2013. For the avoidance of doubt, once such evidence has been provided, licensed activity may take place at the centre.* In 2014, the PR again applied to request the removal of the condition, together with relevant evidence and information as requested by the inspector, and the Licence Committee agreed to the removal of the additional condition from the licence.

The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services. Other licensed activities of the centre include storage of gametes and embryos.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 August 2013 to 31 July 2014 show the centre's success rates are in line with national averages.

In 2013 the centre reported that no cycles of partner insemination treatments had been provided.

Multiple births[2]

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

Between 1 August 2013 to 31 July 2014 the centre's clinical multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 10%: this represents performance that is in line with 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 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 ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including five major and three 'other' areas of non-compliance.

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

Major areas of non compliance:

- The PR should review the centre's processes to ensure that donor sperm samples to be used for treatments are from donors who have been screened in accordance with regulatory requirements.
- The PR should ensure that procedures for screening of patients, partners and donors are compliant with all relevant regulatory requirements and guidance.
- The PR should ensure that CE marked medical devices are used where possible.
- The PR should ensure that the processes by which verbal and written information regarding legal parenthood is provided to patients using donated gametes are clear and well defined within the team.
- The PR should 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 ensure that documentation of the time of witnessing and records pertinent to the egg collection are completed at the time the procedure takes place.
- The PR should establish a summary log of cases where multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer.
- The PR should review sedation practices to ensure they are in line with current professional body guidelines.

Recommendation to the Executive Licensing Panel

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy rates meet the HFEA target. The PR is encouraged to continue to use the quality management system (QMS) to best effect to monitor and improve their success rates and to continually improve the quality of the service offered to patients.

The centre has no critical areas of concern but does have five major areas of concern. Some improvement is required in order for the centre to demonstrate suitability of their practices.

The initial responses provided by the PR in responding to this report did not provide sufficient assurance that the PR would fully implement the recommendations as required and may not fulfil her duties under section 17 of the HF&E Act 1990 (as amended). In response to these concerns 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 there was likely to be ongoing risk to patients, their gametes and embryos, with particular reference to use of donor sperm which had not been fully screened and the use of a non-CE marked media supplement added to the culture medium.

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 if formal regulatory action was to be avoided. The centre's inspector contacted the PR and advised her of the Executive's concerns and provided her with an opportunity to resubmit her response to the recommendations made in the report. The PR subsequently provided revised responses to the recommendations and these have been updated in the section 'Areas of practice requiring action' at the end of this report. The Executive's review has also been updated accordingly. The Executive is now assured that the PR is engaged with the HFEA and the findings of this report, and that the PR has given a commitment to discharge her duty under section 17(1)(d) of the HF&E Act 1990 (as amended) in ensuring that the centre's practices are suitable.

Based on all the information provided to date, the Executive recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

The centre's inspector will continue to monitor the centre's performance closely. Failure to implement the recommendations in this report within the prescribed timescales may 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

Witnessing (Guidance note 18)
In two of five records reviewed the time of the witnessing check when gametes and/or embryos are placed into storage was not documented (SLC T71, Code of Practice 18.8; see recommendation 6).

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 does not currently recruit gamete donors but does provide donor treatments with gametes provided by donors recruited by the Bourn Hall group.

Payments for donors (Guidance note 13; General Direction 0001)
The centre does not currently recruit gamete donors.

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)
Eight out of 22 donor sperm samples used in treatment which had been supplied by their affiliate centre, Bourn Hall Cambridge had not been screened for anti-hepatitis B core antibody (SLC T52b; see recommendation 1).

The centre does not have robust processes in place to review the screening results of gamete donors prior to acceptance and use and do not reference the requirement to ensure that additional testing has been carried out where it is required depending on the donor's origins (HTLV-1 antibody SLC T52g) or travel and exposure history and the characteristics of the tissue or cells donated (e.g., Rh D, Malaria, CMV, T.cruzi (SLC T52h; see recommendation 2).

Payments for donors (Guidance note 13; General Direction 0001)
The centre does not currently recruit donors but the licence renewal application suggests that it may do so in the future. Written information for donors concerning compensation, to be used if recruitment commences, was considered by the inspection team to be inconsistent and potentially misleading. This is not recorded as a non-compliance because donor recruitment is not being performed however, if recruitment commences, the written information should be reviewed against regulatory requirements and a revised copy provided to the centre's inspector.

