Executive Licensing Panel - minutes

Centre 0325 (Bourn Hall Clinic Norwich)

Executive Update – Renewal Inspection Report

Tuesday, 9 April 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Richard Sydee Niamh Marren	Director of Strategy and Corporate Affairs Director of Finance and Resources Regulatory Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Dina Halai Danielle Vincent	Licensing Manager Scientific Policy Manager Communications Manager

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:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last four years.

1.2. The panel noted that Bourn Hall Clinic Norwich has held a treatment and storage licence with the HFEA since May 2013 and provides a full range of fertility services. Other licensed activities at the centre include storage of gametes and embryos.

1.3. The panel noted that the Executive Licensing Panel (ELP) considered the centre's application to renew their treatment and storage licence on the 26 February 2019 and adjourned a decision, noting that the inspectorate was due to receive several reports and summary of actions, on many of the non-compliances identified, by 28 February 2019, and requesting that these be presented to a future ELP.

1.4. The panel noted that the ongoing monitoring of post inspection actions by the centre's inspector has enabled a progress update to be provided. The executive confirms that the Person Responsible (PR) provided his responses to the actions that were due by 28 February 2019, and further clarifications were provided in response to queries from the centre's inspector.

1.5. The panel noted the executive update and the most recent progress report, confirming that the PR had fully implemented the recommendations regarding the Quality Management System (QMS), the assessment and screening of donors, payments for donors, safety and suitability of premises and facilities, prescription of Intralipid 'off-label' and fees. It was also noted that the centre's monthly audit of records regarding consent and welfare of the child, had confirmed that the corrective actions had been effective; further monthly audits will be provided. Progress in implementing the remaining recommendations will continue to be monitored by the centre's inspector.

1.6. The panel noted that the inspection team confirm that there is no change to the original recommendation to the renewal of the centre's treatment and storage licence for a period three, rather than four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribes timescales. The executive proposes reviewing whether it conducts an interim inspection earlier than is standard based on the PR's engagement and the evidence submitted to demonstrate that the recommendations made in this report have been implemented effectively. Furthermore, renewal inspections of other centres in the group are planned over the next 10 months. The findings from these inspections may be used to further inform the executive as to when an interim inspection of this centre should take place.

1.7. The panel noted that The HF&E Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018 (the '2018 Regulations'), to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence, Centre 0325 has an ITE import certificate. The inspection team recommends the renewal of this centre's ITE import certificate in line with the centre's licence.

2. Decision

2.1. 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.

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

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of three years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales.

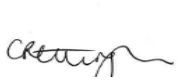
2.5. The panel also agreed to endorse the inspectorate's recommendation, with regards to when the interim inspection occurs, based on the PR's engagement with the recommendations made in the report, also noting that renewal inspections of other centres in the group are planned over the next 10 months; findings from these inspections may be used to further inform the executive as to when an interim inspection of this centre should occur. However, the inspectorate was encouraged to consider that, lessons learned by other centres in the group, where there had been evident failings in the past, had not resulted in effective processes being in place regarding the taking and checking of consent at this particular centre.

2.6. The panel endorsed the inspectorate's recommendation to renew the centre's ITE import certificate, in line with the centre's licence.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

Clare Ettinghausen

Date

15 April 2019

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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: 27 and 28 November 2018

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, Sara Parlett and Julie Katsaros

Date of Executive Licensing Panel: 26 February 2019

Centre name	Bourn Hall (Norwich) Limited
Centre number	0325
Licence number	L/0325/3/c
Centre address	Gateway 11, Unit 3, Farrier Close, Wymondham, Norwich, Norfolk, NR18 0WF, United Kingdom
Person Responsible	Dr Mike Macnamee
Licence Holder	Mr Martyn Blayney
Date licence issued	01 May 2015
Licence expiry date	30 April 2019
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. Other licensed activities at the centre include storage of gametes and embryos.

The current licence has been varied to reflect a change of Licence Holder in January 2018, and a change of Person Responsible (PR) in February 2018.

The centre provided 500 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2018. In relation to activity levels this is a medium sized centre.

Bourn Hall (Norwich) Limited is part of a group that incorporates three other HFEA licensed centres (centre 0100 Bourn Hall Clinic, centre 0188 Bourn Hall (Colchester), centre 0363 Bourn Hall (Wickford) and a 'satellite' service at Bourn Hall Clinic, King's Lynn. All clinics are centrally managed and have common practices and procedures, in particular the quality management system (QMS). In view of the common structures and functioning of the centres within the Bourn Hall Clinic corporate group, the previous renewal inspection of centre 0100 in 2015 was undertaken using the HFEA's 'group approach' methodology.

The HFEA's 'group approach' is one where a single assessment of shared elements such as QMS and operating procedures is undertaken at one centre in the group, thereby reducing duplication when inspecting other centres following these same corporate policies. This allows a focus on practices particular to the individual clinic and maximises regulatory effectiveness. In return, where we find non-compliances in those shared elements we expect to see the clinics within the group respond as a whole, taking all necessary action at each clinic.

The PRs of the centres in the Bourn Hall group have requested that the HFEA uses the same approach for the renewal inspections of licensed centres 0325, 0188 and 0100 which are due in the next 10 months. This centre (0325) is the first in the group to have a renewal inspection, therefore all areas of practice were reviewed in full. The executive will evaluate the findings of the inspection to determine the approach to be used for undertaking the renewal inspections for the other centres in the group.

As part of this renewal application, the PR has requested that the centre name is changed from Bourn Hall (Norwich) Limited to Bourn Hall Clinic Norwich to make the names of the centres in the corporate group consistent with each other.

Pregnancy outcomes[1]
For IVF and ICSI, HFEA held register data for the year ending 31 July 2018 show the centre's success rates are in line with national averages. At the time of the inspection the centre had not submitted data relating to partner insemination for treatments performed in 2016 and 2017 but this was submitted shortly

after the inspection (see 'Obligations and reporting requirements' section below). For the year 2017 the centre reported five cycles of partner insemination with no clinical pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.
HFEA held register data for the year ending 31 July 2018 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target.

[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, Standard Licence Conditions (SLCs) and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable with the exceptions noted in the body of the report;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's 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 eight 'major' and five 'other' areas of non-compliance or poor practice that require improvement.

Since the inspection visit, the PR has given a commitment to fully implement all the recommendations, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

'Major' areas of non-compliance:

1. The PR should ensure that only donors that have been selected on the basis of their health and medical history are used in treatment, and the assessment must consider relevant factors that may assist in identifying and screening out persons whose donations could present a health risk to others or to themselves.
2. The PR should ensure that no money or other benefit must be given or received in respect to any supply of gametes unless authorised by Directions and that advertising or publicity aimed at recruiting donors should not place an emphasis on financial incentives.
3. The PR should ensure that medicines management procedure and practice is in line with statutory and regulatory requirements.
4. The PR should ensure that the assessment of patients undergoing surgical procedures is in line with best practice guidance.
5. The PR should ensure that the centre's QMS and auditing processes are effective in identifying and implementing appropriate corrective actions in response to audit findings.
6. The PR should ensure that appropriate quality indicators are established, audits of all critical activities are completed, and that standard operating procedures (SOPs) to cover all critical activities are in place.
7. The PR should ensure that the centre's processes for the welfare of the child assessments are robust.

8. The PR should ensure that the centre's processes for obtaining and checking are robust, and that the patient's and donor's intentions are clear.

