Executive Licensing Panel - minutes

Centre 0100 (Bourn Hall Clinic)

Renewal Inspection Report

Tuesday, 12 November 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Richard Sydee (Chair) Niamh Marren Danielle Vincent	Director of Finance and Resources Regulatory Policy Manager Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing 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 is located on the outskirts of Cambridge and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services including embryo testing. Other licensed activities at the centre include storage of gametes and embryos.

1.3. The panel noted that Bourn Hall Clinic is part of a group that incorporates three other HFEA licensed centres; centre 0188 Bourn Hall Clinic (Colchester), centre 0325 Bourn Hall Clinic (Norwich) and centre 0363 Bourn Hall Clinic (Wickford). All the clinics are centrally managed and have common practices and procedures, in particular, the Quality Management System (QMS).

1.4. The panel noted that the HFEA's 'group approach' is one where a single assessment of shared elements such as QMS and standard operating procedures (SOPs) 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 there are no 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. This group approach was used during the renewal inspection of this centre in September 2015.

1.5. A renewal inspection of Bourn Hall Clinic (Norwich) was conducted in November 2018, during which all areas of practice were reviewed in full. The Executive used the findings of that inspection of centre 0325 to determine the approach to be used at the renewal inspection of centre 0188 in May 2019. The Executive concluded that whilst a group approach could be used in some areas of practice, critical activities such as consent and legal parenthood were to be reviewed in full on this inspection. Shortly after that inspection, a routine unannounced interim inspection of centre 0363 was conducted in May 2019.

1.6. The panel noted that, with regards to the renewal report for consideration, all areas of practice were reviewed. However, findings of recent inspections of the other three centres in the Bourn Hall group were also taken into account. Group-wide activities that had been found to be compliant across all three centres were not reviewed in detail except where there were different practices locally. Audits of all areas of practice at Bourn Hall Clinic were reviewed, and the effectiveness of learning from the non-compliances identified during the inspections of centres 0325, 0188 and 0363 which impact across the group, were also discussed in detail.

1.7. The panel noted that, in the 12 months to 31 August 2019, the centre provided 1564 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large sized centre.

1.8. The panel noted that, HFEA register data, between 1 June 2018 and 31 May 2019, show the centre's pregnancy outcomes for IVF and ICSI success rates, in terms of clinical pregnancy outcomes, are in line with the national averages, with the following exception:

- success rates following ICSI treatment in women under 38 years old are higher than average at a statistically significant level.

1.9. The panel noted that, in 2018, the centre reported 39 cycles of partner inseminations, with three pregnancies, and this is in line with the national average.

1.10. The panel noted that, between 1 June 2018 and 31 May 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%. This represents performance

that is not likely to produce a multiple live birth rate statistically different from the 10% multiple live birth rate target.

1.11. The panel noted that since the interim inspection was conducted in October 2017, the Person Responsible (PR) has been asked to review the centre's multiple pregnancy rates on six occasions; November 2017, August 2018, September 2018, March 2019, April 2019 and August 2019. The PR responded to these requests and provided evidence and assurance that he continually monitors the centre's success rates taking appropriate actions as necessary. The inspection team acknowledges the efforts taken so far by the PR and centre staff, his commitment to keep this area of practice under review and were assured to note, that at the time of the inspection, the centre's multiple pregnancy rate is not likely to be statistically different to the multiple live birth rate target of 10%.

1.12. An inspection was carried out at the centre on the 17 and 18 September 2019.

1.13. The panel noted that at the time of the inspection, there were four major areas of non-compliance concerning donor screening, medicines management, prescription of intralipid 'off label' and CE marking. There were also seven 'other' non-compliances regarding infection control, third party agreements (TPAs), confidentiality and privacy, adverse incidents, consent to disclosure to researchers, record keeping and document control and fees. Since the inspection visit, the PR has given a commitment to fully implement all the recommendations within the required timescales. The PR has confirmed the actions taken to date and will provide all requested evidence and audits of practice within the required timescales.

1.14. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided.

1.15. The Executive noted that since the time of the recent inspections of the three other centres in the group, the PRs of the Bourn Hall centres have implemented a number of changes and improvements to practices. These have included a comprehensive programme of training in consent requirements (including consent to legal parenthood) provided by external specialist lawyers, and the implementation of new competency assessments and checking processes in this area of practice. The effectiveness of these changes, in particular those related to consent processes, were assessed during this inspection and no significant failings were noted. The Executive is re-assured that no critical non-compliances were noted during this inspection, and that evidence of the changes that have been made were also notable.

1.16. The panel noted that the inspection team recommends the renewal of the centre's treatment (including embryo testing) and storage licence for a period of four years, without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales. The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

1.17. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018; these certificates are generally synchronised to the centre's HFEA licence. The inspection team recommends the renewal of the 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 expressed concern regarding the nature of the non-compliances identified at this renewal inspection, noting some were reoccurrences of issues acknowledged during previous inspections. Given this, the panel strongly recommended that an early interim inspection is conducted.