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

What the centre does well

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

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

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 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 Clinical Pathology Accreditation (CPA) UK Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

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

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

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are broadly 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; General Direction 0003)
The centre's procedures are broadly compliant with HFEA multiple births minimisation strategy requirements for 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; General Direction 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;
- 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; General Direction 0006)
The centre's procedures in place for import and export of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are broadly 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 compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any satellite or transport arrangements.

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

Laboratory accreditation (Guidance note 25)
Diagnostic test results are communicated to the centre by the patient's referring clinician. The PR could not be assured of the validity and accuracy of the results of the tests or that they had been performed by a suitably accredited laboratory (SLC T51a; see recommendation 2).

Pre-operative assessment and the surgical pathway
Patient feedback received at the HFEA included a concern from one patient regarding the sedation that they had received during their treatment at the centre. This was discussed with the PR during the inspection. The inspection team was informed that surgical procedures undertaken at the centre are performed under conscious sedation using protocols drawn up by the clinician at the centre (SLC T2; see recommendation 8).

Multiple births (Guidance note 7; General Direction 0003)
The centre does not keep a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer (General Direction 0003; see recommendation 7).

Traceability (Guidance note 19)
Tubes used to collect follicular fluid during egg collections are not labelled and the centre's risk assessment requires a check of the working area (flow hood) to ensure that no unlabelled tubes remain between patients. In one of five records reviewed there was no documentation of the completion of the step confirming that the flow hood was clear of all unlabelled tubes (SLC T101; see recommendation 6).

Equipment and materials (Guidance note 26)
The following medical device used by the centre is not CE marked: supplement for LifeGlobal culture media (SLC T30; see recommendation 3). The addition of a non-CE

marked supplement to a CE marked culture media product was discussed with centre staff – it is noted that the addition of this product invalidates the CE mark status of the culture medium. Use of the medium is non-compliant with the requirements of SLC T30 which requires the use 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.

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 nursing and has 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/1240/81).

Staff (Guidance note 2)
The centre is 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

Nothing identified at this inspection.

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 does not carry out embryo testing.

What the centre could do better

Not reviewed during this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit no patients agreed to provide feedback to the inspection team. Forty patients provided feedback directly to the HFEA in the time since the last inspection. Of these, 26 patients made positive comments and 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.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not currently provide egg or sperm sharing arrangements.

Surrogacy (Guidance note 14)
The centre does not currently undertake surrogacy.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and / or donors are partially compliant with HFEA requirements. The centre should ensure that they give 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 inspection team found that there was uncertainty within the centre staff as to whose responsibility it was to provide patients using donated gametes with information regarding legal parenthood. In addition written information provided to patients was potentially misleading (SLC T60, Code of Practice 6.2; see recommendation 4).

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

What the centre does well

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

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 (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are 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

Nothing identified at this inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre'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)
Blood samples from patients and partners are not obtained within a timeframe specified by the Authority, i.e. within three months before first use (SLC T51b; see recommendation 2).

In two of six patient notes audited the anti-hepatitis B core antibody test result was not present in the records and the centre staff were not assured that the tests had been performed (SLCs T50a; see recommendation 2).

The centre's processes for screening patients and partners do not include the requirement to consider when additional testing may be required depending on the patient / partner's travel and exposure history and the characteristics of the tissue or cells donated (e.g., Rh D, Malaria, CMV, T.cruzi (SLC T50d; 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 compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

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

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
All of the IVF treatments reviewed at inspection had been reported to the HFEA as required by General Direction 0005. However 20% (3/15) of the DI treatments had not been reported as required (SLC T9e, T41 and General Direction 0005; see recommendation 5).

Section 3: Monitoring of the centre's performance

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

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales, with the exception of the application for accreditation of the assay laboratories of Bourn Hall Cambridge (centre 0100) by the United Kingdom Accreditation Service (UKAS) Ltd. The application for accreditation was submitted in a timely manner but the completion of the application was delayed by UKAS. Accreditation has now been achieved and all recommendations are complete.

