Executive Licensing Panel - minutes

Centre 0363 (Bourn Hall Clinic (Wickford)

Renewal Inspection Report

Tuesday, 21 April 2020

HFEA Teleconference Meeting

Panel members	Richard Sydee (Chair) Kathleen Sarsfield Watson Niamh Marren	Director of Finance and Resources Communications Manager Regulatory Policy 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 three years.

1.2. The panel noted that Bourn Hall Clinic Wickford has been licensed by the HFEA since July 2018, for the standard period of two years for new licences. The centre provides a full range of fertility services. Other licensed activities of the centre include storage of gametes and embryos.

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

1.4. The panel noted that the centre was last inspected in May 2019, shortly after the inspection of sister clinic, centre 0188, during which a number of anomalies in consent to legal parenthood were identified. This is discussed in detail in the renewal inspection report for centre 0188. As a result, the executive held a management review meeting, 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. In view of these concerns the Person Responsible (PR) of centres 0188 and 0363 agreed to a voluntary cessation of the provision of treatments with donor sperm and embryos created with donor sperm, including surrogacy, at both centres. The voluntary cessation of these treatments was lifted in August 2019.

1.5. The panel noted that the HFEA has undertaken licence renewal inspections of all four centres within the Bourn Hall group over the last 15 months; centre 0325 in November 2018, centre 0188 in May 2019 and centre 0100 in September 2019. In addition, a targeted interim inspection was conducted at centre 0325 in January 2020. Progress with implementing recommended actions following those inspections has been reviewed at each subsequent inspection of a centre in the group. The report of the interim inspection of centre 0325 and an update on progress with implementing recommendations following the renewal inspection of centre 0100 in September 2019 would also be considered at this meeting.

1.6. The panel noted that, in the 12 months to 31 January 2020, the centre provided 136 cycles of treatment (excluding partner intrauterine inseminations). In relation to activity this a small sized centre.

1.7. The panel noted that, HFEA held register data, for the year ending 30 November 2019 show the centre's success rates are in line with national averages.

1.8. The panel noted that, in 2019, the centre reported 3 cycles of partner insemination, with no clinical pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.9. The panel noted that, HFEA register data, for the year ending 30 November 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%. This represents performance that is not likely to be statistically different to the 10% multiple live birth rate target.

1.10. An inspection was carried out at the centre on the 25 and 26 February 2020.

1.11. The panel noted that at the time of the inspection, there were two major areas of non-compliance concerning the QMS and obligations and reporting requirements. There were also nine 'other' non-compliances relating to donor screening, safety and suitability of premises, medicines management, equipment, patient feedback, confidentiality and privacy, consent to disclosure to researchers, screening of patients and record keeping. Since the inspection, the PR has given a

commitment to fully implement all of the recommendations made in the report and to provide further information or audits of practice where applicable.

1.12. The executive noted that, since the time of the recent inspections of the 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, noting that the changes made are well embedded in the centre's practices.

1.13. The panel noted that the executive remains concerned that the group's QMS is not used to its best effect to monitor and improve the service provided, as set out in the body of the report. The PRs of the Bourn Hall group centres should ensure that effective actions are taken to address this failing which continues to be noted during inspections across all centres in the group.

1.14. The panel noted that the centre is reasonably well led and provides a good level of patient support.

1.15. The panel noted that, in March 2020, the PRs of the Bourn Hall group centres suspended fertility treatments across all their clinics in accordance with HFEA requirements and professional body guidance issued in response to the Covid-19 pandemic. In view of this, the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing all of this report's recommendations, taking into account the period of time where treatments are suspended as a result of the Covid-19 pandemic.

1.16. The panel noted that the inspection team recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented in a timely manner.

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. 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.

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 her duty under section 17 of the HFE Act 1990 (as amended).

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

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's ITE 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

29 April 2020

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 25 and 26 February 2020.

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

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

Inspectors: Karen Conyers (lead), Polly Todd, Mhairi West, Chris Hall, Zakia Ezzouyar, Victoria Brown (HFEA observer), Bernadette O'Leary (HFEA observer) and Sabah Iqbal (National Audit Office observer).

Date of Executive Licensing Panel: 21 April 2020.

Centre name	Bourn Hall Clinic Wickford
Centre number	0363
Licence number	L/0363/1/a
Centre address	25 London Road, Wickford, Essex, SS12 0AW, United Kingdom
Person Responsible	Mrs Sarah Pallett
Licence Holder	Dr Arpita Ray
Date licence issued	30 July 2018
Licence expiry date	29 July 2020
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Bourn Hall Clinic Wickford has been licensed by the HFEA since July 2018, for the standard period of two years for new licences. The centre provides a full range of fertility services. Other licensed activities of the centre include storage of gametes and embryos.

The centre provided 136 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2020. In relation to activity levels this is a 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).