2.5. The panel noted that evaluations of corrective actions and audits, with regards to many of the non-compliances identified, were due for receipt by 18 December 2019 and 18 March 2020. The panel expected the centre to make significant progression in rectifying the non-compliances, requesting that a progress report is submitted to the Executive Licensing Panel (ELP) in 2020.

2.6. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

2.7. 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

Richard Sydee

Date

18 November 2019

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 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: 17 and 18 September 2019.

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

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

Inspectors: Karen Conyers (lead), Louise Winstone and Sandrine Oakes.

Date of Executive Licensing Panel: 12 November 2019.

Centre name	Bourn Hall Clinic
Centre number	0100
Licence number	L/0100/15/c
Centre address	Bourn, Cambridge, Cambridgeshire, CB23 2TN, United Kingdom
Person Responsible	Dr Michael Macnamee
Licence Holder	Mr Martyn Blayney
Date licence issued	01 April 2016
Licence expiry date	31 March 2020
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 Clinic is located on the outskirts of Cambridge and has held a Treatment and Storage licence with the HFEA since 1992. The centre provides a full range of fertility services including embryo testing. Other licensed activities at the centre include storage of gametes and embryos.

The current licence has been varied to reflect the following changes.

- A change of Licence Holder in January 2018.
- A variation of activities to include embryo testing in December 2017.

The centre provided 1564 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2019. In relation to activity levels, this is a large centre.

Bourn Hall Clinic is part of a group that incorporates three other HFEA licensed centres; centre 0188 Bourn Hall Clinic (Colchester), centre 0325 Bourn Hall Clinic Norwich and centre 0363 Bourn Hall Clinic (Wickford). All clinics are centrally managed and have common practices and procedures, in particular the quality management system (QMS).

The HFEA's 'group approach' is one where a single assessment of shared elements such as QMS and standard operating procedures (SOPs) 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. This group approach was used during the renewal inspection of this centre in September 2015.

A renewal inspection of centre 0325 was conducted in November 2018 during which all areas of practice were reviewed in full. The Executive used the findings of that inspection of centre 0325 to determine the approach to be used at the renewal inspection of centre 0188 in May 2019. The Executive concluded that whilst a group approach could be used in some areas of practice, critical activities such as consent and legal parenthood were to be reviewed in full on this inspection. Shortly after that inspection, a routine unannounced interim inspection of centre 0363 was conducted in May 2019.

For the inspection reported on here, all areas of practice were reviewed, however the findings of recent inspections of the other three centres in the Bourn Hall group were also taken into account. Group-wide activities that had been found to be compliant across all three centres were not reviewed in detail except where there were different practices locally. Audits of all areas of practice at centre 0100 were reviewed, and the effectiveness of learning from the non-compliances identified during the inspections of centres 0325, 0188 and 0363 which impact across the group, were also discussed in detail.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 June 2018 and 31 May 2019 show the centre's success rates are in line with national averages with the following exception:

- success rates following ICSI treatment in women under 38 years old are higher than average at a statistically significant level.

In 2018, the centre reported 39 cycles of partner insemination with three pregnancies which is in line with the national average.

Multiple births[2]

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

Between 1 June 2018 and 31 May 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Since the time of the interim inspection in October 2017, the PR has been asked to review the centre's multiple pregnancy rates on six occasions; November 2017, August 2018, September 2018, March 2019, April 2019 and August 2019. The PR responded to these requests and provided evidence and assurance that he continually monitors the centre's success rates taking appropriate actions as necessary. The inspection team acknowledges the efforts taken so far by the PR and centre staff, his commitment to keep this area of practice under review and are assured to note that at the time of the inspection the centre's multiple pregnancy rate is not likely to be statistically different to the multiple live birth rate target of 10%.

[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 Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged 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;
- 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 Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including four major and seven '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 within the required timescales. The PR has confirmed the actions taken to date and that he will provide all requested evidence and audits of practice within the required timescales.

Major areas of non-compliance:

- The PR should ensure that the group's SOPs for donor recruitment, assessment, selection and screening procedures include all regulatory requirements and professional body guidance.
- The PR should ensure that the centre's practices for the management, use and safe storage of controlled drugs are compliant with regulatory requirements and best practice guidance.
- The PR should ensure compliance with guidance for the prescription of intralipid 'off label'.
- The PR should ensure that patients are provided with comprehensive information regarding the use of a product CE marked as an 'in vitro diagnostic' device being used as a medical device which is 'off label' i.e. for a purpose for which it was not appropriately classified.