On-going monitoring of centre success rates

The centre has not been sent any 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 identified at this inspection			

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. Eight out of 22 donor sperm samples used in treatment which had been supplied by their affiliate Bourn Hall Cambridge had not been screened for anti-hepatitis B virus core antibody. This has been categorised as a major (i.e. not critical) non-compliance as the donors had been screened for hepatitis B virus, but with only one of the two required tests. SLC T52b.	The PR should ensure that with immediate effect donor sperm samples to be used for treatments are from donors who have been fully screened in accordance with regulatory requirements. The PR should confirm to the centre's inspector that's this action has been implemented when responding to this report. The PR should investigate how donor sperm samples from gamete providers who had not been screened for anti-hepatitis B core antibody, which is non-compliant with SLC T52b, had been purchased and used. The	Our initial investigation was as follows: We have investigated this finding as requested and wish to reply that the finding is at odds with our understanding of the screeneing requirements, as clarified in Clinic Focus in January 2012. We acknolwledge that 8 out of 22 donor sperm samples received and used in treatment have not been screened for anti-hepatitis B virus core antibody. The 8 donors completed their quarrantine and screening process prior to January 2012. The Clinic Focus article of the same date gives clarification	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. Further action is required in relation to the completion of the audit due by 10 June 2015.

	findings of this investigation including corrective actions and the timescale for implementation should also be submitted to the centre's inspector when responding to this report. Within three months of the implementation of corrective actions identified in the review, the centre should perform an audit to ensure that changes have been effective. A summary report of the findings of the audit should be provided to the centre's inspector by 10 June 2015.	on the screening for HBv (i.e. gamete donors are screened for both Surface antigen and Core antibody). Since this clarification all donors have been screened as required. The article also indicates that "The HFEA will not usually expect centres to carry out screening for anti-HBc retrospectively" As the donors in question all had their post quarantine exit screening performed before January 2012 retrospective screening was not undertaken. However following receipt of the executive review and discussions with the inspectorate we accept that our interpretation of the guidance on this matter differed from how the Authority intended it to be read and we wish to advise that from hereon, we will only offer to new patients donor sperm from donors who have been fully screened. We envisage that there will be occasions where patients may wish for donor	

		sperm / embryos created using the donor sperm to be used in their treatment – examples of such occasions being a patient's wish to try for siblings or to use frozen embryos in storage. In these instances we aim to complete the screening via contact with the donor or through testing of samples held in storage. An audit of this change will be conducted and the summary of the findings will be presented to the centre's inspector by 10 June 2015.	
2. Blood samples from patients and partners are not obtained within a timeframe specified by the Authority, i.e. within three months before first use. SLC T51b. In two of six patient notes audited the anti-hepatitis B core antibody test result was not present in the records and the centre staff were not assured that the tests had been performed.	The PR should ensure that procedures for screening of patients, partners and donors are compliant with all relevant regulatory requirements and guidance. Due to the significant number of issues found relating to screening requirements it is recommended that the PR performs a full review of the centre's screening procedures. This review should include, but not be limited to, the issues	Blood samples for patients who do not have current* blood test results will be obtained within the timeframe specified by the authority. *Current blood tests means any required blood test related to ongoing infertility investigations that has been obtained from a blood sample obtained within the previous 24 months. Repeat blood tests will be taken to ensure that no result older than 24 months is used.	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed that the centre will ensure that screening tests for patients and partners will be undertaken within three months before their first use and every 24 months thereafter.