'Other' area that requires improvement:

9. The PR should ensure that all fire doors are kept closed in line with statutory and regulatory requirements and remind centre staff of their responsibilities to comply with fire safety legislation.
10. The PR should ensure adherence to infection control best practice guidance and requirements.
11. The PR should ensure that the written information for patients prescribed intralipid therapy specifies that if prescribed to this group of patients the drug is being prescribed 'off label' and gives accurate information about safety and efficacy.
12. The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.
13. The PR should ensure fees payable to the HFEA are made within the required timeframe.

Recommendation to the Executive Licensing Panel

The centre has eight 'major' areas of non-compliance.

The inspection team notes that the success rates are consistent with the national average and its multiple clinical pregnancy rates meet the target. The PR is encouraged to continue to use the QMS to best effect to monitor and improve their success rates and the quality of the service offered to patients. Significant improvement is required in order for the centre to reflect suitable practices.

Given the significant areas for improvement identified during this inspection, the executive held a management review meeting in accordance with the HFEA Compliance and Enforcement Policy to evaluate the centre's performance. The meeting on 17 December 2018 considered the findings of the inspection to inform a recommendation on the length of licence and further, whether a subsequent interim inspection earlier than is standard is warranted.

The consideration was informed by the inspection findings that the centre's processes for ensuring patients' consents were provided appropriately were inadequate, and that assessments of the 'welfare of the child' were not robust.

Furthermore, in relation to consent to legal parenthood requirements, it is apparent that lessons learned by other centres in the group where there had been evident failings in the past has not resulted in effective processes in place for taking and checking these consents in this centre. Whilst the executive acknowledged that the centre had itself identified two failings in consent (to donation and to legal parenthood) in its own routine audit, the executive was not assured that, further to identification, the immediate actions taken were sufficient to ensure that similar errors would not recur.

As such the inspection team recommends the renewal of the centre's treatment and storage licence for a period of three rather than four years, without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales. The executive proposes reviewing whether it carries out an interim inspection earlier than is standard based on the PR's engagement and the evidence that is

submitted to demonstrate that the recommendations made in this report have been implemented effectively. Furthermore, renewal inspections of other centres in the group are planned over the next 10 months. The findings from these inspections may be used to further inform the executive as to when an interim inspection of this centre should take place. ELP is invited to consider the executive's recommendation and to make a decision in this regard.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The HF&E Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018 (the '2018 Regulations'), to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence, Centre 0325 has an ITE import certificate. The inspection team recommends the renewal of this centre's ITE import certificate in line with the centre's licence.

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 compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Assessment and screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Assessment and screening of donors (Guidance note 11)
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. The centre's procedures for assessment and screening of donors are partially compliant with HFEA requirements.

Payments for donors (Guidance note 13; General Direction 0001)
The HFEA's requirements on donor compensation aim to balance the desire to treat donors fairly without creating a financial inducement to donate. The fundamental principle is that donation must be altruistic in nature. 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. The HFEA also allows patients to receive treatment services in exchange for donation of their gametes (eggs and sperm) to treatment or research. The policy is known as 'benefits in kind' or, more commonly, egg or sperm sharing.

The centre's procedures are partially compliant with HFEA requirements for giving and

receiving money or other benefits in respect to any supply of gametes or embryos.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non-identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better

Assessment and screening of donors (Guidance note 11)
During review of the records of a sperm donor, included in a recently completed audit by the centre of donor selection, recruitment and assessment, it was noted that a final physical genital examination of the donor had not been undertaken. This was because the donor had stated that he rather not be examined that day. There was no record of the assessment of any potential risks of not undertaking this examination, or mitigation thereof (see recommendation 1, SLC T52a, CoP 11.23). The inspection team noted that this is a deviation from the centre's SOP 'Recruitment and investigation of sperm donors' which requires a physical genital examination at exit interview and a deviation from best practice guidance, however this was not identified in the centre's audit (see Quality management system' section below.

Payments for donors (Guidance note 13; General Direction 0001)
The Bourn Hall Group offers a 'Gift of Giving' option whereby a person can donate their gametes and in return nominate a friend or family member to receive a free cycle of IVF. The benefit in kind is not received by the gamete donor themselves and therefore, the executive does not consider that this is compliant with General Direction 0001 which states that 'Gamete donors may receive licensed services, such as treatment, storage, or access to licensed services, in return for supplying gametes for donation.' (see recommendation 2, SLC T69 and General Direction 0001). This issue was raised with the PR several months ago when he reiterated to the HFEA that he is of the view that the 'Gift of giving' programme is not non-compliant with General Direction 0001. The PR was asked to provide a legal opinion to support this position, but this has not yet been provided.

The inspection team also noted that the centre places an emphasis on financial incentive rather than altruism, in some advertising and marketing materials, in the way that it markets egg or sperm sharing. At the time of the inspection, the centre's website had a 'Free IVF options' page directing the visitor to pages where it describes 'free IVF cycles for egg and sperm sharers'. This is not compliant with guidance that 'Advertising or publicity aimed at recruiting gamete or embryo donors, or at encouraging donation, should not refer to the possibility of financial gain or similar advantage, although it may refer to compensation permitted under relevant HFEA Directions.' (see recommendation 2, CoP 13.1).

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 broadly compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

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 compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are broadly compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are partially compliant with

guidance.

Prescription of intralipid 'off label'
Intralipid is a sterile liquid soybean and egg yolk-based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is not fully compliant with guidance.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
It is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively. The centre has policies and procedures in place that are partially compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway.

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

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; and
- 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 they are appropriately labelled and are accompanied by 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; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements with the exception noted in the 'Quality management system' section below.

The centre has been allocated an ITE import certificate. Imports of gametes and embryos from TCS outside the EU/EEA not included on the import certificate have not been made since the introduction of the regulations in April 2018. The centre is compliant with General Direction 0006.

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;
- identify any person who has carried out any activity in relation to particular gametes or embryos; and
- 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 that is partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements, including those associated with ITE/TCS import certificates, are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
It is important to ensure that activities performed by transport and satellite clinics on behalf of the licensed centre are suitable and meet HFEA requirements. The centre has systems in place to manage transport and satellite activities that are compliant with HFEA requirements with the exception noted in the 'Quality management system' section below.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All 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 compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
During a tour of the centre it was noted that doors, designated as 'fire doors', to two consultation rooms were being held open by objects. This is not in line with fire safety requirements (see recommendation 9, SLC T2 and CoP 25.4).

Infection control (Guidance Note 25)
Whilst it is noted that the centre is visibly clean and there have been no incidents relating to infection control reported since the centre was first licensed, the following issues were noted during the inspection (see recommendation 10, Department of Health: Health Building Note 00-09: Infection control in the built environment (2013) section 3.105, Healthcare-associated infections: prevention and control in primary and community care 2017, section 1.1.4.4):

- Chairs covered in porous fabric are present in clinical areas, the centre could not provide assurance that these chairs can be cleaned effectively.
- The centre could not provide assurance that staff uniforms were being washed appropriately to prevent the potential spread of infections. Staff were unsure as to

what temperature they should be using to wash their uniforms at home and there was no policy in place to guide them.