The centre was last inspected in May 2019, shortly after the inspection of sister clinic centre 0188 during which a number of anomalies in consent to legal parenthood were identified. This is discussed in detail in the renewal inspection report for centre 0188. As a result of the findings the executive held a management review meeting 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. In view of these concerns the Person Responsible (PR) of centres 0188 and 0363 agreed to a voluntary cessation of the provision of treatments with donor sperm and embryos created with donor sperm, including surrogacy, at both centres. The voluntary cessation of these treatments was lifted in August 2019.

The HFEA has undertaken licence renewal inspections of all four centres within the Bourn Hall group over the last 15 months; centre 0325 in November 2018, centre 0188 in May 2019 and centre 0100 in September 2019. In addition, a targeted interim inspection was carried out at centre 0325 in January 2020. Progress with implementing recommended actions following those inspections has been reviewed at each subsequent inspection of a centre in the group. The report of the interim inspection of centre 0325 and an update on progress with implementing recommendations following the renewal inspection of centre 0100 in September 2019 are being considered by ELP together with this report.

Pregnancy outcomes[1]

HFEA held register data for the year ending 30 November 2019 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2019 the centre reported three cycles of partner insemination with no clinical pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

Multiple births[2]

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

HFEA held register data for the year ending 30 November 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP) and standard licence conditions (SLCs), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required.
- the application has designated an individual to act as the PR.
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended).
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended).
- the premises (including those of relevant third parties) are suitable.
- the centre's practices are suitable.
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence.
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement including two major and nine 'other' areas of non compliance or poor practice.

Since the inspection visit, the PR has given a commitment to fully implement all of the following recommendations and to provide further information or audits of practice where applicable. In view of the current suspension of treatment services due to the COVID-19 pandemic the centre's inspector will liaise with the PR to consider appropriate timescales for the implementation of the recommendations.

Major areas of non compliance:

- The PR should ensure that the centre's QMS is effective.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

'Other' areas that requires improvement:

- The PR should ensure that donor recruitment, assessment and screening procedures are compliant with HFEA and professional body guidance.
- The PR should ensure that the men's sample production rooms have emergency call bell facilities.
- The PR should ensure compliance with controlled drugs regulatory requirements and practice guidance.
- The PR should ensure that the processes for monitoring critical equipment are robust.
- The PR should ensure that there are robust processes in place to assess patients' satisfaction with the counselling service.
- The PR should ensure that the provider (and their staff) of the out-of-hours on-call service to the Bourn Hall group comply with the requirements of the HF&E Act 1990 (as amended), specifically in relation to confidentiality.
- 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 all standard licence condition requirements relating to screening tests for patients and partners are incorporated in the centre's practices and are documented in the centre's standard operating procedures (SOPs).
- The PR should ensure that staff review audit logs of a patient's access to informational videos within the e-consent platform to determine if further steps are necessary to ensure patients have provided fully informed consent.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of non compliance but does have two major area of concern.

The inspection team notes that the success rates are consistent with the national average 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 executive notes that since the time of the recent inspections of the 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 noted that the changes that have been made are well embedded in the centre's practices. However, the executive remains concerned that the group's QMS is not used to its best effect to monitor and improve the service provided, as set out in the body of the report. The PRs of the Bourn Hall group centres should ensure that effective actions are taken to address this failing which continues to be noted during inspections across all centres in the group.

The centre is reasonably well led and provides good level of patient support.

The inspection team recommends the renewal of the centre's 'Treatment and Storage' licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented in a timely manner. In March 2020 the PRs of the Bourn Hall group centres suspended fertility treatments across all their clinics in accordance with HFEA requirements and professional body guidance issued in response to the COVID-19 pandemic. In view of this the centre's inspector will liaise with the PR to consider an appropriate timescale for fully implementing all of this report's recommendations taking into account the period of time where treatments are suspended as a result of the COVID-19 pandemic.

Centre 0363 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 broadly 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)
Several issues in relation to the screening of donors were identified at the time of the licence renewal inspection of centre 0325 in November 2018 and centre 0188 in May 2019. As a result of these findings the Bourn Hall group's Medical Director undertook a major overhaul of the group's processes for the recruitment, assessment and screening of gamete and embryo donors to ensure compliance with HFEA regulatory requirements and recently released professional guidelines (UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors (2019)).

Actions taken in response to those findings were reviewed at the time of the licence renewal inspection of centre 0100 in September 2019 and the targeted interim inspection of centre 0325 in January 2020. During this inspection the Medical Director was able to provide a further update on progress with this action and confirmed that the group remains on target for full implementation of all changes to processes by 18 March 2020.

During the inspection, records of the centre's two most recent egg donors (donating in January 2020 and February 2020) were reviewed and it was noted that they had not had a repeat test for Gonorrhoea at the time of donation, as recommended by professional guidance (UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors (2019)). The Medical Director confirmed that he has already noted this and had made further changes to processes to ensure that this test would be carried out on future donors. In view of the actions already taken the inspection team did not consider that any further recommendation is necessary.

