# Licence Committee - minutes

## Centre 0363 (Bourn Hall Clinic (Wickford)
## Interim Inspection

Thursday, 11 July 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

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| Committee members | Kate Brian (Chair)<br>Anita Bharucha (Deputy Chair)<br>Ruth Wilde<br>Gudrun Moore<br>Jonathan Herring | |
| Members of the Executive | Dee Knoyle | Committee Secretary |
| Legal Adviser | Eve Piffaretti | Blake Morgan LLP |
| Specialist Adviser | | |
| Observers | Alistair Robertson | Solicitor (Induction) |

## Declarations of interest:

- Members of the committee declared that they had no conflicts of interest in relation to this item.

## The committee had before it:

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

## The following papers were considered by the committee:

Papers enclosed:

- Letter from the Person Responsible dated 5 July 2019
- Interim Inspection Report
- Previous licensing minutes for the last three years:
    - Executive Licensing Panel (ELP) Minutes - July 2018 – Initial Inspection Report

## 1. Background

**1.1.** Bourn Hall Clinic (Wickford), centre 0363 is located in Essex. The centre has held a licence with the HFEA since July 2018 and provides a full range of fertility services.

### Current Licence

**1.2.** The centre's current licence was issued for a period of 2 years. An initial treatment licence would normally be offered for up to two years as there would be no history of compliance to support a longer licence. Newly licensed centres are subject to an unannounced interim inspection after one year, to assess whether they are operating in a compliant manner.

**1.3.** The centre's current licence is due to expire on 29 July 2020.

### Bourn Hall Group

**1.4.** Bourn Hall Clinic (Wickford) is part of a group of HFEA licensed centres including:

- Bourn Hall Clinic, centre 0100
- Bourn Hall Clinic (Colchester), centre 0188
- Bourn Hall Clinic Norwich, centre 0325
- Bourn Hall Clinic (Wickford), centre 0363

**1.5.** All centres are centrally managed and have common practices and procedures, in particular the Quality Management System (QMS).

**1.6.** 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 centre and maximises regulatory effectiveness. In return, where HFEA finds non-compliances in those shared elements it expects to see the centres within the group respond as a whole, taking all necessary action at each centre.

### Compliance with recommendations made at the initial inspection

**1.7.** The committee noted that at the time of the initial inspection of centre 0363, in May 2018, there were some recommendations for improvement to address two major non-compliances relating to infection control and air quality and equipment validation and one 'other' non-compliance relating to the Quality Management System (QMS). The PR had implemented these recommendations prior to the granting of the new licence.

### Unannounced Interim Inspection May 2019

**1.8.** On 8 and 9 May 2019, shortly before the interim inspection of centre 0363 on 14 May 2019, the Executive conducted a renewal inspection of centre 0188 and similar findings were identified. Both centres share the same Person Responsible. The Executive requested that the reports of both inspections are considered by the Licence Committee, rather than the Executive Licensing Panel.

## 2. Consideration of application

### Interim Inspection

**2.1.** The committee noted that an unannounced interim inspection was conducted at centre 0363 on 14 May 2019. The inspection report covers the findings from this inspection, together with an assessment of the centre's performance based on information received, including the centre's self-assessment of its service and progress made implementing the recommendations identified at the initial inspection.

**2.2.** The inspection covered:

- Quality of care
- Patient safety
- Patient experience

**2.3.** The committee noted that in the 12 months to 31 March 2019, the centre provided 85 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

**2.4.** The committee noted that HFEA-held register data for the year ending 28 February 2019 showed the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

**2.5.** For the year 2018 the centre reported one cycle of partner insemination with no clinical pregnancy. This represents a clinical pregnancy rate which is comparable to the national average.

**2.6.** The committee noted that HFEA-held register data for the year ending 28 February 2019 showed the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 11%. This represents performance that is not likely to be significantly different to the 10% maximum multiple live birth rate target for this period.

### Quality Management System (QMS)

**2.7.** Centre 0363 has held a HFEA licence since July 2018, therefore it is not expected that all audits of critical activity would have been undertaken. The inspectorate was pleased to find that the centre had completed an audit of records in April 2019, which included a review of several areas of practice such as:

- provision of information
- offer of counselling
- consent
- welfare of the child assessments
- consent to storage of gametes and embryos
- confidentiality
- witnessing
- traceability.