'Other' areas that require improvement:

- The PR should ensure compliance with infection prevention and control regulations.
- The PR should ensure that all agreements with third parties include a condition that the third party, satellite or transport centre will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice.
- The PR should ensure that that all HFEA reportable adverse incidents and near misses are reported to the Authority.
- The PR should ensure that he provides for the privacy, dignity and respect of all prospective and current patients and donors.

- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.
- The PR should ensure that proper records are maintained and that only current versions of documents are in use.
- The PR should ensure fees payable to the HFEA are made within the required timeframe.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have four major areas of non-compliance.

The inspection team notes that the centre's success rates are consistent with the national average, with those following ICSI treatment in women under 38 years old being higher than average at a statistically significant level, and their multiple clinical pregnancy/live birth rates meet the target.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided.

The Executive notes that since the time of the recent inspections of the three other centres in the group, the PRs of the Bourn Hall centres have implemented a number of changes and improvements to practices. These have included a comprehensive programme of training in consent requirements (including consent to legal parenthood) provided by external specialist lawyers, and the implementation of new competency assessments and checking processes in this area of practice. The effectiveness of these changes, in particular those related to consent processes, were assessed during this inspection and no significant failings were noted. The Executive is re-assured that no critical non-compliances were noted during this inspection, and that evidence of the changes that have been made were also notable.

The inspection team recommends the renewal of the centre's 'Treatment (including embryo testing) and Storage' licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales. The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

Centre 0100 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the 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

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

What the centre does well

Screening of donors (Guidance note 11)
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 screening donors are partially compliant with HFEA requirements.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
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

Screening of donors (Guidance note 11)
Following the findings during the renewal inspection of centre 0188 in May 2019, the centre initiated a full review of the group's practices in relation to the recruitment, selection and assessment of gamete and embryo donors. As part of this review, the group's Medical Director has updated the centre's SOPs, incorporating the most recent professional body guidelines released in June 2019. The inspection team noted that these new SOPs which are not yet fully implemented do not capture all aspects of the professional body guidance such as asking sperm donors about their health and recent travel at each donation and ensuring the appropriate frequency of some of the screening tests (see recommendation 1; 'UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors' (2019)).

The inspection team noted that there are a number of work instructions in development and whilst most of the required information was eventually found within these documents it was necessary to look at several of them to be able to gain the information needed. For example, the work instruction (MN003-WI04 rev. 4 of 11/09/19), seen on inspection states 'donated sperm must be quarantined for a period of time and not released for use until follow-up screening requirements have been successfully met' but does not specify the criteria to determine the period of quarantine. During discussions with the group's Medical Director and Lead Nurse it was clear that they are aware of the requirements in relation to the quarantine periods, but these are not clearly stated in the work instructions (see recommendation 1; SLC T33(b)). The inspection team was concerned that as there are so many documents that do not appear to be cross-referenced there is a risk that a member of staff may miss some information if they were not aware that it is contained in another document.

Five sets of records of gamete donors were reviewed during the inspection. As had been noted at the time of the renewal inspection of centre 0188 in May 2019, no NAT testing had been carried out for three egg donor cycles completed in March 2019. However, the inspection team was assured to note that for a further cycle completed in September 2019 the required NAT testing had been undertaken. The inspection team also noted that HTLV testing had not been completed for these donors, however the rationale for this had not been documented. The group's Medical Director confirmed that the centre had also recognised this failing as part of their recent review of practices and corrective actions had already been implemented therefore no further recommendation is considered necessary.

Suitable premises and suitable practices
Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management

Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

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

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

The premises of the centre's satellite/transport 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 accreditation 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 with the exceptions noted below.

Written information provided to patients offered intralipid therapy is compliant with guidance.

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

Multiple births (Guidance note 7; 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;
- 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.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, 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 TCS, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have been made since the introduction of the ITE import certification scheme on 1 April 2018.

During the initial period of implementation of these new regulations the centre had undertaken a 'one-off' import of patient's embryos from a TCS not specified on the centre's ITE import certificate. The inspection team reviewed this case and was satisfied that the centre had assured the quality and safety of the imported embryos prior to import. Since that time no imports have been made from TCS which are not specified on the centre's ITE import certificate. The inspection team was satisfied that 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 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 broadly compliant with HFEA requirements.

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

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. Most of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is 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)
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.
The centre's procedures for reporting adverse incidents are broadly compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA with the exception noted below. The centre investigates all adverse incidents that have occurred.

What the centre could do better

Infection control (Guidance Note 25)
The inspection team noted that the flooring of the central corridor from the theatre area does not have any coving up the wall, the sealant was damaged in places and sections between theatre and the recovery area are carpeted (see recommendation 5; 'Health Building Note 00-09: Infection control in the built environment (2013)' sections 3.109, 3.110 and 3.115, CoP 25.19 and 25.20). This is not compliant with infection control regulations in that all flooring in clinical areas should be seamless and smooth, slip-resistant, easily cleaned and appropriately wear-resistant. There should also be coving between the floor and the wall to prevent accumulation of dust and dirt in corners and crevices.