SLC T50a. The centre's processes for screening patient's, partners and donors do not include the requirement to consider when additional testing may be required depending on the patient/partner's/donor's travel and exposure history and the characteristics of the tissue or cells donated (e.g., Rh D, Malaria, CMV, T.cruzi). SLCs T50d and T52h. Diagnostic test results are communicated to the centre by the patient's referring clinician. The PR could therefore not be assured of the validity and accuracy of the results of the tests or that they had been performed in a suitably accredited laboratory. SLCs T51a.	identified during the inspection and described in the body of the report. The findings of the review including corrective actions and the timescale for implementation should be submitted to the centre's inspector by 10 March 2015. Within six months of the implementation of corrective actions identified in the review, the centre should perform an audit to ensure that changes have been effective. A summary report of the findings of the audit should be provided to the centre's inspector by 10 September 2015.	From January 2014 all patients starting treatment have been screened for HB core. A checklist process is in place on IDEAS to ensure that all required testing has been completed. The centres Standard Operating Procedures MN012 and associated Work Instruction MN012-WI04 detail the management of medical and non-routine issues and are included with this response. These documents will be reviewed to ensure they cover all the requirements detailed in the finding. Patient referrals from Consultants at level II facilities (NHS hospitals) detail the diagnostic test results current at the time of referral and these are checked by centre staff for completeness before the referral is accepted. We consider this as adequate assurance that the tests are valid.	The updated SOPs reflecting screening requirements and practices are awaited. The Executive acknowledges the PR's responses that the majority of testing will be performed in suitably accredited laboratories. The PR has provided assurance that she has reviewed the centre's processes and will put in place measures to ensure that evaluation of the accreditation status of all testing laboratories used will be undertaken e.g. if tests have been initiated by a GP. A summary of the findings of the review of screening processes due by 10 March 2015 is awaited. Further action is required in relation to the completion of the audit due by 10 September 2015.

		NHS hospitals are required to use approriately accredited laboratories. Testing initiated by the centre is primarily conducted in the clinical science laboratory at Bourn Hall Clinic Cambridge (centre 0100) that has achieved ISO17025 accreditation or the Norfolk and Norwich Hospital that has Clinical Pathology Accreditation. Both facilities are included on the Quality Assurance department's supplier audit programme. In addition, for NHS funded patients, we have requested, via the CCGs, that copies of blood tests are provided with the referral forms. This will help us to confirm that the laboratories commissioned to undertake the tests are appropriately qualified and a review of this activity will be included in the audit to be conducted. For non NHS patients GP's will be requested to provide hard copies of diagnostic reports to	

		support their referrals. If necessary we will repeat the test if considered clinically relevant. The clinic is implementing a new pathway which at the initial visit it will be determined if the virologies are within the required date range and can also be aligned to the anticipated treatment date. Repeat bloods tests will be taken by the clinic at this consultation if required to ensure compliance with the EU Directive 2012/39/EU. A review of the centres screening procedures will be undertaken and provided to the centres inspector by 10th March 2015. This will be followed by an audit of the screening processes and proecedures by 10th September.	
3. The following medical device used by the centre is not CE marked: supplement for LifeGlobal culture media.	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.	Following receipt of the executive review and discussions with the inspectorate we accept that assurances given to us by the manufacturer regarding the CE	The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation.

The addition of a non-CE marked supplement to a CE marked culture media product was discussed with centre staff – it is noted that the addition of this product invalidates the CE mark status of the culture medium. Use of the medium is non-compliant with the requirements of SLC T30 which requires the use 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. The centre did not act on this guidance. SLC T30. Clinic Focus April 2013.	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 is and inform the centre's inspector of this by 10 March 2015. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this it is expected that all medical devices should be CE marked by 10 December 2015.	marked status of their product is incorrect and we undertake to evaluate and introduce a fully CE marked alternative by 10th December 2015. A list of all medical devices will be provided by 10th March	Further action is required in relation to providing a list of medical devices in use by 10 March 2015, and confirming that all only CE marked medical devices will be used by 10 December 2015.

4. The inspection team found that there was uncertainty within the centre staff as to whose responsibility it was to provide patients using donated gametes with information regarding legal parenthood. In addition, written information provided to patients was potentially misleading. SLC T60 and Code of Practice 6.2. This puts the centre at risk of failing to provide proper information to patients giving consent, as required the HF&E Act 1990 (as amended). HF&E Act, Schedule 3 S.3 (1)(b).	The PR should ensure that the processes by which verbal and written information regarding legal parenthood is provided to patients using donated gametes are clear and well defined within the team. The PR should provide the centre's inspector with a summary report of the review of information and processes and copies of the updated patient information by 10 March 2015.	Review of associated processes and documentation is already being undertaken. Information will be provided by the 10th March 2015.	The Executive acknowledges the PR's responses and her commitment to fully implementing this recommendation. Further action is required in relation to a summary of the findings of the review and copies of updated patient information due by 10 March 2015.
5. 20% (3/15) of the DI treatments reviewed in the course of the inspection had not been reported to the HFEA as required SLC T9e, T41 and General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should confirm that treatments identified as not reported at the time of the inspection have been reported	All activity has now been reported.	The Executive acknowledges the PR's findings of the review and her commitment to fully implementing this recommendation. Further action is required in relation to the findings of the