**2.8.** The inspectorate was informed that relevant staff were still reviewing the findings and considering what corrective actions were necessary as well as timescales for implementation.

**Major areas of Non-Compliance:**

### Consent

**2.9.** The inspectorate reviewed the initial findings of the centre's audit of records and discussed those related to inaccuracies or errors in consent forms with the PR and Head of Quality Assurance for the Bourn Hall group during the inspection. From these discussions the inspection team concluded that the centre's procedures for auditing and checking consent were considered to be partially compliant for the reasons outlined in the interim inspection report.

**2.10.** The inspectorate had concerns that these errors had not been identified by the centre prior to provision of treatment. Also, the amendment noted by the inspectorate had not been noted by the auditors.

**2.11.** The committee noted that monthly audits will start from July 2019, reviewing previous months consents to assess if the immediate corrective actions have been effective. These audits will continue until the PR and inspectorate are satisfied that the centre's process for consenting is robust and compliant with requirements.

**2.12.** A root cause analysis will be carried out to ascertain the cause of the anomalies identified at the inspection of centre 0188. Corrective actions will be communicated and implemented at centre 0363. A copy of the root cause analysis report will be forwarded to the inspectorate by 14 August 2019.

Legal Parenthood

**2.13.** The committee noted that 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.

**2.14.** The Executive was particularly concerned with consent to legal parenthood given the Bourn Hall group's history of failure in this area. Centre 0363 has only been active since July 2018, therefore an audit of consent to legal parenthood has not yet been undertaken and is planned for July 2019. The centre's proposed legal parenthood consenting practices were considered compliant at the time of licensing.

**2.15.** To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspectorate reviewed several records where treatment with donor sperm or embryos created with donor sperm had taken place. The findings of anomalies and near miss were outlined in the inspection report.

**2.16.** The committee noted that anomalies in consent to legal parenthood were also identified at centre 0188 in the renewal inspection carried out on 8 and 9 May 2019. As a result of those findings the Executive held a management review meeting on 23 May 2019 in accordance with the HFEA's Compliance and Enforcement Policy. The Executive found that the issues identified on inspection were significant, and posed direct and indirect risks to patients, and concluded that the centre was not able to demonstrate compliance with the Human Fertilisation and Embryology Act 1990 (as amended) and other relevant legal requirements in a number of areas of practice.

**2.17.** In view of these concerns the Executive recommended that the PR should voluntarily suspend the provision of treatments with donor sperm and surrogacy at centre 0188 until such time that it was satisfied that the centre's processes in this area of practice are robust. As the PR of centre 0188 is also PR of centre 0363, and the two centres' processes are closely linked, the PR agreed to implement the recommended suspension at both centres 0188 and 0363.

### Executive update

**2.18.** The Executive provided an update on the findings of the audits of records at centre 0188 and 0363.

**2.19.** The Executive reported that the audit for centre 0363 included all patients who had had a live birth, ongoing pregnancy or unknown outcome following treatment between 1 August 2018 (when the centre commenced licensed activity) and 30 April 2019.

**2.20.** No issues or anomalies in consent to legal parenthood were identified in the records of six patients who had undergone 11 cycles of treatment in that time.

### Medicines Management

**2.21.** During the inspection, the centre's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance with the following exception:

- The keys for the cupboard where controlled drugs are stored are kept in a digitally locked safe accessible by all staff, contrary to the centre's SOP which states that 'Only senior designated nurses may hold the keys to the CD cabinets'.

**2.22.** The committee noted that access to these keys should be restricted to designated senior staff only. The PR has provided a summary of the immediate actions taken to address the issue. The Executive is assured that the PR will ensure that the new key safe will be installed at centres 0188 and 0363.

**2.23.** The Executive acknowledged the PR's response and her commitment to fully implementing the recommendation, which will be reviewed at the time of the next inspections of these centres.