Medicines management (Guidance Note 25)
The following non-compliances related to the management of controlled drugs were identified during the inspection (see recommendation 2; 'The Misuse of Drugs (Safe Custody) Regulations (1973)' section 5, and 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England) (2007)' sections 4.5.2, 4.5.4, 4.11.1.3).

- During a procedure observed by the inspection team a box of fentanyl (a Schedule 2 controlled drug) containing several ampoules was stored in an unlocked cupboard in theatre together with other non-controlled drugs. This is not compliant with the safe storage requirements for controlled drugs as they must be stored in a locked receptacle which can only be opened by a person who can lawfully be in possession of a key to that cupboard and must be locked away when not in use. The inspection team noted that the cupboard where controlled drugs are kept is in the nurse's office away from theatre and considered that this contributed to the non-compliant practice observed during the inspection.
- During a procedure observed by the inspection team, the controlled drugs register was completed by the nurse performing the sedation. The inspector noted that the nurse discarded the unused portion of the controlled drug, but this was not witnessed by the doctor who subsequently signed the register as having witnessed that discard.

Prescription of intralipid 'off label'
During the inspection three records of patient's consent to treatment with intralipid treatment were reviewed and the following issues were noted. In one record the patient's signature was missing, in a second the consultant's signature was missing and in the third the patient's details and the staff witnessing signature was missing (see recommendation 3; SLC T2 and Clinic Focus July 2015).

The inspection team also noted that in one record the rationale and/or clinical indication for prescribing and treating patients with intralipids were documented as 'patient choice' and nothing was noted in the other two records. Whilst there was a record of the clinician's discussion on the use of intralipids with the patients there was no clear documentation of the rationale for prescribing this 'off label' use of intralipids, and patient choice is not a clinical indication for its use (see recommendation 3; SLC T2 and Clinic Focus July 2015).

Third party agreements (Guidance note 24)
During the inspection, three third party agreements currently in place at the centre were reviewed. These agreements did not include a condition that the third party, satellite or transport centre will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice (see recommendation 6; SLC T116).

One of the agreements with an overseas donor sperm bank included a statement that the donors are compensated '45 euros irrespective of actual loss of expenses' which would not be compliant with HFEA requirements for compensation of overseas donors (see recommendation 6; General Direction 0001). Soon after the inspection the centre had obtained an updated agreement which confirms that the compensation arrangements for the sperm donors is in accordance with General Direction 0001.

Equipment and materials (Guidance note 26)
The centre occasionally uses a product to activate sperm prior to ICSI treatment. This product is CE marked as an 'in vitro diagnostic' device but is being used as a medical

device which is 'off label' i.e. for a purpose for which it was not appropriately classified. Where a centre is using a product as a medical device for which there is no CE marked alternative available, it is expected that appropriate information is provided to patients regarding the use of a non-CE marked product as a medical device (such as any possible risks associated with the use of this item) prior to use in treatment (see recommendation 4; SLC T30 and CoP 26.5).

The centre uses serological pipettes for dispensing culture media and in preparing the culture systems. The inspection team noted that these pipettes are not CE marked as medical devices, and that the centre's rationale for their use is that these do not come into contact with gametes or embryos. Soon after the inspection, the Head of Science for the Bourn Hall group confirmed that they have replaced these products with ones that are CE marked as medical devices with immediate effect.

Adverse incidents (Guidance note 27)
The centre had not reported one adverse incident relating to the quality and safety of gametes and embryos to the HFEA (see recommendation 7; SLC T118).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

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

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 compliant with

HFEA requirements with the exception noted in the section 'Record keeping'.

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
Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

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

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA and
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons.

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

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

2. The experience of patients

Patient feedback

What the centre does well

During the inspection the inspectors spoke to one patient who provided positive feedback on their experience at the clinic.

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Seven patients have provided feedback in the last 12 months, giving an average 4-star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment and the majority of patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting staff at the clinic however there were also several negative comments regarding their experiences at the centre.

The low level of feedback to the HFEA has been noted across the recent inspections of the other Bourn Hall group of centres and the PRs had provided their assurances that further actions are being taken to address the low level of feedback such as providing electronic tablets for patients to use whilst in the centre. The impact of this has not yet been seen and will be reviewed at the time of the next inspection of a centre in the group which is likely to be late 2019/early 2020.