Medicines management (Guidance Note 25)
Medicines management practices were reviewed, and the following issues were noted (see recommendation 3, SLC T2):

- In the controlled drugs register there were numerous pages where the 'carry over to page', 'carried over from page' and 'carried over' stock level numbers were not completed.
- There was no master list of signatures for the controlled drugs register.
- The controlled drugs audit lacked robustness because:
    - there were no quality indicators documented;
    - there was one area identified in relation to the correction of an entry which had not been corrected as per regulatory guidelines, but there was no timeframe for the implementation of the corrective action or any record that this had been completed;
    - there was no date on the audit to indicate when the re-audit date was scheduled; and
    - it did not identify the non-compliances found at this inspection.
- There was no evidence that the medicines management competency assessments for nursing staff were regularly reviewed.
- Nurses routinely dispense fertility drugs to patients, whereas NMC guidance states that 'Registrants may in exceptional circumstances label from stock and supply a clinically appropriate medicine to a patient, against a written prescription (not PGD), for self-administration or administration by another professional, and to advise on its safe and effective use.'

Relevant legislation and guidance:
Misuse of Drugs (safe custody) Regulations 2001.
Department of Health 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007).
NICE Guidelines 'Controlled drugs: safe use and management' (April 2016).
NMC Standards for Medicines Management (2010).

Pre-operative assessment and the surgical pathway (Guidance Note 25)
During the inspection a review of patient records in relation to the 'perioperative care document' (World Health Organisation (WHO) checklist equivalent) was undertaken. The outcome of the review identified several areas where there was a lack of completed documentation at the end of the performed procedure (see recommendation 4, SLC T2 and 'WHO surgical safety checklist and implementation manual' https://www.who.int/patientsafety/safesurgery/ss_checklist/en/):

- There was no documentation whether or not there was any blood loss.
- There was no confirmation that the swabs, instruments and needle counts were correct.
- There was no documentation whether or not there were any concerns by the doctor performing the procedure.
- There was no record if the patient required prophylactic antibiotics post procedure.
- There was no record whether there had been the insertion of a vaginal pack during the procedure and removal post procedure.

These concerns were immediately brought to the attention of the PR and senior nurse

during the inspection. The inspection team noted there were no procedures planned at the centre that week. In addition, the centre's inspector emailed the PR immediately after the inspection to seek his assurance that staff working in the relevant areas undertake re-training with regard to the issues identified before any further procedures are undertaken, which he provided.

Prescription of intralipid 'off label'

The following issues were noted in the written patient information regarding intralipid therapy: 'Understanding treatments 'Intralipid infusions' (see recommendation 11, SLC T2 and Clinic Focus article 'Off-label use of intralipid infusions' (July 2015)):

- The information does not specify that, if prescribed to this group of patients, the drug is being prescribed 'off label'.
- The patient information also refers to pregnancy success rates: 'In our experience, after treating over 100 women of different age ranges with intralipid, we have observed a success rate of 39%.' The inspection team was concerned that it is not clear what the 'success rate' refers to (i.e. clinical pregnancy or live birth rate). More significantly, this statement does not provide any form of like-for-like comparison such as what the success rate is for a similar patient group that does not have intralipid therapy as a treatment add on.
- There are some side effects associated with this treatment mentioned in the patient information leaflet, but the serious side effects of clotting or infection are not described.
- Information to patients contained on the HFEA website states: 'Not only will reproductive immunology treatments not improve your chances of getting pregnant, there are risks attached to all these treatments, some of which are very serious.' This sentiment is not reflected in the centre's information to patients.

Quality management system (QMS) (Guidance note 23)

A number of issues were noted in the centre's audits in relation to the immediate actions taken by the centre in response to findings (see recommendation 5, SLC T32 and SLC T36).

- The centre's recent 'consent' audit of records identified cases where a WD form ('Your consent to donating your eggs') was missing, and a case where a welfare of the child assessment had not been completed. In both cases, treatment had already been provided. The audit report did not document how this error had been missed and what immediate remedial actions had been taken to consider the implications and impact of the findings. For example, there was no record of actions taken to consider how embryos had been created and stored without a WD consent form, and whether actions need to be taken to ensure this would not happen again for other cases. Furthermore, there was no record as to whether there were any concerns regarding the case where there was a missing or incomplete welfare of the child assessment prior to carrying out treatment. The inspection team noted that following the audit the centre had reported the missing WD consent as an incident to the HFEA.

- In the same audit, it was noted that a same sex couple had completed the incorrect consent to legal parenthood forms; the woman having the treatment had completed the PP form ('Your consent to being the legal parent') whereas she should have completed a WP form ('Your consent to your partner being the legal parent') and vice versa, the partner had completed the WP form, but she should have completed the PP form. The couple had two cycles of treatment before the

error was identified by the auditors. No pregnancy resulted from those treatments therefore this failing is a near-miss, and the correct forms are now in place. The audit report did not document how this error had been missed and what immediate remedial actions had been taken to ensure this would not happen again for other cases.

- A further concern was noted in relation to the finding in the same audit that a patient had completed two 'consent to disclosure' forms and one was mistakenly recorded as being completed by her partner. This couple have had successful treatment. Centre staff have placed an alert on the records to prevent any contact with their GP etc until the partner's consent wishes could be determined and have noted that the incorrectly submitted partner's consent to disclosure decisions already provided to the HFEA must also be updated. However, the inspectors were of the view that this action should have been completed immediately to prevent the inadvertent disclosure of information by the HFEA until the partner's wishes can be verified.

- The issue described in the section 'Assessment and screening of donors' whereby the physical genital examination of the donor had not been undertaken is a deviation from the centre's SOP 'Recruitment and investigation of sperm donors' which requires this examination at exit interview. The inspection team noted that these records had been reviewed in this comprehensive audit, which included assessing compliance with the relevant SOP, but this omission and deviation from the SOP had not been identified.

Whilst the inspection team acknowledges that the 'consent' audit has only recently been completed (September-October 2018) and the report is not yet finalised, it was not clear how these errors had not been identified and what immediate actions had been taken to prevent recurrence of the significant issues identified, nor to consider the potential impact on the patients involved. A similar failing was noted at the most recent inspection of another clinic in the group in October 2017 (centre 0100 interim inspection) and recommendations were made to review the centre's auditing processes. However, these recommendations do not seem to be fully embedded in the centre's QMS. Overall, the inspection team was concerned that the centre's auditing process is so complex that the QMS it is not as effective as it could be (see recommendation 5, SLC T32 and SLC T36). The audits are long and detailed covering a great deal of information for a small sample of records. This can be a good approach, but also leads to risk that significant findings can get lost in the volume of information collected (such as in the audit of 'Assessment and screening of donors' described above), and appropriate immediate actions are not considered, taken and/or documented.

Quality management system (QMS) (Guidance note 23)
The following were also noted in relation to the centre's quality indicators, audits and SOPs (see recommendation 6, SLC T33b, SLC T35 and SLC T36):

Quality indicators:

- The inspection team considered that the centre's quality indicators for the provision of information, submission of data to the HFEA and breaches of confidentiality were not appropriate. For example, the quality indicator for the provision of information is 85%, however this should be 100% in order to ensure compliance with the requirements for consent in accordance with Schedule 3 of the HF&E Act

1990 (as amended).

Audits:

- The inspection team did not consider that the centre's audits have assessed compliance with the regulatory requirement that all patients and donors have been provided with such relevant information as is proper prior to giving consent to activities under Schedule 3 HF&E Act 1990 (as amended).

- The centre has not audited the activities at its satellite clinic to assess compliance with regulatory requirements. The inspection team noted that an issue with missing consent related to a patient seen at the satellite centre (see 'Consent' section below).

- Issues were identified in the inspection team's audit of controlled drugs as described in the section 'Medicines management' above, that were not identified in the centre's own audit.