### CE marked medical devices

**2.24.** The committee noted that CE mark status of some medical devices was reviewed in the course of the inspection including culture medium, vitrification and warming medium, culture dishes and plastic ware. The centre uses a culture dish for the process of vitrification and warming of embryos which is CE marked as an 'in vitro diagnostic' device, rather than a medical device. This classification means the product is suitable for diagnostic use only. However, the product is being used 'off label' i.e. for a purpose for which it was not classified. The centre has not completed a robust risk assessment and has not provided appropriate information to the patient 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.

**2.25.** The PR provided the Executive with a copy of the group's validation of the culture dish used for vitrification which was completed in May 2017. The Executive noted that the validation concluded that the product is 'approved for use with human 'gametes', however, the product is also being used for 'embryos'. The Executive considers that it is likely that this is a typographical error as the document refers to gametes and embryos and will seek confirmation of this from the PR. The Executive awaits a copy of information provided to patients regarding the use of this product as a medical device (such as any possible risks associated with the use of this item) by 14 August 2019.

**Other areas of Non-Compliance:**

Equipment

**2.26.** The PR has provided a copy of the root cause analysis into the processes for checking the centre's two resuscitation trolleys. The centre noted that staff misunderstood the use of the two checklists and further training is to be carried out by 31 July 2019. An audit to evaluate the effectiveness of changes in this area of practice is due by 14 August 2019. The Executive acknowledges the PR's response and her commitment to fully implementing this recommendation.

Premises

**2.27.** The committee noted that the centre's root cause analysis identified that there was a training issue and the PR confirmed that all cylinders are safely stored.

HFEA Guidance

**2.28.** The committee noted that if a centre is to achieve continuous improvement and encourage a learning culture, then it is important that they act to review their practices when guidance is issued by the HFEA and other bodies. The inspectorate reviewed the centre's procedures for acting on HFEA guidance in detail during the renewal inspection of centre 0188 the previous week and concluded that the Bourn Hall group is partially effective in implementing guidance and learning from its audits. The PR at centre 0188 has committed to implementing the recommendations across the two centres.

### Recommendation

**2.29.** The committee noted that the Executive is reassured that no further issues have been identified in the centres' audits of consent to legal parenthood records. The committee also noted that the Executive's recommendation to suspend new treatments involving donor sperm, or embryos created with donor sperm, and surrogacy at centres 0188 and 0363 remains.

**2.30.** Once the PR is able to provide satisfactory evidence that staff training, and competency assessments have been completed, the Executive will be able to consider recommending that the provision of new treatments with donor sperm, embryos created with donor sperm and surrogacy can resume.

**2.31.** Once treatments resume, the Executive will require the PR to provide monthly audits of consent to legal parenthood to provide further assurance that the centre's procedures for obtaining and checking consent to legal parenthood are robust.

## 3. Decision

**3.1.** The committee had regard to its decision tree and the HFEA Compliance and Enforcement Policy.

**3.2.** The committee considered the Executive update, interim inspection report and letter from the PR dated 5 July 2019.

**3.3.** The committee deliberated on the non-compliances at the centre, in particular the centre's procedures for obtaining effective consent to legal parenthood.

**3.4.** The committee noted that the Executive is reassured that no further issues have been identified in the centres' audits of consent to legal parenthood records and this area is being closely monitored by the centre and the Executive.

**3.5.** The committee agreed to the continuation of the centre's licence.

## 4. Chair's signature

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

**Signature**

**Name**

Kate Brian

**Date**

31 July 2019

# Interim Licensing Report

**Centre name:** Bourn Hall Clinic (Wickford)
**Centre number:** 0363
**Date licence issued:** 30 July 2018
**Licence expiry date:** 29 July 2020
**Additional conditions applied to this licence:** None
**Date of inspection:** 14 May 2019
**Inspectors:** Karen Conyers (lead) and Katie Best
**Date of Licence Committee:** 11 July 2019

## Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Newly licensed centres usually receive a licence to operate for two years and are subject to an unannounced interim inspection after one year, to assess whether they are operating in a compliant manner. If the licence is renewed, it can be awarded for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLCs).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Licence Committee with information on which to make a decision about the continuation of the licence.

## Summary for Licence Committee

The inspection team recommends the continuation of the centre's licence.

On 8 and 9 May 2019, shortly before the inspection reported on here, the executive conducted a renewal inspection of centre 0188. As these centres are within the same corporate group, and similar findings were identified in both inspections, the executive requests that the reports of both inspections are considered by the same licensing committee hence this report is being presented to Licence Committee with the report for centre 0188, rather than to the Executive Licensing Panel as is usual.