The centre's most recent patient feedback, which is in the form of an electronic survey sent out at the time of egg collection, frozen embryo transfer or insemination, was also reviewed. This was introduced on 22 May 2019, and 45 responses to 275 surveys sent out up to 27 August 2019 had been analysed. The survey included questions on why patients decided to choose this centre, their experience from the initial enquiry stage onwards, the availability of appointments, cost, treatment, aftercare and support. Feedback was comparable to that provided to the HFEA. Most respondents either strongly agreed, agreed or neither agreed or disagreed with all the questions indicating that they were satisfied with their experience. However, 50% of respondents did not find the counselling service easy to access and 65% were not happy with the service they received from counsellors. Centre staff advised the inspectors that actions will be taken to address this feedback. One patient also provided feedback regarding the privacy in recovery area which reflected the concerns noted by the inspection team as discussed in the section 'Confidentiality and privacy' below. Overall 89% of patients reported that they would recommend the centre to a friend or relative.

The centre is disappointed with the low response rate from their own patient feedback survey and are considering ways to address this across the group.

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

- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

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)
The centre's procedures for egg and sperm sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

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

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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

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

What the centre could do better

Confidentiality and privacy (Guidance note 30)
The inspection team had some concerns for the confidentiality and privacy of patients

when they are in the recovery area (see recommendation 8; CoP 25.9 and 25.14). The curtains shared between adjacent bays did not close fully so it is possible to see patients in another bay. In addition, despite the radio being played in the background, the inspection team could clearly hear conversations taking place in the recovery area.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

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

What the centre does well

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

Legal parenthood (Guidance note 6)
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 the last inspection in October 2017, 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. Eight 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 compliant with HFEA requirements.

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

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
One discrepancy was found between completed patient and partner disclosure consents and the related consent data submitted for inclusion on the Register in ten patient files audited (see recommendation 9; CH(10)05 and General Direction 0005). 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 such that could pose a risk that the HFEA may inadvertently release patient identifying information to researchers without their consent.

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 15)

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

Obligations and reporting requirements (Guidance note 32; 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. 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. In the sample of data audited, all 131 IVF/ICSI cycles and 43 out of 44 donor insemination treatments had been reported to the HFEA. 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

Record keeping and document control (Guidance note 31)
The following issues were noted during the inspection (see recommendation 10).

- In one of a sample of six records reviewed in the course of the inspection, there was no documented evidence that a potential concern in the assessment of the welfare of the child had been reviewed. The inspection team noted that there was evidence that the patient's GP had confirmed there were no further concerns but there was no evidence in the records that it had been acknowledged and reviewed by staff in the clinic (SLC T46(e)).
- The inspection team noted that in one record of an egg donor, the section of the WD ('*Your consent to donating your eggs*') form for the donor to indicate if she wished to record any restrictions on her donation was left blank. This form was completed in April 2019; however, the donor also completed a WD form in 2018 at which time she had completed this section confirming that she did not have any restrictions to her donation. There was no indication to confirm that the this had been discussed and that the donor had not changed her mind regarding her previous indication that she did not have any restrictions to her donation (SLC T46(f)).
- In some cases, counselling sessions are organised by phone and/or Skype and these take place away from the centre. The counsellor does not have remote access the centre's electronic record keeping system and therefore there is no documentation in the patient's records that they have attended a counselling session (SLC T46(c)).
- During the inspection staff provided three different out-of-date patient information sheets dated 2012, 2014 and 2016 (SLC T34).

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 11; SLC T9d and CH (10)02).

Section 3: Monitoring of the centre's performance

Following the interim inspection in October 2017, recommendations for improvement were made in relation to three major and one 'other' area of non-compliance or poor practice.

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

The inspection team noted some areas of practice that have recurred since the time of the last inspections at this centre, and across the group and as highlighted in the section 'Areas of practice requiring action' below.

On-going monitoring of centre success rates

At the time of the renewal inspection in September 2015, the centre's clinical pregnancy rate following frozen embryo transfer (FET) in patients aged less than 40 years was lower than average at a statistically significant level. In 2017 and 2018, the centre was again asked to review procedures for the provision of FET in patients aged less than 40 years. The PR responded to these requests and during discussions at the time of the inspection, provided evidence and assurance that he continually monitors the centre's success rates and has already taken appropriate actions as necessary.

The inspection team acknowledges the efforts taken so far by the PR and centre staff, and his commitment to keep success rates in this group of patients under review, and notes that this outcome is now in line with the national average.