SOPs:

- The centre does not have a detailed SOP for the process of import and export of gametes and embryos. It is noted that the inspection team did not have any concerns with the centre's processes, however it is considered that a comprehensive SOP is necessary to guide this complex activity.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of 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.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better
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 before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are partially compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
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

Welfare of the child (Guidance note 8)
During the audit of nine of the centre's records it was noted that for one male patient two questions in the welfare of the child assessment form had been left blank, but the assessment and form had been signed, and treatment provided. Another male patient had signed but not dated the assessment form (see recommendation 7, SLC T56).

The centre's audit of welfare of the child assessments also identified issues with the completion of 9/118 forms reviewed. The issues noted included missing assessment forms for one cycle of treatment (subsequent forms were in place), missing signatures or dates by the doctor or patient, incorrect dates and the use of correction fluid by the patient (see recommendation 7, SLC T56 and SLC T36).

Whilst the inspection team acknowledges that the welfare of the child has been taken into consideration, the errors noted during audits of records by both the centre staff and inspectors indicate that the processes for recording, reviewing and checking the assessment of the welfare of the child before the provision of treatment are not robust.

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 and therefore this area of practice is not relevant to this inspection.

What the centre could do better
Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspector spoke to two patients who provided positive feedback on their experiences at the centre.

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. The centre has a rating of 3.5 out of 5 on the HFEA website and this is based on six responses. The website also gives the ability for patients to comment on the cost of treatment. Most patients confirmed that they had paid what they expected to. Five of these patients provided additional free text comments. Feedback was mixed with two patients complimenting staff at the clinic and three individuals providing negative comments on their experience. Themes and trends noted in this feedback were discussed with the PR and centre staff.

Only one patient provided feedback in the last 12 months, suggesting that the clinic does not actively seek patient's feedback to the HFEA for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. On discussing the low levels of feedback with the PR during the inspection, he reported that they have considered introducing tablets in the waiting room for patients to use to give their feedback but was concerned that the IP address collected by the HFEA would then be identical, which may be incorrectly considered as false representation by the clinic as consumers. The inspection team assured the PR that this would not be an issue and encouraged them to explore ways of promoting this facility further. This will be followed up at the next inspection of the centre in the corporate group.

The centre's most recent surveys of patient feedback of 53 responses between August and October 2018 were reviewed on inspection, and these included both positive and negative feedback. The centre's quality manager explained that the survey responses were reviewed and discussed at monthly operations meetings and actions were taken to address any issues identified.

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; General Direction 0001)
It is important to ensure that:

- care is taken when selecting egg and/or sperm providers donating for benefits in kind
- egg and/or sperm providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg or sperm provider and recipients (where relevant).

The centre's procedures for egg and sperm sharing arrangements are compliant with HFEA requirements with the exceptions noted in section 'Consent'.

Surrogacy (Guidance note 14)
This centre does not undertake surrogacy treatments therefore this area of practice was not reviewed during this inspection.

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

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

What the centre could do better
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH (11)02)
It is important that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions. The

centre's procedures for providing information to patients and/or donors are compliant with HFEA requirements.

What the centre could do better
Nothing identified at this inspection.

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

What the centre does well

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

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At that inspection in November 2016, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are partially compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The HFEA Register is a rich source of information about treatment using assisted reproductive technologies (ART). It can be used by researchers and linked to other health registers to improve knowledge about the health of patients who have undergone ART and those born as a result of it. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA, so that the HFEA holds an accurate record of patients' consent and only releases patient identifying information to researchers with a patient's consent.

The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

What the centre could do better

Consent (Guidance note 5;6)
The following issue was noted during the centre's audit of records which had recently been undertaken (September-October 2018):

- No WD form ('Your consent to donating your eggs') was found in the records of the only egg share patient audited. The egg share cycle had been completed and embryos had been frozen for both the sharer and recipient. The inspection team was concerned how this treatment had been provided without centre staff identifying that this WD consent form was not in place. The auditors recorded that there was an in-house form recording the woman's consent to donate her eggs however centre staff stated that this form does not include all requirements of the HFEA WD form. It is not clear if the WD form was completed and misplaced, or not completed at all.

  Whilst the inspection team acknowledges that this audit has only recently been completed (September-October 2018) and the report is not yet finalised, there is no evidence of any immediate actions taken to consider the potential impact of the audit findings on the donor and patients involved, and consideration of why these were missed before treatment was provided. In addition, there is no record of immediate actions taken to prevent similar failings from happening (see recommendation 5, SLC T32 and SLC T36).

  The inspection team noted that this patient had been seen at the satellite centre and that activities of the satellite service had not been audited to assess compliance with regulatory requirements (see 'Quality management section' section above).

During the inspection team's audit of four egg sharer records the following issues were noted:

- One egg sharer had undertaken her counselling appointment after signing her WD consent form, and in this form the 'restrictions' section had been left blank (neither 'yes' or 'no' had been selected, nor any restrictions recorded).

- For another egg sharer, the family limit section of the WD form was not completed, and the 'restrictions' section had been left blank (neither 'yes' or 'no' had been selected, nor any restrictions recorded).

The inspection team was concerned that these errors in consent had not been identified by centre staff before the provision of treatment (see recommendation 8, Schedule 3 Human Fertilisation & Embryology (HFE) Act 1990 (as amended) and SLC T57).

Legal parenthood (Guidance note 6)
The following issue was noted during the centre's audit of records which had recently been undertaken (September-October 2018):

- A same sex couple had completed the incorrect consent to legal parenthood forms; the woman having the treatment had completed the PP form ('Your consent

to being the legal parent') whereas she should have completed a WP form ('Your consent to your partner being the legal parent') and vice versa, the partner had completed the WP form, but she should have completed the PP form. The couple had two cycles of treatment before the error was identified by the auditors. No pregnancy resulted from those treatments therefore this failing is a near-miss, and the correct forms are now in place.

The inspection team was concerned that these errors in consent had not been identified by centre staff before the provision of treatment (see recommendation 8, Sections 37(1) and 44(1) of Part 2 of the Human Fertilisation & Embryology (HFE) Act 2008). Furthermore, the inspection noted that in 2015, a court declaration to establish legal parenthood was necessary following anomalies in consent to legal parenthood identified at another centre in the Bourn Hall group (0100). Given this failing it is expected that all centres in the group would have implemented robust consent checking processes such that any anomalies in consent to legal parenthood would be identified before treatment. Such consent checking processes have not been effective in this centre.

Whilst the inspection team acknowledges that this audit has only recently been completed (September-October 2018) and the report is not yet finalised, there is no evidence of any immediate actions taken to consider the potential impact of the audit findings on the patients involved and consideration of why these were missed before treatment was provided. In addition, there is no record of immediate actions taken to prevent similar failings from happening (see recommendation 5, SLC T32 and SLC T36).

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)

One discrepancy was found between completed patient/partner disclosure consents and the related consent data submitted for inclusion on the register in 10 patient files audited by the inspection team (see recommendation 12, CH (10)05 and General Direction 0005). This is in addition to the discrepancy described in the 'Quality management system' section above. Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure to researchers. The inspection team noted that the discrepancy was not one that could pose a risk that the HFEA may inadvertently release patient identifying information to researchers without consent but did not accurately reflect the consent giver's wishes. The error has now been corrected.

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) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- 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 and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, 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

Nothing identified at this inspection.