The Licence Committee is asked to note that this report makes recommendations for improvement in relation to three major and two '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:

- The PR should ensure that the centre's processes for obtaining and checking consent are robust.
- The PR should ensure that the access to controlled drugs is restricted to designated staff members only.
- The PR should ensure that CE marked medical devices are used where possible.

'Other' areas of practice that require improvement:

- The PR should ensure that the contents of the centre's resuscitation trolleys are checked in accordance with their protocols.
- The PR should ensure that all medical gases are kept secure at all times.

## Information about the centre

Bourn Hall Clinic (Wickford) has held a licence with the HFEA since 30 July 2018. The centre provides a full range of fertility services. Other licensed activities of the centre include storage of gametes and embryos.

The centre provided 85 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 March 2019. In relation to activity levels this is a very small centre**.**

Bourn Hall Clinic (Wickford) is part of a group that incorporates three other HFEA licensed centres (centre 0100 Bourn Hall Clinic, centre 0188 Bourn Hall Clinic (Colchester), centre 0325 Bourn Hall Clinic Norwich). All clinics are centrally managed and have common practices and procedures, in particular their quality management system (QMS).

## Details of Inspection findings

## Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

### Pregnancy outcomes[1]

HFEA held register data for the year ending 28 February 2019 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2018 the centre reported one cycle of partner insemination with no clinical pregnancy. 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 28 February 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target.

### Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. During the inspection, the inspection team was able to observe laboratory staff undertaking the thawing of an embryo which was witnessed in accordance with HFEA requirements using an electronic and manual witnessing systems.

[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%.

## Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, a review of records of stored gametes and embryos, and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

## Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

## Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The Bourn Hall group's procedures for auditing and acting on the findings of audits have been reviewed at the previous inspection of centre 0325 in November 2018. At that time the HFEA executive recommended that the group should ensure that audits are not overly complex such that significant findings can get lost in the volume of information collected, and that if any significant issues are identified this triggers immediate actions to address the findings, to consider the potential impact on the patients involved and to prevent recurrence of such issues. Following that inspection, the group had implemented a 'quality control' check of records to ensure there are no anomalies or errors in consent forms and welfare of the child assessments for patients in treatment.

The effectiveness of learning from the findings of inspection at centre 0325 was reviewed during the inspection of centre 0188 on 8 and 9 May 2019, the week before this inspection. The findings of that inspection are discussed in detail in the inspection report but in summary, further concerns in relation to the Bourn Hall group's QMS were noted. In addition, the inspection team was not assured that that centre's processes for obtaining and checking consent were robust.

This centre (0363) has been active for 10 months, therefore it is not expected that all audits of critical activity would have been undertaken. The inspection team was pleased to find that the centre had recently completed an audit of records which included a review of several areas of practice such as; provision of information, offer of counselling, consent, welfare of the child assessments, consent to storage of gametes and embryos,

confidentiality, witnessing and traceability. This audit had only been completed in April 2019 and the inspection team was informed that relevant staff were still reviewing the findings and considering what corrective actions were necessary as well as timescales for implementation.

The inspection team reviewed these initial findings of the centre's audit of records and discussed those related to inaccuracies or errors in consent forms with the PR and Head of Quality Assurance for the Bourn Hall group during the inspection. From these discussions the inspection team concluded that the centre's procedures for auditing and checking consent were considered to be partially compliant for the following reason.

- The centre's audit noted that in one case there was no entry for the number of years of storage for embryos in the MT ('*Men's consent to treatment and storage form (IVF and ICSI)*') form. The inspection team noted that this couple did not have any embryos in storage following their recent treatment. As the findings of the audit are still being reviewed it is expected that the centre will investigate why this error in the form had not been captured by the centre's processes prior to treatment.

  On reviewing these patients records further, the inspection team also noted an error in a corresponding WT ('Wom*en's consent to treatment and storage form (IVF and ICSI)*') form where an amendment had not been initialled by the patient. This had not been noted in the centre's audit. The inspection team was concerned that these errors had not been identified by the centre prior to provision of treatment and one error had not been noted by the auditors (see recommendation 1). Similar findings were made during the renewal inspections of centres 0325 (November 2018) and 0188 (May 2019) and are discussed in detail in those reports.