Areas of practice requiring action

This 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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Donor screening As part of the centre's review of the group's practices in relation to the recruitment, selection and assessment of gamete and embryo donors the group's Medical Director has updated SOPs, incorporating the most recent professional body guidelines released in June 2019. The inspection team noted that these new SOPs which are not yet fully implemented do not capture all aspects of the professional body guidance such as asking sperm donors about their health and recent	The PR should ensure that the group's SOPs for donor recruitment, assessment, selection and screening procedures include all regulatory requirements and professional body guidance. The PR should review the group's SOPs to ensure that they include all regulatory requirements and professional body guidance and consider what actions can be taken to address the concerns regarding the number of documents that are not clearly cross-referenced. A summary	We will review all SOPs and Work Instructions relating to screening of donors with a view to simplyfying the information so there are clear instructions for all staff and to ensure they include all regulatory requirements and professional body guidance. We will provide a summary report of the review by 18 Dec 2019. Any corrective actions will be implemented by 18 March 2020. Three months after the review	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that all SOPs and 'Work Instructions' related to screening of donors will be reviewed to ensure that these include all regulatory requirements and address the concerns raised by the inspection team. The PR has confirmed that a summary of the findings of this review will be provided to the centre's inspector by 18 December

travel at each donation and the ensuring the appropriate frequency of some of the screening tests. The inspection team noted that there are a number of work instructions in development and whilst most of the required information was eventually found within these documents it was necessary to look at several of them to be able to gain the information needed. Further details as to the inspection team's concerns are set out in the body of the report. UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors' (2019). SLC T33(b) *This has been graded as a major non-compliance as issues have continued to be identified in this area of practice since 2015; 0100 (September 2015), 0325 (November 2018) and 0188*	report of the findings of this review, including timescales for implementation of corrective actions identified should be provided to the centre's inspector by 18 December 2019. It is expected that the implementation of any corrective actions required are completed by 18 March 2020. Three months after the review the PR should audit practice to ensure any corrective actions taken have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 18 June 2020.	an audit will be conducted, a summary report will be provided by 18 June 2020.	2019, and that any corrective actions required will be implemented by 18 March 2020. The findings of an audit to evaluate the effectiveness of any corrective actions taken in this area of practice due by 18 June 2020 is awaited. **Further action is required.**

(May 2015 and May 2019).			
2. Medicines management The following non-compliances related to the management of controlled drugs were identified during the inspection. • During a procedure observed by the inspection team a box of fentanyl (a Schedule 2 controlled drug) containing several ampoules was stored in an unlocked cupboard in theatre together with other non-controlled drugs. • During a procedure observed by the inspection team, the controlled drugs register was completed by the nurse performing the sedation. The inspector noted that the nurse discarded the unused portion of the controlled drug, but this was not witnessed by the doctor who subsequently signed the register as having witnessed that	The PR should ensure that the centre's practices for the management, use and safe storage of controlled drugs are compliant with regulatory requirements and best practice guidance. The PR should review the centre's practices and procedures relating to the use and safe storage of controlled drugs and investigate why the issues identified by the inspection team have occurred. The PR should also risk assess the suitability of the location of the cupboard where controlled drugs are stored. A summary report of the findings of this review, including timescales for implementation of corrective actions identified should be provided to the centre's inspector by 18 December 2019. Three months after the review the PR should audit practice to ensure any corrective actions taken have been effective in	We will review our practices and procedures relating to the use of controlled drugs. A summary report of this review will be provided by 18 December 2019. We have assessed the suitability of the location of the cupboard where the Controlled Drugs were stored. The cupboard has been moved to a secure area in the theatre complex. Three months after the review an audit will be conducted and a summary report provided by 18 March 2020.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The Executive notes that the centre have relocated the cupboard where controlled drugs are stored to a secure area in the theatre complex. The findings of the review due by 18 December 2019, and of the audit to evaluate the effectiveness of any corrective actions taken in this area of practice due by 18 March 2020 are awaited. **Further action is required.**

discard. The Misuse of Drugs (Safe Custody) Regulations (1973) section 5. Safer Management of Controlled Drugs; A guide to good practice in secondary care (England) (2007) section 4.5.2, 4.5.4 and 4.11.1.3.	achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 18 March 2020.		
3. Prescription of intralipid 'off label' During the inspection three records of patient's consent to treatment with intralipid treatment were reviewed and the following were noted. In one record the patient's signature was missing, in a second the consultant's signature was missing and in the third the patient's details and the staff witnessing signature was missing. The inspection team also noted that in one record the rationale and/or clinical indication for prescribing and treating patients with intralipids were documented as 'patient	The PR should ensure compliance with guidance for the prescription of intralipid 'off label'. The PR should review the centre's processes for the documentation of the rationale for the prescription of intralipids 'off label' and the recording of the consent of the patient for this treatment. A summary report of the findings of this review, including timescales for implementation of corrective actions identified should be provided to the centre's inspector by 18 December 2019. Three months after the review	We will review our process for documenting the rationale for the prescription of intralipids 'off label' and the recording of the consent of the patient for this treatment. A summary report of the findings of this review will be provided by 18 December 2019. Three months after the review we will conduct an audit and a summary report will be provided by 18 March 2020.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The findings of the review due by 18 December 2019, and of the audit to evaluate the effectiveness of any corrective actions taken in this area of practice due by 18 March 2020 are awaited. **Further action is required.**