Use of embryos for training staff

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 and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
Good medical records are essential for the continuity of the patient's care. The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained, with the exceptions noted elsewhere in the report.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements. However, 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:

- All 33 DI and 117 of 118 IVF cycles in the sample audited had been reported to the HFEA.
- Treatment reporting is timely with 91% (30/33) of the DI and 93% (109/118) of the IVF treatments reviewed reported to the HFEA within the period required by General Direction 0005.
- At the time of the inspection the centre has not submitted data relating to partner insemination for treatments performed in 2016 and 2017, but this was submitted shortly after the inspection.

The PR is aware of these findings and the missing treatment cycle has now been reported to the HFEA.

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
Fees payable to the HFEA have not always been paid within the required timeframe (see recommendation 13, SLC T9d and CH (10)02).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, recommendations for improvement were made in relation to two major areas of non-compliance and two 'other' areas of practice.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. However, areas of improvement that were noted at previous inspections of this centre and another centre in the group have recurred relating to the QMS and the payment of HFEA fees.

On-going monitoring of centre success rates

Since the last interim inspection in November 2016 the centre has not received any performance related risk tool alerts.

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, General 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.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None identified.			

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.

A major area of non-compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Assessment and screening of donors During review of the records of a sperm donor, included in a recently completed audit by the centre of donor selection, recruitment and assessment, it was noted that a final genital physical examination of the donor had not been undertaken. This was because the donor had stated that he rather not be examined that day. There was no record of the assessment of any potential risks of not undertaking this examination, or mitigation thereof.	The PR should ensure that only donors that have been selected on the basis of their health and medical history are used in treatment, and the assessment must consider relevant factors that may assist in identifying and screening out persons whose donations could present a health risk to others or to themselves. The PR should review the case identified during the inspection and fully assess the	A risk assessment will be conducted with regards to the donor who did not have a physical genital examination at exit interview by 28th Feb 2019. A review of our procedures will be conducted to include the rejection of donors who refuse a physical examination. We will review the audit 'Donor selection, recruitment and assessment' to determine whether the audit is satisfactory or should be	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The executive notes that the PR has provided his assurance that he will review the centre's procedures for the recruitment, assessment and selection of donors and expects that this will include activities across all centres within the Bourn Hall group. The executive requests that

The inspection team noted that this is a deviation from the centre's SOP 'Recruitment and investigation of sperm donors' which requires a physical genital examination at exit interview and a deviation from best practice guidance, however this was not identified in the centre's audit. SLC T52a, CoP 11.23 and UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors (2008).	risks to recipients who have had treatment with these donated gametes. The review should consider whether patients affected are to be contacted and advised on the possible risks of their treatment. The PR should also review the centre's recent audit of 'Donor selection, recruitment and assessment' to determine whether the audit is satisfactory or should be repeated to ensure no further unidentified issues remain. The HFEA should be advised of the anticipated timescale for the completion of these reviews and risk assessment when responding to this report. It is expected that these will be completed by 28 February 2019.	repeated by 28th Feb 2019.	the PR provide a summary of the findings of that review to the centre's inspector when it has been completed. The risk assessment of the case identified, and the review of the centre's recent audit of 'Donor selection, recruitment and assessment' due by 28 February 2019 are awaited. **Further action is required**.
2. Payments for donors The Bourn Hall Group offers a 'Gift of Giving' option whereby a person can donate their	The PR should ensure that no money or other benefit must be given or received in respect	The Gift of Giving programme has been terminated. An alternative programme will be	The executive acknowledges the PR's response and his commitment to fully

gametes and in return nominate a friend or family member to receive a free cycle of IVF. The benefit in kind is not received by the gamete donor themselves and therefore, the executive does not consider that this is compliant with General Direction 0001 which states that 'Gamete donors may receive licensed services, such as treatment, storage, or access to licensed services, in return for supplying gametes for donation.' SLC T69 and General Direction 0001. The inspection team also noted that the centre places an emphasis on financial incentive rather than altruism, in some advertising and marketing materials, in the way that it markets egg or sperm sharing. At the time of the inspection, the centre's website had a 'Free IVF options' page directing the visitor to pages where it describes 'free IVF cycles for	to any supply of gametes unless authorised by Directions and that advertising or publicity aimed at recruiting donors should not place an emphasis on financial incentives. The executive notes the PR's assertion that the benefits in kind arrangement in the 'Gift of giving' programme is not non-compliant with General Direction 0001. However, this is not the view of the HFEA and a legal opinion supporting the PR's position has not been provided. Therefore, the PR should halt this programme and provide confirmation that this is no longer to be offered when responding to this report. The PR should review all marketing, advertising and publicity materials relating to gamete donation and revise them to ensure compliance with guidance. The PR should confirm to the centre's inspector that this has been completed by 28 February	submitted to the HFEA for approval by 28th Feb 2019. All marketing, advertising and publicity material will be reviewed and revised to ensure compliance with guidance, confirmation will be provided by 28th Feb 2019.	implementing this recommendation. The executive notes that the 'Gift of Giving' programme has been terminated. Confirmation that all marketing, advertising and publicity materials relating to gamete donation have been reviewed to ensure compliance with guidance due by 28 February 2019 is awaited. **Further action is required**.

egg and sperm sharers'. This is not compliant with guidance that 'Advertising or publicity aimed at recruiting gamete or embryo donors, or at encouraging donation, should not refer to the possibility of financial gain or similar advantage, although it may refer to compensation permitted under relevant HFEA Directions.' CoP 13.1.	2019.		
3. Medicines management Several issues were noted in the centre's medicines management practices and audit of these practices, as detailed in the body of the report. In summary: • Numerous entries in the controlled drugs were not completed. • There was no master list of signatures for the controlled drugs register. • The controlled drugs audit lacked	The PR should ensure that medicines management procedure and practice is in line with statutory and regulatory requirements. The PR should review practices relating to the management of medicines, to include, but not be limited to, management of controlled drugs, staff training requirements and that effective audits are in place to ensure compliance with legislation and best practice guidance. A summary of the	All drug reciept and dispensing was accurately recorded. There were some pages in the CD register that did not include the 'carry over' of the stock balance from the previous page, and these have now been completed. Relevant staff have been made aware of the necessity to do this in the future. A master list of signatures for the controlled drug register is now in place at all clinics. The controlled drugs audit form is being edited to include the requirements to audit (as	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. A summary reports of the findings of the PR's review of practices related to medicines management due by 28 February 2019 is awaited. The audit of medicines management practices due by 28 May 2019 is awaited. The PR has confirmed that he

robustness. • There was no evidence that the medicines management competence assessments for nursing staff were regularly reviewed. Nurses routinely dispense fertility drugs to patients whereas NMC guidance states that 'Registrants may in exceptional circumstances label from stock and supply a clinically appropriate medicine to a patient, against a written prescription (not PGD), for self-administration or administration by another professional, and to advise on its safe and effective use.' SLC T2. DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'. Misuse of Drugs (safe custody) Regulations 2001.	findings of the review including corrective actions and the timescales for implementation and staff training requirements should be provided to the centre's inspector by 28 February 2019. Within three months of this review, the centre should carry out an audit of medicines management practices and procedures to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 28 May 2019. In relation to the routine dispensing of fertility drugs, the PR should commission a review of dispensing practice and management of medicines by an independent registered pharmacist. The PR should advise the centre's inspector of the timescale for achieving this by 28 May 2019.	already stated in the SOP). This form will be provided by 28th February 2019. The induction and appraisal processes are in place to ensure the relevant competency assessments are carried out at least annually and for new staff after 3 months in post. The necessity of the 3 month review for new starters has been re-enforced to relevant staff. An audit will be carried out of medicines mangement and controlled drugs practices and a report will be provided by 28th May 2019. With regards to the dispensing practices, in accordance with an existing prescription, we only provide 'top ups' in exeptional circumstances. The variability of an individuals ovarian response and the individualisation of treatment necessitates flexibility around the time of trigger and thereafter. This flexibility can only be maintained by providing small amounts of	will commission an independent registered pharmacist to review dispensing practice and management of medicines. Confirmation of the anticipated timescale for completion of this review should be provided by 28 May 2019. **Further action is required**.

NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. NMC Standards for Medicines Management 2010.		medication when necessary and ensures minimisation of risks to patient treatment. This is an industry wide practice. We will commission an independent registered Pharmacist to review the dispensing practice and management of medicines.	
4. Pre-operative assessment and the surgical pathway During the inspection a review of patient records in relation to the 'perioperative care document' (World Health Organisation (WHO) checklist equivalent) was undertaken. The outcome of the review identified several areas where there was a lack of completed documentation at the end of the performed procedure which are detailed in the body of the report. These concerns were immediately brought to the attention of the PR and senior nurse during the inspection. SLC T2 and 'WHO surgical safety checklist and implementation manual'.	The PR should ensure that the assessment of patients undergoing surgical procedures is in line with best practice guidance. The PR should review the centre's procedures for the assessment of patients undergoing surgical procedures and provide a summary report, including any corrective actions taken when responding to this report. Within three months of this review, the centre should carry out an audit of practices relating to the assessment of patients undergoing surgical procedures to ensure that the proposed corrective actions	There are processes in place to record this information on the perioperative care document at the end of a procedure and this was demonstrated during the inspection. New members of staff were responsible for the incomplete records identified. All staff have now been re-trained in how to complete the perioperative care document. The electronic medical records contained comparable relevant information in each case. An audit will be conducted of practices relating to the assesssment of patients undergoing surgical procedures and a report will	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of his review of the centre's procedures for the assessment of patients undergoing surgical procedures. An audit of audit of practices relating to the assessment of patients undergoing surgical procedures due by 28 May 2019 is awaited. **Further action is required**.

	have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 28 May 2019.	be provided by 28th May 2019.	
5. QMS A number of issues were noted in the audits in relation to the centre's immediate actions taken in response to significant findings as detailed in the body of the report. Overall, the inspection team was concerned that the centre's auditing process is so complex that the QMS it is not as effective as it could be. The audits are long and detailed covering a great deal of information for a small sample of records. This can be a good approach, but also leads to risk that significant findings can get lost in the volume of information collected and appropriate immediate actions are not considered, taken and/or documented SLC T32 and SLC T36.	The PR should ensure that the centre's QMS and auditing processes are effective in identifying and implementing appropriate corrective actions in response to audit findings. The PR should undertake a root-and-branch review of the QMS to determine what changes can be made to improve the effectiveness of the auditing processes such that these are effective in ensuring compliance with regulatory requirements and to continually improve the quality of the service. A summary report of the findings of this review including corrective actions, with timescales for implementation, should be provided to the centre's inspector by 28 May 2019.	Our QMS is fully compliant with ISO 9001:2015 (which is the ISO standard for Quality Managment Systems). This standard is inspected annually, the last one being April 2018 without any issues being identified. We agree that some of our audits and reports are complex. Our interpretation of the Code of Practice is that we are required to audit all critical areas. We will review our audit scheules again and try to make them less complex. We have identified that there is a need for stricter Quality Control within our operations. We will review and implement a QC system to compliment our QMS. A report outlining our plans will be provided by	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The executive notes that the centre will be implementing stricter quality control measures to improve the effectiveness of the QMS and a report outlining these plans is to be provided by 31 March 2019. The executive anticipates that this report will include a root-and-branch review of the QMS so as to identify changes to current processes that will address the inspection team's concerns as set out in this report. **Further action is required**.

		31st March 2019.	
6. QMS The following were noted in relation to the centre's quality indicators, audits and SOPs as described in the body of the report Quality indicators: • The inspection team considered that the centre's quality indicators for the provision of information, submission of data to the HFEA and breaches of confidentiality were not appropriate. Audits: • The inspection team did not consider that the centre's audits have assessed compliance with the regulatory requirement that all patients and donors have been provided with such relevant information as is proper prior to giving consent	The PR should ensure that appropriate quality indicators are established, audits of all critical activities are completed, and that SOPs to cover all critical activities are in place. Quality indicators: • The PR should ensure that the all quality indicators are reviewed to ensure that they are appropriate to the relevant critical activity. Audits: The PR should undertake the following: • An audit the provision of information to ensure compliance with regulatory requirements. • An audit of satellite activities to assess compliance with General Direction 0010.	We will review the Quality Indicators to ensure they are appropriate to the relevant critical activity. Two audits for the provision of information were carried out, one by an external auditor (IRCA Lead Auditor) and one in-house. During the inspection the 'Medical Consultation Checklists' that were reviewed demonstrated that patients and donors have been provided with relevant information. We will complete a QC check/audit of these forms and a report will be provided by 28th February 2019.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that he will review the centre's quality indicators to ensure that they are appropriate to the relevant critical activity. Two audits of provision of information described by the PR were reviewed on inspection. These audits evaluated compliance with the centre's SOPs in relation to provision of information and followed two consultations at centre 0100. Whilst these audits are valuable in ensuring that the centre staff are complying with their own processes, the inspection team did not consider that this was an appropriate audit to assess compliance with the requirement that patients are being provided such relevant

to activities under Schedule 3 HF&E Act 1990 (as amended). • The centre has not audited the activities at its satellite clinic to assess compliance with regulatory requirements. • Issues were identified in audit of controlled drugs as described in the section 'Medicines management' above. SOPs: • The centre does not have a detailed SOP for the process of import and export of gametes and embryos. SLC T32, SLC T33b, SLC T35 and SLC T36.	• A robust audit of controlled drugs and/or medicines management. Copies of the findings of these audits should be provided to the centre's inspector by 28 February 2019. SOPs: • The PR should develop an SOP for the management of import/export of gametes and embryos, to include the requirements of General Direction 0006 and CoP guidance. A copy of the SOP should be provided to the centre's inspector by 28 May 2019.	The satellite clinic (Bourn Hall Clinic King's Lynn) is part of the Bourn Hall Ltd group. It is staffed by Bourn Hall staff and the same QMS is used at the site. Records from the satellite clinic were audited (as demonstrated at the inspection). Records are audited as part of the BH Norwich (Primary centre) audit (demonstrating compliance with Direction 0010). The audit that was conducted of the satellite clinic included areas such as infection control, equipment and medicines management etc. A further audit will be conducted of satellite clinic activities and a report will be provided by 31st March 2019. Controlled drugs-As detailed in finding 3 we will carry out an audit of medicines management and controlled drugs and provide a report by 28th May 2019. Import and export- There are SOPs and Work Instructions	information as is proper prior to giving consent to activities under Schedule 3 HF&E Act 1990 (as amended). Furthermore, the audits had taken place at centre 0100, not 0325. The centre's processes for auditing this critical activity should be reviewed and an audit of this area of practice submitted by 28 February 2019. The executive agrees to receive the audit of satellite activities by 31 March 2019 and the audit of controlled drugs and/or medicines management to be carried out in response to finding 3 above by 28 May 2019. New SOPs for the management of import/export of gametes and embryos, to include the requirements of General Direction 0006 and CoP guidance have been provided. The centre's inspector has reviewed this information and provided feedback to centre staff on areas where further