The records of one sperm donor were reviewed during the inspection and it was noted that he had initially been recruited as a donor prior to the changes in requirements of SLC T53 which were implemented in January 2019. For gametes first stored after 19 October 2018, if the blood donation sample taken at the time of donation is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, the donor sperm must be quarantined for a minimum of three months, after which a further donor blood sample should be taken and subjected to repeat serological and NAT testing. In this case, the gametes were stored in January 2019 and March 2019, soon after the date of implementation of the changes to T53. As the blood donation sample taken at the time of donation had not been additionally tested by NAT the donor sample must be quarantined for a minimum of 180 days, after which repeat serological testing is required. However, the donated samples were released for treatment after a blood donation sample was additionally tested by NAT for HIV, HBV and HCV three months later. This period of quarantine would be in accordance with T53c (applicable for gametes stored before 19 October 2018) but not in accordance with T53f (applicable for gametes stored after 19 October 2018) (see recommendation 3, SLC T53).

The inspection team noted that at the time of the inspection the donated sperm had not yet been used in treatment. The PR agreed that serological testing of a further blood donation sample would be undertaken immediately which would ensure compliance with

the requirement to quarantine for 180 days. The PR has confirmed that the donor was re-screened the day after the inspection and these tests were negative.

The inspection team noted that the recruitment of this donor occurred during a period of change in screening requirements and before the issues in donor screening were highlighted during the inspection of centre 0188 in May 2019. Following those findings, a group-wide overhaul of donor assessment, recruitment and screening processes was initiated, and full implementation is due by 18 March 2020.

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)
It is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose. The centre's premises are suitable with the exception noted below.

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 with the exception noted below.

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

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the

quality of the services provided.

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

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

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

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

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

Written information provided to patients offered intralipid therapy is 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 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. The single biggest risk of fertility treatment is a multiple

pregnancy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if 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 TCSs, 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. No imports have been made from TCSs which are not specified on the centre's ITE import certificate. The centre is therefore 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;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

The group's 'Head of Quality Assurance confirmed that following the findings during the inspection of centre 0100 in September 2019 all of the group's third party agreements had been reviewed. The third party agreements relating to this centre (0363) had been prioritised and reviewed. The group's 'Head of Quality Assurance confirmed that all of the group's third party agreements will be updated by the end of December 2020.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport and satellite arrangements therefore this area of practice is not relevant to this inspection.

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

The centre is 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 with the exception noted below.

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

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

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
The inspection team noted that the men's sample production rooms did not have emergency call bells (see recommendation 4; 'Health Technical Memorandum 00 Policies and principles of healthcare engineering' (2014) section 4.55).

Medicines management (Guidance note 25)
The following issues were noted during the inspection (see recommendation 5, HCPC (2014) 'Standards of proficiency – Operating department practitioners', section 10.1; Misuse of Drugs Regulations 2001 regulation 20 (c); 20 (d)).

- There were several entries in the controlled drug register that were illegible, for example it was not clear what dosage of drug had been given to the patient. The inspection team noted that the illegible entries in the register were attributed to one individual and were not a systemic issue. All entries were correctly witnessed and there were no other concerns, however all records should be clear and comprehensible.

- One entry had been amended by over-writing the original text which is not in accordance with regulatory requirements; where a correction of an entry shall be made only by way of marginal note or footnote which shall specify the date on which the correction is made.

Quality management system (QMS) (Guidance note 23)
The following issues were noted during the inspection (see recommendation 1; SLC T32).

- The centre's records of corrective and preventative actions (CAPAs) were reviewed and although several had been completed, these remained recorded as 'incomplete' in the QMS. The group's 'Head of Quality Assurance' explained that staff allocated each CAPA are asked to confirm that the action had been completed, however if that person does not confirm this, then the CAPA remains 'incomplete' in the system. The inspection team was concerned why completed CAPAs remained recorded as 'incomplete' and how the centre can assess the effectiveness of the QMS if it is not clear if actions had been completed within the specified timescales. During the inspection the quality assurance team took immediate action to close CAPAs where evidence of completion could be confirmed.

- During the inspection records of surgical procedures were reviewed, and the inspection team noted that the 'post-operative record' form had been updated following an incident at centre 0325 in December 2019, and this form now included a section to record allergies. However, the inspection team noted that this section of the form was not completed in all the records reviewed. The inspection team was concerned that changes implemented following an incident do not appear to have been properly embedded and no additional audits of this area of practice had been planned to assess the effectiveness of the preventative actions taken as a result of the incident at centre 0325 beyond those in the routine audit schedule (due April 2021). The actions taken in response to the incident at centre 0325 had been discussed and reviewed during the inspection of centre 0325 in January 2020. Whilst the inspection team was assured that appropriate investigations and actions had been taken these did not appear to be documented in the group's

'CAPA' records. The group's 'Head of Quality Assurance' explained that those actions would have been documented in the paper reports which were held at centre 0100 in Cambridge. These were not available to review during the inspection.