	to the HFEA in responding to this report. The systems and processes used for licensed treatment data submission should be reviewed to enable the reasons for non-reporting of the DI treatments to be identified. The PR should inform the centre's inspector of the findings and corrective actions identified by 10 March 2015. The PR should conduct an audit six months after implementing any changes to confirm that any changes made to systems and processes are having the desired effect. A summary repor of the findings of the audit should be provided to the centre's inspector by 10 September 2015.	 The processes required for reporting are already in place but had been overlooked in these instances. The staff have been reminded of these requirements. An audit will be conducted as requested.	review of systems and processes used for data submission due by 10 March 2015, and completion of the audit due by 10 September 2015.

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
6. In two of five records reviewed the time of the witnessing check when gametes and/or embryos are placed into storage was not documented. Tubes used to collect follicular fluid during egg collections are not labelled and the centre's risk assessment requires a check of the working area (flow hood) to ensure that no unlabelled tubes remain between patients. In one of five records reviewed there was no documentation of the completion of the step confirming that the flow hood was clear of all unlabelled tubes. SLC T71, T101 and Code of Practice 18.8.	The PR should ensure that documentation of the time of witnessing and records pertinent to the egg collection are completed at the time the procedure takes place. The PR should review the relevant procedures and the documentation of witnessing. A summary report of the review findings including corrective actions and copy/copies of any amended documentation should be forwarded to the centre's inspector by 10 March 2015. Within three months of the implementation of any changes to the witnessing procedures, the centre should conduct an audit of witnessing and a summary report of the findings of the audit should be provided to the centre's inspector by 10 June 2015.	The two record reviewed at the time of inspection had the location recorded but the time of witnessing had been omitted. This information is added to our cryo sheet however the form does not accommodate this information in its current format. The document has been updated and is currently in our document control processes. The updated version will be provided to the inspectorate by 10th March 2015 The associated SOP is clear on the process of witnessing. The correct process has been reinforced with the embryology team. Audit to be actioned.	The Executive acknowledges the PR's findings of the review and her commitment to fully implementing this recommendation. A copy the updated document due by 10 March 2015 is awaited. Further action is required in relation to the completion of the audit due by 10 June 2015.

7. The centre does not keep a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. General Direction 0003.	The PR should establish a summary log of cases where multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer with immediate effect and confirmation of establishment of the log should be provided to the centre's inspector when responding to this report. Within three months of the establishment of the log the PR should conduct an audit of the documentation of cases where multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer in the log. A summary report of the audit findings including corrective actions and the timescale for their implementation should be submitted to the centre's inspector by 10 June 2015.	A summary log has been implemented. Audit to be actioned.	The Executive acknowledges the PR's response that a summary log has already been implemented. Further action is required in relation to the completion of the audit due by 10 June 2015.
8. Patient feedback received at the HFEA included a concern from one patient regarding the sedation that they had received during their treatment at the centre. This was discussed with the PR during the inspection. The inspection team was	The PR should review sedation practices to ensure that they are in line with current professional body guidelines: 'Safe Sedation Practice for Healthcare Procedures: Standards and Guidance issued by the Academy of Medical Royal Colleges in 2013' (http://www.rcoa.ac.uk/system/files/PUB-SafeSedPrac2013.pdf). The PR should inform the centre's	Action agreed. The recommended actions were agreed in the PR's original response and a review of the sedation practices against current guidelines has been undertaken. An addition to the sedation medication has been implemented and	The Executive acknowledges the PR's response and commitment to fully implementing this recommendation. Further action is required in relation to the outcome of the review of sedation practices against professional guidelines due

informed that surgical procedures undertaken at the centre are performed under conscious sedation using protocols drawn up by the clinician at the centre. SLC T2.	inspector that this review has been completed by 10 March 2015.	a patient satisfaction questionnaire is being utilised to assess the effectiveness of the change. The outcome of this review will be provided to the centres inspector by 10th March 2015	by 10 March 2015.

Reponses from the Person Responsible to this inspection report