		for the management of Import/Export of gametes in place and these refer to Direction 0006. We have included the documents with this response.	clarification is required to ensure all relevant regulatory requirements and clearly explained. This will be followed up by the centre's inspector. **Further action is required**.
7. Welfare of the child A number of issues related to the welfare of the child assessments such as incomplete records or errors in forms were noted by the inspection team, and in the centre's own audit of records. These are described in the body of the report. The inspection team was concerned that these issues in the completion of the welfare of the child assessments had not been identified by centre staff before the provision of treatment. Whilst the inspection team acknowledges that the welfare of the child has been taken into consideration, the errors noted audits of records by both the centre staff and inspectors	The PR should ensure that the centre's processes for the welfare of the child assessments are robust. The PR should ensure that the issues identified are addressed. A summary of the progress made in addressing these issues, and the timescales for completion should be provided to the centre's inspector with the PR's response to this report. The PR should undertake a detailed review of the centre's processes for the welfare of the child assessments, in particular how issues identified by the inspection team and within the centre's own audits have occurred. A summary of	The Lead Clinician and Head of QA have reviewed all of the Welfare of the Child cases where there were issues with the assessment forms. The Lead Clinician carried out a risk assesment and concluded there are no Welfare of the Child concerns for any patients. All clinical staff have been made aware of the issues and have been reminded to follow the pathway. We are also adapting the current medical consultation checklist and the medical staff and two nurses will sign to state they have checked the WOC forms and they have been completed correctly. This will be in use by 28th February 2019.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The executive is reassured by the PR's confirmation that there are no welfare of the child concerns for the cases identified during the inspection and in the centre's own audits. The PR has confirmed that medical staff have been made aware of the issues and that immediate actions have been taken to ensure that more robust processes for recording, reviewing and checking the assessment of the welfare of the child before the provision of treatment are

indicate that the processes for recording, reviewing and checking the assessment of the welfare of the child before the provision of treatment are not robust. SLC T56.	the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 28 February 2019. Given the number of issues identified the PR should undertake monthly audits of records to determine if proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector until audits provide assurance that the issues identified have been fully addressed. Compliance with this recommendation is expected to be completed by 28 May 2019.	Prior to the use of the checklist, three senior nurses have been appointed with immediate effect to be responsible for checking the forms are present and have been completed correctly. As detailed in finding 5, we are reviewing the clinic's QMS with regards to Quality Control. We will be implementing a system to ensure all consents and WOC assesssments are completed correctly and are checked at a point in the patients cycle to ensure any issues can be dealt with in a timely manner. As detailed in finding 5 a report will be provided by 31st March 2019. QC checks will be completed monthly, an audit will be conducted and a report of the findings will be provided to the HFEA by 28th June 2019, 3 months after implementation of the QC programme.	in place. The executive notes that quality control measures for checking welfare of the child assessments are to be introduced. Whilst these provide additional reassurance, the executive would urge the PR to ensure that robust processes for undertaking these assessments are in place such that these are completed effectively at the time rather than relying on additional QMS/quality control processes to identify any errors or failings. The executive requested that the PR should undertake a detailed review of the centre's processes for the welfare of the child assessments, in particular, to establish how issues identified by the inspection team and within the centre's own audits have occurred. A summary of the findings of this review due by 28 February 2019 is awaited.

			The executive required that the PR should undertake monthly audits of records to determine if proposed corrective actions have been effective in ensuring compliance and provide a summary report of the findings of these audits to the centre's inspector until audits provide assurance that the issues identified have been fully addressed. The PR should submit the first such audit by 28 March 2019. The executive agrees to receive a summary of the findings of an audit of welfare of the child assessments to ensure that the proposed corrective actions have been effective in ensuring compliance by 28 June 2019. **Further action is required**.
8. Consent The following issues were noted during the centre's audit of records which had recently been undertaken (September-October 2018) and are	The PR should ensure that the centre's processes for obtaining and checking consent are robust, and that the patient's and donor's	There are pathways in place to ensure all consents are completed. Re-training will be provided to staff to ensure correct completion of	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation.

discussed in more detail in the body of the report: • No WD form ('Your consent to donating your eggs') was found in the records of the egg share patient audited. • A same sex couple had completed the incorrect consent to legal parenthood forms. During the inspection team's audit of four egg sharer records the following issues were noted: • One egg sharer had undertaken her counselling appointment after signing her WD consent form, and in this form the 'restrictions' section had been left blank (neither 'yes' or 'no' had been selected, nor any restrictions recorded). • For another egg sharer, the family limit section	intentions are clear. The PR should implement immediate actions to ensure that the processes for providing and recording consent are robust and confirm what actions have been taken when responding to this report. The PR should undertake a detailed review of the centre's processes for completing and checking consent forms to address the reasons why these issues had occurred. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 28 February 2019. The PR should undertake monthly audits of records to determine if proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the	consents. As detailed in finding 7 we are also adapting the current medical consultation checklist and the medical staff and two nurses will sign to state they have checked the consent forms and they have been completed correctly. This will be in use by 28th February 2019. Prior to the use of the checklist, three senior nurses have been appointed with immediate effect to be responsible for checking the forms are present and have been completed correctly. As detailed in finding 5, we are reviewing the clinic's QMS with regards to Quality Control. We will be implementing a system to ensure all consents and WOC assesssments are completed correctly and are checked at a point in the patients cycle to ensure any issues can be dealt with in a timely manner. As detailed in finding 5 a report will be provided by 31st	The executive notes that the PR has taken immediate actions to ensure that all consent forms are checked for accuracy and completeness. This is until a new process of reviewing and checking consent is implemented by 28 February 2019. The PR states that re-training will be provided to staff but has not provided a date by which this re-training will be given. The executive anticipates that this re-training will be completed prior to the introduction of the new checking processes by 28 February 2019. The PR confirms that there are pathways in place to ensure all consents are completed correctly but has not provided any information as to why these pathways failed in the cases reviewed on inspection. A detailed review of the centre's processes for completing and checking consent forms to address the reasons why these issues had occurred

of the WD form was not completed, and the 'restrictions' section had been left blank (neither 'yes' or 'no' had been selected, nor any restrictions recorded). The inspection team was concerned that these errors in consent had not been identified by centre staff before the provision of treatment. Schedule 3 Human Fertilisation & Embryology (HFE) Act 1990 (as amended). Sections 37(1) and 44(1) of Part 2 of the Human Fertilisation & Embryology (HFE) Act 2008.	centre's inspector until audits provide assurance that the issues identified have been fully addressed. Within three months of this review, the centre should carry out an audit of consent forms to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 28 May 2019.	March 2019. QC checks will be completed monthly, an audit will be conducted and a report of the findings will be provided to the HFEA by 28th June 2019, 3 months after implementation of the QC programme.	due by 28 February 2019 is awaited. It is expected that this will include a root cause analysis for each of the significant failings identified. The executive notes that quality control measures for checking consents are to be introduced. Whilst these provide additional reassurance, the executive would urge the PR to ensure that robust processes for taking consents are in place such that these are completed effectively at the time rather than relying on additional QMS/quality control processes to identify any errors or failings. The executive required that the PR should undertake monthly audits of records to determine if proposed corrective actions have been effective in ensuring compliance and provide a summary report of the findings of these audits to the centre's inspector until audits provide assurance that the issues