- Two versions of the questionnaire that patients complete to document any recent travel were noted in the records. The older version of the form had included sections where two members of staff can check and confirm that they had reviewed the patient's travel history and that treatment can proceed. The recently issued version does not contain these sections and it was not clear to the inspection team why this omission had been made to a previous robust version of the form.

- The centre's most recent version of their SOP for surrogacy (issued January 2020) does not reference Department of Health and Social Care (DHSC) guidance which was issued in February 2018 ('Care in Surrogacy: Guidance for the care of surrogates and intended parents in surrogate births in England and Wales' and 'The Surrogacy Pathway; surrogacy and the legal process for intended parents and surrogates in England and Wales'). This was noted at the time of the inspection of centre 0188 in May 2019. Following that inspection, the PR confirmed that the SOP had been updated to include reference to DHSC guidance however this recently issued version does not contain these sections and it was not clear to the inspection team why this had happened. The PR confirmed that staff involved in surrogacy treatments had been provided training on the new guidance in 2018 and 2019.

- Changes in practice in January 2019 regarding the reporting of ovarian hyperstimulation syndrome (OHSS) cases to the HFEA were not detailed in the group's SOPs. During discussions with staff the inspection team was assured that staff were aware of the new requirements but were not able to identify where these processes were described.

- Several issues in relation to the Bourn Hall group's QMS have been identified during recent inspections. Following the inspection of centre 0325 in January 2020 the executive recommended that the PR commission a review of the centre's auditing and audit review processes by a suitably qualified individual who is independent of the organisation and its QMS. The PR of centre 0325 confirmed that an external audit had been conducted by an International Register of Certificated Auditors (IRCA) Lead Auditor and the report of this audit conducted in December 2019 was reviewed on this inspection. Whilst the scope of that audit did not overlap with that of the inspection team, similar findings were noted such as several CAPAs that were open or overdue, no effective closure dates for CAPAs and audits that were outside the date on the audit schedule.

The lead inspector who is the inspector for all centres in the group has noted that the Bourn Hall group's QMS is a combination of a number of electronic and paper records therefore changes and updates have to be recorded in many different places. There are often several SOPs for one activity and access to documents in the QMS is not straightforward, discouraging full engagement from all the staff in the group. Furthermore, in some cases the reports of audits can take a number of months to finalise because the quality assurance team are not able to meet with relevant staff to review their findings,

agree the appropriate CAPA, and complete a root cause analysis. The inspection team was concerned that there appeared to be a disconnect between staff and the QMS which is a further hindrance to the effectiveness of the QMS. These concerns have been raised during previous inspections and were discussed again during this inspection. The group's 'Head of Quality Assurance' has been considering ways to improve the effectiveness of the QMS and was of the view that an integrated QMS software program would be a valuable tool in resolving several of the issues that have been noted during recent inspections.

Overall, the inspection team was concerned that the QMS is not functioning to best effect and that staff are not fully engaged with the processes and activities undertaken by the QMS team.

Equipment and materials (Guidance note 26)
Laboratory equipment is subject to routine monitoring to ensure that the critical parameters are maintained within acceptable limits, however the acceptable ranges are not documented on the laboratory record sheet. The inspection team was concerned that although this information was recorded in protocols these are held within the electronic document management system and may not be readily accessible to the person performing the task and may be missed (see recommendation 6, SLC T24).

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
Staff

What the centre does well

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

Leadership
Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

The centre is compliant with HFEA guidance regarding effective leadership.

The HFEA has undertaken licence renewal inspections of all four centres within the Bourn Hall group over the last 15 months and as a result the group has been subject to a high level of regulatory scrutiny. Whilst issues have been noted at each inspection the inspection team considers that, overall, the PR provides a good level of leadership and therefore makes no formal recommendation in this regard at this time. The PR is encouraged to fully engage with all aspects of the centre team's work to ensure effective

leadership is consistently demonstrated.

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.

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 does not carry out embryo testing and therefore this area of practice is not relevant to this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well

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 two patients have provided feedback in the last 12 months, giving an average 5-star rating to the clinic. There were no additional comments. The website also gives the ability for patients to comment on the cost of treatment and both respondents confirmed that they had paid what they expected to.

The low level of feedback through the HFEA's website has been noted at all other inspections across the Bourn Hall group. The inspection team saw several HFEA information leaflets and notices about the 'Choose a Fertility Clinic' website page in the centre and was assured that this facility is well publicised. The provision of electronic tablets for patients to use in the clinic to facilitate this feedback process has been considered but has not yet been implemented. The PR continues to consider ways to increase the amount of feedback from patients.