choice' and nothing was noted in the other two records. Whilst there was a record of the clinician's discussion on the use of intralipids with the patients there was no clear documentation of the rationale for prescribing this 'off label' use of intralipids, and patient choice is not a clinical indication for its use. SLC T2 and Clinic Focus July 2015. *This has been graded as a major non-compliance as issues have continued to be identified in this area of practice since 2015; 0100 (September 2015), 0325 (November 2018) and 0188 (May 2019).*	the PR should audit practice to ensure any corrective actions taken have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 18 March 2020.		
4. CE marking The centre occasionally uses a product to activate sperm prior to ICSI treatment. This product is CE marked as an 'in vitro diagnostic' device but is being used as a medical device which is 'off label' i.e. for a purpose for which it was not	The PR should ensure that patients are provided with comprehensive information regarding the use of a product CE marked as an 'in vitro diagnostic' device being used as a medical device which is 'off label' i.e. for a purpose for which it was not appropriately	We will ensure information relating to the use of this product is provided to patients and their consent to its use will be obtained. Copies of these documents will be provided by 18 December 2019.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that patients will be provided information about the product

appropriately classified. Where a centre is using a product as a medical device for which there is no CE marked alternative available, it is expected that appropriate information is provided to patients regarding the use of a non-CE marked product as a medical device (such as any possible risks associated with the use of this item) prior to use in treatment. SLC T30 and CoP 26.5.	classified. If the PR considers that there is no CE marked medical device available, or no other process using CE marked medical devices can be used to activate sperm for ICSI, then he should ensure that patients are informed that a product not appropriately classified as a CE marked medical device is to be used. The PR should devise relevant patient information and consent forms relating to the use of this product and provide a copy of the documents to the centre's inspector by 18 December 2019.		noted in the report, and their consent to its use will be obtained. Copies of the patient information and consent forms relating to the use of the product due by 18 December 2019 are awaited. **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
5. Infection control The inspection team noted that the flooring of the central corridor from the theatre area does not have any coving up the wall, the sealant was damaged in places and sections between theatre and the recovery area are carpeted Health Building Note 00-09: Infection control in the built environment (2013), sections 3.109, 3.110 and 3.115. CoP 25.19 and 25.20.	The PR should ensure compliance with infection prevention and control regulations. When responding to this report, the PR should provide an action plan with timeframes for implementation to address infection control observations described in this report. It is expected that the implementation of any corrective actions required have been completed by 18 March 2020.	Our premises and processes for Infection Control have been inspected by external agencies (including the HFEA at Interim and Renewal inspections) and are subject to regular internal audit. Where issues have been identified the neccessary corrective actions have been taken. It is surprising that none of these previous inspections have raised the issues highlighted here. These will be addressed as part of our repairs and maintainence schedule for 2020. Given the scale of the requested alterations and the use of solvent based adhesives the timing of the works will have to be considered carefully.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that the issues highlighted by the inspection team will be addressed as part of the centre's 2020 'repairs and maintenance' schedule. The Executive acknowledges the PR's concerns regarding the use of solvent based adhesives within the centre and requests that an update on the proposed timeframes for implementation is provided by 18 March 2020. **Further action is required.**

6. Third party agreements During the inspection, three third party agreements currently in place at the centre were reviewed. These agreements did not include a condition that the third party, satellite or transport centre will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice. One of the agreements with an overseas donor sperm bank included a statement that the donors are compensated '45 euros irrespective of actual loss of expenses' which would not be compliant with HFEA requirements for compensation of overseas donors. SLC T116. General Direction 0001.	The PR should ensure that all agreements with third parties include a condition that the third party, satellite or transport centre will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice. A plan for the completion of this action should be provided to the centre's inspector by 18 December 2019. The PR should investigate why the centre's processes for assessing and auditing third parties did not identify the non-compliance with compensation arrangements noted by the inspection team. A summary of the findings of the investigation including whether any further issues have been identified and corrective actions with timescales for implementation should be provided to the centre's inspector by 18 December 2019.	We will review all third party agreements to ensure the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice are included. A plan for the completion of this will be provided by 18 Dec 2019. An investigation will be completed to determine why the information relating to overseas donor compensation was not identified during the review of the agreements and a summary of the findings will be provided by 18 December 2019. The donor sperm bank was not included on our audit schedule, therefore this could not have been identified during that process. All overseas sperm banks are now included on the audit schedule and compensation information will be reviewed during those audits.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that he will provide a plan for the completion of the centre's review of all third party agreements and a summary of the findings of the investigation by 18 December 2019. The Executive notes that the all overseas sperm banks, including those TCS which the centres in the Bourn Hall group have an ITE, are now on the centre's audit schedule. Reports of those audits will be reviewed at future inspections in the group. **Further action is required.**
7. Adverse incidents	The PR should ensure that all	We will review all adverse	The Executive acknowledges