  Other findings noted in the centre's audit included a missing passport number and entry of year of birth instead of year of signing on a welfare of the child assessment form. The PR explained that the centre has just started using an electronic consenting process where these types of errors or omissions would be flagged, and the form would not be able to be completed so that such errors would not occur in future.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture, then it is important that they act to review their practices when guidance is issued by the HFEA and other bodies.

The clinic's procedures for acting on guidance from the HFEA had been reviewed in detail during the renewal inspection of centre 0188 the previous week. The following guidance was discussed, and the inspection team concluded that the Bourn Hall group is partially effective in implementing guidance from the HFEA and learning from their audits. This is discussed in detail in the renewal inspection report for centre 0188 and is not discussed further in this report. The PR at centre 0188 is the same as the PR at this centre and she has committed to implementing the HFEA executive's recommendations across the two clinics.

- leadership
- patient support
- information provision
- implications of treatment and consent

- counselling
- extension of storage consent
- consent
- surrogacy
- screening
- egg sharing
- data protection and confidentiality
- imports of gametes and embryos from outside the EU/EEA
- the use of the Single European Code
- data submission to the HFEA
- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood

### Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance with the following exception:

- The keys for the cupboard where controlled drugs are stored are kept in a digitally locked safe accessible by all staff. Access to these keys should be restricted to designated senior staff only (see recommendation 2).
  Furthermore, the inspection team noted that the centre's standard operating procedure (SOP) states that '*The keys to the CD cabinet are to be stored in a key safe when not in use. Only senior designated nurses may hold the keys to the CD cabinets. Key safes are best to have a combination lock entry. The combination should only be issued to senior members of staff and must be regularly changed to prevent it being compromised.*'

### 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 compliant with guidance.

### Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be compliant with guidance.

### Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed in the course of the inspection: culture medium, vitrification and warming medium, culture dishes, plastic ware. The centre uses a culture dish for the process of vitrification and warming of embryos which is CE marked as an 'in vitro diagnostic' device, rather than a medical device. This classification means the product is suitable for diagnostic use only. Whilst the inspection team recognises that the product is designed to be used for this specific purpose, it is being used 'off label' i.e. for a purpose for which it was not appropriately classified. The centre has not completed a robust risk assessment and has not provided appropriate information to the patient 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 3).

## Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only one patient has provided feedback in the last 12 months, giving a 5-star rating to the clinic. This suggests that the clinic does not actively seek patient's feedback to the HFEA for comparison purposes. This concern has been noted and discussed during the previous inspection of centres 0188 and 0363. The inspection team was informed that the group has now obtained electronic tablets for patients to use in the clinic so that they can encourage them to provide feedback directly to the HFEA's 'Choose a Fertility Clinic' page whilst in the clinic.

The Bourn Hall group's most recent surveys of patient feedback for both centres in Essex (centre 0363 and 0188) for 2018 recorded 26 responses of which 16 included positive

comments, and 10 noted areas for improvement. This feedback was discussed at the group's annual management review meeting held in March 2019 and actions have been taken to address the issues identified.

During the inspection the inspectors spoke to one couple who also provided positive feedback on their experiences at the centre.

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

- treats patients with privacy and dignity;
- 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.

## Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

### Compliance with HFEA standard licence conditions

The following issues were noted after review of information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre.

- Centre staff undertake a weekly check of the entire contents of the centre's two 'resuscitation' trolleys and there is a sheet indicating that a daily check of the top tray of each trolley is carried out. The inspection team noted that the records on the trolleys indicate that they had been checked weekly, but the daily check of the top tray had not been carried out (see recommendation 4). This was the same for both trolleys.
- At the time of the inspection it was noted that some gas cylinders (oxygen and 'Entonox') in the medical gas storage area on the ground floor were not secured to the wall with chains, although the chains are available (see recommendation 5). There is a risk that these cylinders may fall over and hurt staff.

### Compliance with recommendations made at the time of the last inspection

Following the initial licence inspection in 2018 recommendations for improvement were made in relation to two major and one 'other' area of non-compliance or poor practice.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented prior to the granting of the new licence.