The centre's own most recent patient survey responses were reviewed. 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. The survey included patients who had undergone treatment between September and November 2019 across centres 0188 and 0363. Only nine responses had been received from 77 electronic surveys that were issued. This is a 12% return rate, similar to that seen at other centres in the Bourn Hall group. The inspection team noted that of the respondents, 89% would recommend the centre to a friend or relative. There were several positive comments complimenting the support from staff, but there were a few negative comments relating to support after treatment and accessibility of the counselling service. Whilst the feedback is anonymous, patients are offered a chance to discuss their feedback with a member of staff should they wish.

During the inspection the inspectors spoke to four patients who provided positive feedback on their experiences.

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.

What the centre could do better

Patient feedback

The inspection team noted that the patient feedback for centres 0188 and 0363 is similar to that seen for centres 0325 and 0100 reviewed during the inspections in 2019 and 2020. In all surveys the inspection team noted negative responses from patients to

questions asking whether they found the counselling service easy to access and whether they were happy with the service they received from the counsellors (see recommendation 7; CoP 23.17). Furthermore, there were only five responses to these questions in the surveys for centres 0188 and 0363 and the inspection team did not consider this provided sufficient information to be able to assess their patients' satisfaction with the counselling service.

Treating patients fairly
Patient support
Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non discriminatory way.

Patient support (Guidance note 3)
New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Counselling (Guidance note 3)
It is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood. The centre's counselling procedures are compliant with HFEA requirements with the exception noted in the section 'Patient feedback' above.

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)
It is important to protect the surrogate and any children born as a result of the treatment. The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements with the exception noted in the 'Quality Management System' section above.

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

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

What the centre could do better

Confidentiality and privacy (Guidance note 30)
The East of England Ambulance Service provides an out-of-hours on-call service to the Bourn Hall group. The inspection team reviewed the centre's current agreement in place from 1 August 2017 and reviewed every two years. The inspection team did not consider that the agreement provides sufficient emphasis or clarity in relation to the confidentiality requirements of the HF&E Act 1990 (as amended) (see recommendation 8; SLC T43). The agreement also contains the name of a member of staff who left the group in January 2018.

Information

What the centre does well

Information (Guidance note 4)
It is important that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions. The centre's procedures for providing information to patients and donors are compliant with HFEA requirements.

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

Consent

Legal parenthood

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

What the centre does well

Consent (Guidance note 5;6)
It is important that patients and donors have provided all relevant consents before

carrying out any licensed activity. The centre's procedures for obtaining consent are compliant with HFEA requirements.

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

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 was not required to provide this audit.

An interim inspection of this centre was carried out on 14 May 2019 shortly after a renewal inspection of centre 0188 on 8 and 9 May 2019. Significant anomalies in consent to legal parenthood were identified at centre 0188 and 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). In view of these concerns, on 23 May 2019 the executive informed the PR that it recommended that she voluntarily suspended the provision of treatments with donor sperm and embryos created with donor sperm, including surrogacy, at centre 0188 until such time that it was satisfied that the centre's processes in this area of practice were 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 voluntary suspension was lifted on 15 August 2019 and treatments with donor sperm and embryos created with donor sperm, including surrogacy resumed. The PR was asked to submit monthly audits of consent to legal parenthood for all treatments that had been provided. Audits covering treatments with donor sperm and embryos created with donor sperm, including surrogacy, each month from August 2019 to January 2020 have been submitted and no issues were identified.

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. Six 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)

Two discrepancies were found between completed patient and partner disclosure consents and the related consent data submitted for inclusion on the register in 15 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. This failing leads to a risk that the HFEA may 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)

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. The centre's procedures for screening patients are broadly compliant with HFEA requirements.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Screening of patients (Guidance note 15)

The centre does not include consideration of circumstances when additional testing for HTLV-1 antibody testing may be required depending on whether the person originates from high prevalence areas or has sexual partners originating from those areas (see recommendation 10, SLC T50c).

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.

5. 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 accurate 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 partially 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.

What the centre could do better

Record keeping and document control (Guidance note 31)
During the inspection, four sets of records of patients who had completed their consents to treatment via the electronic (e-consent) pathway were reviewed. Prior to completion of the e-consent forms, patients are provided with access to videos which contain information of various aspects of treatment including the completion of consents. The e-consent platform logs the date, time and amount of time that each patient has spent viewing the informational video. In several cases the patients had watched some videos for as little as 3 seconds, which was not the full length of the video. In some cases, the patients had watched the entire video. However, there was no record that the clinician or nurse who had seen the patients had considered the short amount of time that the patients had spent watching the informational videos (see recommendation 11; SLC T32). The inspection team noted that 'Medical checklists' recording the information that had been provided were seen in the patients' records documenting that patients had been provided information to enable them to make informed decisions.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The inspection team was provided with evidence of regular audits and the data submission SOP being in place for reference purposes. Prior to the start of the inspection, the team was made aware that the clinic had suffered serious IT issues for an extended period during 2019 and this had resulted in a catch-up process being instituted to address the backlog of outstanding register data submissions. The inspection team was shown copious evidence of the centre liaising with both their third-party system supplier and the HFEA about the data submission issues and it is acknowledged that the following findings will have been impacted by the centre's inability to submit data to the HFEA for a six month period.