The centre had not reported one adverse incident relating to the quality and safety of gametes and embryos to the HFEA. SLC T118. *This non-compliance has been graded as 'other' because the inspection team accepts that incident reporting and investigation at the centre is thorough and generally compliant.*	HFEA reportable adverse incidents and near misses are reported to the Authority. The PR should review all adverse incidents in the centre's incident register since the time of the last inspection in 2017 and report retrospectively to the HFEA any which fulfil the criteria of adverse incidents or near misses. This recommendation should be implemented by 18 December 2019.	incidents since the time of the last inspection in 2017 and report any relevant adverse incidents retrospectively by 18 December 2019	the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that he will review all adverse incidents in the centre's incident register since the time of the last inspection in 2017 and report retrospectively to the HFEA any which fulfil the criteria of adverse incidents or near misses by 18 December 2019. **Further action is required.**
8. Confidentiality & privacy The inspection team had some concerns for the confidentiality and privacy of patients when they are in the recovery area. The curtains shared between adjacent bays did not close fully so it is possible to see patients in another bay. In addition, despite the radio being played in the background, the inspection team could clearly hear conversations taking place through the curtains.	The PR should ensure that he provides for the privacy, dignity and respect of all prospective and current patients and donors. The PR should provide an action plan with timeframes for implementation to address the concerns noted during the inspection by 18 December 2019.	Our Family and Friends test score is over 95% positive. Our patient feedback supports our care for their privacy and dignity. As this is a Nurse controlled recovery area it is good practice to have the curtains open whenever possible to enable the monitoring and observation of patients. The issue of inadequate curtaining to each of the bays	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that he will take actions to address the concerns noted during the inspection and provide an action plan with timeframes for completion by 18 December 2019. The Executive notes that a

CoP 25.9 and 25.14.		will be addressed and an action plan for implementation will be provided by 18 December 2019. Where practicable all sensitive communication with patients in recovery are held in a separate room where conversations cannot be overheard. Given the nature of the recovery area general conversation between patients may be overheard.	private room is used wherever practicable to carry out any sensitive discussions with patients. **Further action is required.**
9. Consent to disclosure to researchers One discrepancy was found between completed patient and partner disclosure consents and the related consent data submitted for inclusion on the register in 10 patient files audited. The inspection team noted that the discrepancy was such that could pose a risk that the HFEA may inadvertently release patient identifying information to researchers without the patients consent.	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register. The PR should confirm that the incorrect submissions identified have been corrected when responding to this report. 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	We have corrected the submissions identified. We will review our procedures to ensure the disclosure consent information supplied to the authority accurately reflects that given and recorded on the patients consent form. A summary of the findings will be provided by 18 December 2019. We will carry out an audit of records and provide a summary report by 18 June 2020.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that the incorrect submissions have been corrected and that he will review procedures to ensure that the disclosure consent information supplied to the Authority is accurate. The findings of the review due by 18 December 2019, and an audit to evaluate the effectiveness of any corrective

CH(10)05 and General Direction 0005. *NB. The Centre's designated HFEA form returnee has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected.*	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 18 December 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 18 June 2020.		actions taken in this area of practice due by 18 June 2020 are awaited. **Further action is required.**
10. Record keeping and document control A number of issues in relation to record keeping and document control were noted by the inspection team as detailed in the body of the report. SLC T46(e), SLC T46(f), SLC T46(c) and SLC T34.	The PR should ensure that proper records are maintained and that only current versions of documents are in use. The PR should review the issues noted in this report relating to record keeping and document control with a view to considering why these have arisen. A summary report of the findings of this review, including timescales for	We will review the issues noted in this report relating to record keeping and document control and provide a summary report by 18 December 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 issues noted in this report relating to record keeping and document control and provide a summary of the findings of this review by 18 December 2019.

	implementation of corrective actions identified should be provided to the centre's inspector by 18 December 2019.		**Further action is required.**
11. Fees Fees payable to the HFEA have not always been paid within the required timeframe. SLC T9d and CH (10)02). *This is noted as an issue across all centres in the group.*	The PR should ensure fees payable to the HFEA are made within the required timeframe. 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 18 December 2019.	The PR has secured agreement with the Bourn Hall finance department that future HFEA invoices are prioritised.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that future HFEA invoices are prioritised. This will be monitored by the centre's inspector and reviewed at the time of the next inspection of a centre in the group in late 2019/early 2020. **No further action is required.**

Responses from the Person Responsible to this inspection report
The Bourn Hall team would like to thank the Inspector and her colleagues for the open and thorough approach taken to the inspection. As a group we are commited to contiuous improvement and the recognition of this was much appreciated.