### On-going monitoring of centre success rates

Since the initial inspection in May 2018 the centre has not received any performance related risk tool alerts.

## Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register. The clinic is compliant with requirements to submit information to the HFEA and there are currently no significant data submission issues.

## Legal parenthood

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.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. Although part of the Bourn Hall group, this centre has only been active since July 2018, therefore an audit of consent to legal parenthood has not yet been undertaken and is planned for July 2019. The centre's proposed legal parenthood consenting practices were considered compliant at the time of licensing.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team reviewed several records where treatment with donor sperm or embryos created with donor sperm had taken place. A number of these patients were single women therefore consent to legal parenthood was not relevant. Two sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were reviewed and no issues were noted.

In another set of records reviewed it was not clear what the patient's relationship status was, as the database recorded the patient as single, but she had a partner and the couple had different surnames. The recording of marital status was also noted as a concern at the time of the renewal inspection at centre 0188. The couple had completed consent to legal parenthood forms prior to their recent treatment. The inspection team noted that the patient had made an error in the name of her partner in the WP ('*Your consent to your partner being the legal parent*') form and had crossed this out, but the amendment had not been initialed or signed by the patient. This couple's recent treatment cycle was negative; therefore, this is considered a near-miss. The inspection team was concerned that this error in the form had not been identified by the centre before treatment (see recommendation 1).

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. However there remain concerns why the error in the form was not identified by the centre before treatment, and why marital status was not accurately recorded.

Anomalies in consent to legal parenthood were identified at centre 0188 in the renewal inspection carried out on 8 and 9 May 2019. As a result of those findings the executive held

a management review meeting on 23 May 2019 in accordance with the HFEA's Compliance and Enforcement Policy. The management review meeting found that the issues identified on inspection were significant, and posed direct and indirect risks to patients, and concluded that the centre was not able to demonstrate compliance with the Human Fertilisation and Embryology Act 1990 (as amended) and other relevant legal requirements in a number of areas of practice. Of particular concern were the findings in relation to consent to legal parenthood.

In view of these concerns, on 23 May 2019 the executive informed that PR that it recommended that she voluntarily suspended the provision of treatments with donor sperm and surrogacy at centre 0188 until such time that it was satisfied that the centre's processes in this area of practice are robust. As the PR of centre 0188 is also PR of centre 0363, and the two centres' processes are closely linked, the PR agreed to implement the recommended suspension at both centres (0188 and 0363). The PR also attended a meeting with the HFEA executive on 10 June 2019 to discuss its concerns. This is discussed in detail in the renewal inspection report for centre 0188 and is not discussed further in this report.

**Annex 1**

# Areas of practice that require the attention of the Person Responsible

The section sets out matters which the inspection team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be made.

## Critical areas 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 child who may be born as a result of treatment services. A critical 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 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;
- which can comprise 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 |
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| **1. Consent**<br>The following issues were noted by the inspection team during an audit of records and a review of the centre’s audit.<br>• The centre’s audit noted that in one case there was no entry for the number of years of storage for embryos in the MT (‘*Men’s consent to treatment and storage form (IVF and ICSI)*’) form.<br>• In the corresponding WT (‘Wom*en’s consent to treatment and storage form (IVF and* | The PR should ensure that the centre’s processes for obtaining and checking consent are robust.<br><br>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.<br><br>The PR should undertake monthly audits of records to determine if those immediate actions have been effective in ensuring compliance. A | Attached is a copy of completed and proposed actions to ensure the processes for providing and recording consent are robust for the Bourn Hall group<br><br>Monthly audits will commence from July 19 reviewing the previous months consents to assess if the immediate corrective actions have been | The executive acknowledges the PR’s response and her commitment to fully implementing this recommendation.<br><br>The PR has provided a summary of the immediate actions taken across the group to address the issued identified during the inspection.<br><br>The PR has implemented a suspension of new treatments involving donor sperm, or embryos created with donor sperm, and surrogacy at centre 0363 as a result of findings at |