The HFEA register audit team identified the following issues with the timeliness and accuracy of the centre's submission of data to the HFEA Register (see recommendation 2; General Direction 0005, SLC T41).

- Four percent (3/82) of the IVF and 25% (3/12) of the DI treatments reviewed at inspection (i.e. sample period 01/01/2019-31/12/2019) had not been reported to the HFEA (General Direction 0005).

- Seventy percent (55/79) of the IVF and 66% (8/12) of the DI treatments reviewed at inspection (i.e. sample period 01/01/2019-31/12/2019) had been reported to the HFEA outside the period required by General Direction 0005.

- Eight percent (4/51) of the IVF treatments reviewed post inspection (i.e. sample period 01/08/2018-31/12/2018) had not been reported to the HFEA as required by General Direction 0005.

- Thirty six percent (17/47) of the IVF treatments reviewed post inspection (i.e. sample period 01/08/2018-31/12/2018) had been reported to the HFEA outside the period required by General Direction 0005.

- We found a small number of mainly minor issues in the quality of data submitted. Importantly, the backlog of submissions in relation to treatment outcomes adversely impacts the effectiveness of the HFEA's regulatory monitoring mechanism (i.e. Risk based assessment tool and alert system).

Since the time of the last inspection in May 2019 the centre has received five risk based assessment tool alerts in relation to late payment of fees. The inspection team noted that this has been a recurring issue for all centres in the Bourn Hall group and the PRs have committed to ensuring that fees payable to the HFEA will be within the required timeframe. The effectiveness of changes implemented continue to be monitored via the centre's inspector through post-inspection activities and risk tool alerts, therefore no additional recommendation is being made here.

Section 3: Monitoring of the centre's performance

Following the interim inspection on 14 May 2019, recommendations for improvement were made in relation to three major and two 'other' areas of non compliance or poor practice that require improvement.

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

On-going monitoring of centre success rates

The centre has not been issued with any risk tool alerts in relation to success rates.

Areas of practice requiring action

The section sets out matters which the inspection team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, 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 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 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 areas of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several 'other' areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

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

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. QMS The inspection team considered that the centre's QMS is not effective for the reasons set out in the body of the report. Overall, the inspection team was concerned that the QMS is not functioning to best effect and that staff are not fully engaged with the processes and activities undertaken by the QMS team. SLC T32.	The PR should ensure that the centre's QMS is effective. The PR should ensure that immediate actions are taken to address the issues noted and provide a summary of these when responding to this report. Following the inspection of centre 0325 in January 2020 the executive recommended that the PR commission a review of the centre's auditing and audit review processes by a suitably qualified individual who is independent of the organisation and it's QMS. The	With the suspension of fertility treatments due to the COVID-19 panademic some planned Immediate actions to address the issues have needed to be postponed until services can recommence.. Actions already taken:- Improvement to the QMS has been set as group wide company goal/objectives	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The executives notes the immediate actions that have been taken by the PR to address the findings of the inspection team, and acknowledges the impact that the suspension of treatments and activity at the centre has on fully implementing this recommendation. The PR has confirmed that she

	PR of centre 0325 confirmed that an external audit had been conducted by a lead IRCA auditor and the report of this audit was reviewed on inspection. Taking this into account the executive recommends that the PR provides the IRCA Lead Auditor with the HFEA inspection reports of the four Bourn Hall centres since 2017 up to and including this report, so that they can undertake root cause analyses of these issues and consider what corrective and preventative actions can be developed to address the issues identified across the group's QMS. The PR should advise the centre's inspector of the timescale for achieving this when responding to this report.	Quality will be on each top level, function meeting, and other related meetings agendas. QA to provide details of events/incidents/complaints/ shared learning and CAPAs at each of these meetings Actions pending :- Root cause analysis super users and training this was planned for Q2 CAPA training , to include sit down sessions with teams to review, action and complete thier CAPAs within the set timescale Root cause analysis of the issues relating to the QMS system to identify suitable corrective actions The Lead IRCA auditor will be given the HFEA reports for all centres since 2017 so that root cause analysis can be conducted and corrective actions can be identified. IRCA auditor planned visit for Dec 20	intends to provide the IRCA Lead Auditor with the HFEA inspection reports of the four Bourn Hall centres since 2017, up to and including this report, so that they can undertake root cause analyses of the various issues identified and appropriate corrective and preventative actions can be developed. The executive notes that the IRCA auditor is scheduled for December 2020. Ordinarily the executive would not consider this to be a reasonable timescale to implement this recommendation, due to the number of issues identified in this area of practice over several recent inspections across the group. In view of the current COVID-19 pandemic the executive will liaise with both PRs of the Bourn Hall group centres to confirm an appropriate timescale for completing this audit by the IRCA Lead Auditor. The PR will be urged to