			identified have been fully addressed. The PR should submit the first such audit by 28 March 2019. The executive agrees to receive a summary of the findings of an audit of consent forms to ensure that the proposed corrective actions have been effective in ensuring compliance by 28 June 2019. **Further action is required**.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non-compliance, but which indicates a departure from statutory requirements or good practice.
An 'other' area of non-compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
9. Safety and suitability of premises and facilities During a tour of the centre it was noted that doors, designated as 'fire doors', to two consultation rooms were being held open by objects. SLC T2 and CoP 25.4.	The PR should ensure that all fire doors are kept closed in line with statutory and regulatory requirements and remind centre staff of their responsibilities to comply with fire safety legislation. The PR should confirm that this has been actioned when responding to this report.	All doors are designated as fire doors and all are to be fitted with door guards. Therefore, if the fire alarm is activated these doors will close automatically. The door guards are to be fitted by 28th Feb 2019.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The executive notes that all designated fire doors are to be fitted with door guards by 28 February 2019. The executive has the PR's assurance that the practice of holding doors open with objects has been stopped. **Further action is required.**
10. Infection control During this inspection, the following issues were noted: • Chairs covered in	The PR should ensure adherence to infection control best practice guidance and	A review of all chairs in clinical areas will be completed and a report provided by 28th	The executive acknowledges the PR's response and his commitment to fully

porous fabric are present in clinical areas, the centre could not provide assurance that these chairs can be cleaned effectively. • The centre could not provide assurance that staff uniforms were being washed appropriately to prevent the potential spread of infections. Staff were unsure as to what temperature they should be using to wash their uniforms at home and there was no policy in place to guide them. Department of Health: Health Building Note 00-09: Infection control in the built environment (2013) section 3.105. Healthcare-associated infections: prevention and control in primary and community care 2017, section 1.1.4.4.	requirements. The PR should review infection control practices and procedures and address the issues identified in this report to ensure compliance with this recommendation by 28 February 2019. Within three months of this review, the centre should carry out an audit of the centre's cleaning and infection control practices to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 28 May 2019.	February 2019. All staff have been made aware that staff uniforms are to be washed at 60C and the training slides with regards to infection control have been updated to include this requirement. An audit will be conducted of the cleaning and infection control practices and a report will be provided by 28th May 2019.	implementing this recommendation. The review of infection control practices and procedures due by 28 February 2019, and the audit due by 28 May 2019, are awaited. **Further action is required.**

11. Prescription of intralipid 'off label' A number of issues were noted in the written patient information regarding intralipid therapy ('Understanding treatments 'Intralipid infusions') as set out in the body of the report. SLC T2 and Clinic Focus article 'Off-label use of intralipid infusions' (July 2015).	The PR should ensure that the written information for patients prescribed intralipid therapy specifies that if prescribed to this group of patients the drug is being prescribed 'off label' and gives accurate information about safety and efficacy. The PR should review and revise the centre's patient information relating to the use of intralipid therapy, including that on the centre's website, to ensure that it is compliant with HFEA and professional body guidance. A copy of the updated patient information should be provided to the centre's inspector by 28 February 2019.	The patient information for Intralipids was reviewed by the HFEA during another BHC inspection, and we updated the information to be in line with the requirements. This updated document was reviewed in June 2018 and accepted by the HFEA. However, we will review the document and our website to include reference to the HFEAs traffic light system, so patients always have access to up to date information. The updated document will be provided by 28th Feb 2019	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The executive has reviewed patient information regarding intralipids at the time of previous inspections, but the leaflet seen during this inspection was not the same as those that had been seen previously. A copy of the updated patient information due by 28 February 2019 is awaited. **Further action is required.**
12. Consent to disclosure to researchers One discrepancy was found between completed patient/partner disclosure consents and the related consent data submitted for	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the	We will review the procedure for ensuring disclosure of information supplied to the authority reflects that given and recorded on patients	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation.

inclusion on the register in 10 patient files audited. This error has now been corrected. The issue discussed in the 'Quality management system' section above where one patient completed two 'consent to disclosure' forms has not yet been addressed. CH (10)05 and General Direction 0005.	HFEA register. The PR should review the centre's procedures to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on patient's consent forms. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 28 February 2019. Within six months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 28 August 2019.	consent forms and provide a summary of findings by 28th Feb 2019. An audit will be conducted and a report provided by 28th August 2019.	The review of procedures due by 28 February 2019, and the audit due by 28 August 2019, are awaited. **Further action is required.**
13. Fees Fees payable to the HFEA have not always been paid within the required timeframe.	The PR should ensure fees payable to the HFEA are made within the required timeframe.	We will review the processes in place with regards to paying the HFEA invoices within the required timescales and	The executive acknowledges the PR's response and his commitment to fully implementing this

SLC T9d and CH (10)02. This was also noted as an issue at the time of the last inspection.	The PR should take appropriate action to ensure that all HFEA invoices are paid within the timescales specified by the Authority and advise the centre's inspector of these actions by 28 February 2019.	provide a response by 28th Feb 2019.	recommendation. A summary of actions taken to address this issue due by 28 February 2019 is awaited. **Further action is required.**

Reponses from the Person Responsible to this inspection report
We are in the process of implementing an e-consent platform throughout the group. This system will address many of the issues around informed consent. The platform is being tested in our Wickford site and is planned to be rolled out in Q2 2019. We will introduce a re-education programme on QC for relevant staff after review of the current processes and incorporation of a specific QC competency into our Competency Framework. This will be completed by Q2 2019. With regards to the percieved over-complexity of our audits, we would like some guidance from the HFEA on their simplification, and provision of any training to to ensure compliance.

Executive Update for Executive Licensing Panel
9 April 2019

Centre number	0325
Centre name	Bourn Hall Clinic Norwich
Person Responsible	Dr Mike Macnamee

Further update to progress report requested by Executive Licensing Panel

1. At this meeting, the Executive Licensing Panel is re-considering the renewal inspection report for centre 0325, together with a progress update on recommended actions relating to non-compliances identified at the centre's renewal inspection in November 2018. This is a further update on the centre's progress with recommended actions.

2. Since the time of the progress update the PR has provided evidence in relation to four additional post-inspection actions that were due by 28 and 31 March 2019.

    - Recommendation 5: a review of the centre's quality management system (QMS). The centre has identified areas for improvement in the QMS which will be implemented across all centres in the Bourn Hall group. Progress with implementing these will be evaluated by the executive at future inspections of the other centres in the group due to take place during 2019. **No further action is required.**

    - Recommendation 6: a report of the centre's audit of satellite activities. Two issues were noted in the centre's audit of satellite activities, and corrective actions identified have been fully implemented. One further action remains which is the audit of controlled drugs and/or medicines management to be carried out in response to recommendation 3, which is due by 28 May 2019 therefore **no further action is required.**

    - Recommendations 7 and 8: the centre's monthly audit of records to determine if proposed corrective actions have been effective in addressing the issues identified in relation to consent and welfare of the child assessments. No issues were identified in the records audited. **Further monthly audits will be provided.**

3. A total of five recommendations have now been fully implemented. Progress in implementing the remaining recommendations will continue to be monitored by the centre's inspector.

4. The executive confirms that there is no change to the recommendations made by the inspection team as set out in the renewal inspection report.

Karen Conyers
Inspector
1 April 2019