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| *ICSI)*') form the woman had made an amendment but this had not been initialled by the patient. This had not been noted in the centre's audit.<br>• In one set of records where consent to legal parenthood was required it was not clear what the patient's relationship status was, as the database recorded the patient as single, but she had a partner and the couple had different surnames. The inspection team noted that the patient had made an error in the name of her partner in the WP ('*Your consent to your partner being the legal parent*') form and had crossed this out, but the amendment had not been initialed or signed by the patient. This couple's recent treatment cycle was negative; therefore, this | 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.<br><br>Following the inspection of centre 0188, the PR has been asked to conduct a root cause analysis into the circumstances which led to the failure of that centre's processes to identify the anomalies found by the inspection team. In view of similar findings at this centre, it is expected that the PR will review the outcome of that root cause analysis and implement any corrective actions identified to centre 0363 as well. A copy of the root cause analysis undertaken by the PR should be provided to the centre's inspector by 14 August 2019.<br><br>On receipt of the information the HFEA executive will liaise with the PR to determine what further actions and/or recommendations are required. | effective. A copy of the report will be forwarded to the centre's inspector by 31st July 2019.<br><br>Monthly audits will continue until the PR and centre's inspector are satisfied that the centre's process for consenting is robust and compliant with requirements.<br><br>A root cause analysis will be carried out to acsertain the cause/s of the anomalies identified at centres 0188 inspection, corrective actions will be communicated and implemented at centre 0363..<br><br>A copy of the root cause analysis report will be forwarded to the centre's inspector by 14 August 19 | sister clinic 0188 where she is also PR. Once the executive is satisfied that the procedures for obtaining and checking consent to legal parenthood at both centres are robust, it will be able to recommend that the provision of new treatments with donor sperm, embryos created with donor sperm or surrogacy can resume.<br><br>The PR presented a summary of the findings of her review of the group's processes for taking consent during the meeting with the HFEA executive on 10 June 2019. Several corrective actions had been identified, and some had already been implemented.<br><br>The PR has confirmed that she will provide a copy of the monthly audit of records of consent by 31 July 2019, and that these will continue until such time the executive and PR are satisfied that processes are robust and compliant with regulatory requirements.<br><br>The PR will provide a copy of |

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| is considered a near-miss.<br><br>The inspection team was concerned why these errors had not been identified by the centre prior to provision of treatment and why the amendment noted by the inspection team had not been noted by the auditors.<br><br>Schedule 3 Human Fertilisation & Embryology Act 1990 (as amended).<br><br>SLC T57 and SLC T36. | | | the root cause analysis by 14 August 2019.<br><br>**Further action is required.** |
| **2. Controlled drugs**<br>The keys for the controlled drugs cupboard are kept in a digitally locked safe accessible by all staff, however access to these keys should be restricted to designated senior staff only. This is not in accordance with the centre's SOP.<br><br>SLC T2. | The PR should ensure that the access to controlled drugs is restricted to designated staff members only.<br><br>When responding to the report, the PR should provide an update on immediate actions that have been taken to address this issue identified by the inspection team. | A separate coded key safe for the drug keys is to be installed at both centre's 0363 and 0188.<br><br>The code to access the key safe to be provide to designated senior staff only. | The executive acknowledges the PR's response and her commitment to fully implementing this recommendation.<br><br>The PR has provided a summary of the immediate actions taken to address the issue identified during the inspection.<br><br>The executive is assured that the PR will ensure that the new key safe will be installed at |

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| | | This requirement and required corrective action has been communicated to other clinics within the group to ensure that all clinics are compliant . | centres 0188 and 0363. This will be reviewed at the time of the next inspections of these centres.<br><br>**No further action is required.** |
| **3. CE marking**<br>The centre uses a culture dish for the process of vitrification and warming of embryos which is CE marked as an 'in vitro diagnostic' device, rather than a medical device. This classification means the product is suitable for diagnostic use only. Whilst the inspection team recognises that the product is designed to be used for this specific purpose, it is being used 'off label' i.e. for a purpose for which it was not appropriately classified.<br><br>The centre has not completed a robust risk assessment and has not provided appropriate information to the patient regarding the use of a non-CE marked product as a medical device (such as any possible risks associated with the use | The PR should ensure that CE marked medical devices are used where possible.<br><br>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 for vitrification and warming of embryos, then she should ensure that a robust risk assessment and validation has been undertaken prior to use of this product, and that patients are informed that a product that is not appropriately classified as a CE marked medical device is to be used. A copy of the risk assessment and validation for the use of this product in treatment, and patient information, should be provided to the centre's inspector by 14 August 2019. | A risk assessment and validation of the product has been carried out by Bourn Hall's Director of Science .<br><br>The validation report is attached. | The executive acknowledges the PR's response and her commitment to fully implementing this recommendation.<br><br>The PR has provided a copy of the group's validation of the culture dish used for vitrification. The executive notes that this was completed in May 2017 but was not provided to the centre's inspector until now. The executive notes that the validation concluded that the product is 'approved for use with human gametes'. However, the product is also being used for embryos. The executive considers that it is likely that this is a typographical error as the document refers to gametes and embryos and will seek confirmation of this from the |