		Timescale to be agreed between PR and inspector post COVID-19 panademic	implement this recommendation as soon as possible so that corrective and preventative actions can be implemented to ensure that the QMS is effective. **Further action is required.**
2. Obligations and reporting requirements A number of issues in relation to the reporting of data to the HFEA were noted on inspection and are detailed in the body of the report. General Direction 0005 and SLC T41.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. It is expected that the PR will be able to confirm that significant progress has been made in addressing the outstanding backlog of register data submissions when responding to this report. The PR should review the systems and processes used for licensed treatment data submission to identify and address the reasons for non-reporting and delayed submissions. A summary of the findings of the review including corrective actions and the timescales for	There has been a substantial amount of evidence provided to the inspector outlining the centre's communications with the HFEA and the centre third part provider regarding the serious IT and data submission issues which has spanned a period of six months. Based on the evidence provided, the HFEA's inability to resolve the issue to enable the centre to report data the PR does not consider this finding should be catagorised as a major and should be down graded to 'other'. The PR can confirm that there has been significant progress to address the backlog of registered data.. As	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The inspection team has acknowledged that the findings have been impacted by the centre's inability to submit data to the HFEA for a six month period during 2019. In view of this the HFEA register audit team also analysed a sample of data submissions between 1 August and 31 December 2018 and similar issues were noted. The executive has taken all of the above into account when determining the grading of this non compliance. The executive notes that the

	implementation should be provided to the centre's inspector by 26 May 2020. The PR should audit the effectiveness of changes introduced in this area of practice. In view of the current suspension of treatment services due to the COVID-19 pandemic the centre's inspector will liaise with the PR to consider an appropriate timescale for submitting this audit.	ther is over six months backlog this is ongoing. We will review our systems and processes used for licensed treatment data submission and provide a summary of the findings and any planned corective actions by an agree date once fertility treatments can recommence. We will caryout an audit of the changes effectiveness and provide a summary report withi the timscale as agree by the PR and inspector post the COVID-19 pandemic.	PR has confirmed that significant progress has been made in addressing the outstanding backlog of register data submissions. The centre's inspector will liaise with the PR to consider an appropriate timescale for submitting the review and audit of practice, taking into account the period of time where treatments are suspended as a result of the COVID-19 pandemic. **Further action is required.**

Other areas of practice that require improvement

'Other' areas of practice that require improvement are any areas of practice 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
3. Donor screening The records of one sperm donor were reviewed during the inspection and it was noted that he had initially been recruited as a donor prior to the changes in requirements of SLC T53 which were implemented in January 2019. However, he donated gametes after the implementation of the changes to SLC T53 but they were not quarantined in accordance with the requirements for gametes stored after 19 October 2018. The PR has confirmed that the donor was re-screened the day after the inspection and these tests were negative. SLC T53.	The PR should ensure that donor recruitment, assessment and screening procedures are compliant with HFEA and professional body guidance. The PR should audit all gamete and embryo donors recruited across all centres in the Bourn Hall group since January 2019 to ensure that screening is compliant with HFEA and professional body guidance. A summary report of the findings of the audit should be provided to the centre's inspector by 26 May 2020. If cases are identified the PR should seek expert advice to fully assess if there may have been any risks to the recipients that have undergone treatment	An audit of all gamete and embryo donors screening will be conducted across all centres and a summury of the findings will be provided to the centre's inspector . If cases are identified expert advice will be obtained and reccomended actions will be implemented to omitigate risk to patients The timeframe for when the audit findings should be provided to the centre's inspector will need to be discused and agreed between	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed that she will audit all gamete and embryo donors recruited across the centres in the Bourn Hall group since January 2019, to ensure that screening is compliant with HFEA and professional body guidance, and that if any cases are identified she will seek expert advice on the potential risks to the recipients that have undergone treatment with these gametes and/or embryos. The centre's inspector will