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| of this item) prior to use in treatment.<br><br>SLC T30, SLC T24, SLC T28, SLC T72 and CoP 26.5. | | | PR.<br><br>The executive awaits a copy of information provided to patients regarding the use of this product as a medical device (such as any possible risks associated with the use of this item) by 14 August 2019.<br><br>**Further action is required.** |

## ‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non-compliance, but which indicate 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 |
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| **4. Equipment**<br>Centre staff undertake a weekly check of the entire contents of the centre’s two ‘resuscitation’ trolleys and there is a sheet indicating that a daily check of the top tray of each trolley is carried out. The inspection team noted that the records on the trolleys indicate that they had been checked weekly, but the daily check of the top tray had not been carried out. This was the same for both trolleys.<br><br>SLC T2. | The PR should ensure that the contents of the centre’s resuscitation trolleys are checked in accordance with their protocols.<br><br>The PR should review the processes for checking the centre’s two ‘resuscitation’ trolleys and take action to ensure that the checks are carried out in accordance with their protocols. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre’s inspector with the PR’s response to this report.<br><br>Within three months of the | A review of the centre's processes for checking and recording the daily check of the centre's two rescusitation trolley's has been conducted. Attached is a root cause analysis including corrective actions and timelines.<br><br>An audit of the process will be conducted to ensure the | The executive acknowledges the PR’s response and her commitment to fully implementing this recommendation.<br><br>The PR has provided a copy of the root cause analysis into the processes for checking the centre’s two resuscitation trolleys. The centre noted that staff misunderstood the use of the two checklists and further training is to be carried out by 31 July 2019.<br><br>An audit to evaluate the effectiveness of changes in this area of practice due by 14 August 2019 is awaited.<br><br>**Further action is required.** |

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| | review, the centre should carry out an audit of this area of practice 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 14 August 2019. | corrective actions put in place are adhrered to and effective.<br><br>A copy of the report will be forwarded to the centre's inspector 3 months after the review by 14th September 2019 | |
| **5. Premises**<br>At the time of the inspection it was noted that some gas cylinders (oxygen and 'Entonox') in the medical gas storage area on the ground floor were not secured to the wall with chains.<br><br>SLC T17 and Health Technical Memorandum 02-01: Medical gas pipeline systems Part B: Operational management. | The PR should ensure that all medical gases are kept secure at all times.<br><br>When responding to the report, the PR should provide an update on immediate actions that have been taken to address this issue identified by the inspection team.<br><br>The PR should undertake a review to identify the factors that have led to this non-compliance. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector when responding to this report. | A review of the causes leading to the non compliance has been conducted.<br>Attached is a root cause analysis including corrective actions and timelines. | The executive acknowledges the PR's response and her commitment to fully implementing this recommendation.<br><br>The PR has confirmed that all cylinders are now safely stored.<br><br>The PR has provided a copy of the root cause analysis into this non-compliance and identified that it was due to a 'training issue'. Further training is to be carried out by 31 July 2019.<br><br>**No further action is required.** |

| Additional information from the Person Responsible |
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| We have implemented e-consenting at centres 0188 and 0363 from March 2019. This system will address many of the issues around legal parenthood and consenting . The platform is planned to be rolled out to all clinics within the group by Q3<br><br>We have implemented a re-education programme for consenting and legal parenthood consenting.<br><br>We have introduced a re-education programme on QC for relevant staff and seconded a nurse to the roll of QC officer. |