This non compliance has been graded as 'other' because the inspection team noted that the donor was recruited during a period of transition between requirements for donor screening and the donor had been screened in accordance with previous requirements.	with these gametes and/or embryos. The review should also consider whether recipients affected are to be contacted and advised of possible risks of their treatment. The PR should inform the centre's inspector of the timeline for completing this risk assessment by 26 May 2020.	the PR and centre's inspector once the centre is able to recommence fertiliy treatments post the COVID-19 pandemic .	liaise with the PR to consider an appropriate timescale for submitting the audit and review of cases, taking into account the period of time where treatments are suspended as a result of the COVID-19 pandemic. **Further action is required.**
4. Safety and suitability of premises The inspection team noted that the men's sample production rooms did not have emergency call bells. Health Technical Memorandum 00 Policies and principles of healthcare engineering (2014) section 4.55.	The PR should ensure that the men's sample production rooms have emergency call bell facilities. When responding to this report the PR should inform the centre's inspector of the actions that will be taken to address this non compliance.	The instalation of an emergency call bell to each of the men's producton rooms was scheduled for week commencing 6 April 2020 . Due to the COVID-19 pandemic this has had to be postponed and will be rescheduled at the earliest opportunity post the pandemic.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The centre's inspector will liaise with the PR to confirm that emergency call bells are installed in the men's production rooms as soon as practicable. **Further action is required.**
5. Medicines management The following issues were noted during the inspection: • There were several entries in the controlled drug register that were	The PR should ensure compliance with controlled drugs regulatory requirements and practice guidance. The PR should ensure that all	Identified staff member/s have	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation.

illegible. • One entry had been amended by over-writing the original text which is not in accordance with regulatory requirements. HCPC (2014) 'Standards of proficiency – Operating department practitioners', section 10.1. Misuse of Drugs Regulations 2001 regulation 20 (c); 20 (d)) *This non compliance has been graded as 'other' because the inspection team noted that the illegible entries in the register were attributed to one individual and were not a systemic issue.*	staff are compliant with requirements to ensure that their records are legible, and that the individual concerned undergoes training and review of their documentation of entries in the controlled drugs register. The PR should inform the centre's inspector of the actions taken to address the issues identified when responding to this report. It is expected that the implementation of any corrective actions required will be completed by 26 May 2020. The PR should audit the effectiveness of changes introduced in this area of practice. In view of the current suspension of treatment services due to the COVID-19 pandemic the centre's inspector will liaise with the PR to consider an appropriate timescale for submitting this audit.	been informed of the findings and a review of thier documneted entries has been conducted. Further training is planned inline with related competencies along with on going reviews of thier doumentation entires to ensure compliace and identify any further training needs. With fertility treatments suspended due to the COVID-19 pandemic the timeframe for implementation of corrective actions will need to be reconsidered post the pandemic we will carry out an auit of the changes effectiveness and provide a sumary report within the timescale as agreed by the PR and inspector post the COVID-19 pandemic	The executives notes the immediate actions that have been taken by the PR to address the findings of the inspection team, and acknowledges the impact that the suspension of treatments and activity at the centre has on fully implementing this recommendation. The centre's inspector will liaise with the PR to consider an appropriate timescale for implementing the recommended actions and for submitting the audit of practice, taking into account the period of time where treatments are suspended as a result of the COVID-19 pandemic. **Further action is required.**
6. Equipment	The PR should ensure that the		The executive acknowledges

Laboratory equipment is subject to routine monitoring to ensure that the critical parameters are maintained within acceptable limits. However, the acceptable ranges are not documented on the laboratory record sheet. The inspection team was concerned that although this information was recorded in protocols these are held within the electronic document management system and may not be readily accessible to the person performing the task and may be missed. SLC T24.	processes for monitoring critical equipment are robust. The PR should review the centre's processes for equipment monitoring to ensure that the issues identified on inspection are addressed. 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 26 May 2020.	We have reviewed our processes, regarding equipment monitoring and revised the related laboratory record sheet.	the PR's response and her commitment to fully implementing this recommendation. The PR has confirmed that she has completed a review of the centre's processes for equipment monitoring and that the related laboratory record sheet has been revised. **No further action is required.**
7. Patient feedback The inspection team noted that the patient feedback for centres 0188 and 0363 is similar to that seen for centres 0325 and 0100 reviewed during the inspections in 2019 and 2020. In all surveys the inspection team noted negative responses from patients to questions asking whether they found the counselling service easy to	The PR should ensure that there are robust processes in place to assess patients' satisfaction with the counselling service. The PRs of the Bourn Hall group centres should undertake a focused and specific survey of patient satisfaction of the counselling service. In view of the current suspension of treatment	We wil carryout a specific patient satifaction survey of our counelling services . A summary of the findings will be provided . Timescale for undertaking the	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The centre's inspector will liaise with the PR to consider an appropriate timescale for completing the patient satisfaction survey, taking into account the period of time where treatments are

access and whether they were happy with the service they received from the counsellors. CoP 23.17.	services due to the COVID-19 pandemic the centre's inspector will liaise with the PR to consider an appropriate timescale for undertaking this survey.	the survey to be agreed by the PR and inspector post the COVID-19 pandemic	suspended as a result of the COVID-19 pandemic. **Further action is required**
8. Confidentiality & privacy The East of England Ambulance Service provides an out-of-hours on-call service to the Bourn Hall group. The inspection team reviewed the centre's current agreement and did not consider that it provides sufficient emphasis or clarity in relation to the confidentiality requirements of the HF&E Act 1990 (as amended). The agreement also contains the name of a member of staff who left the group in January 2018. SLC T43.	The PR should ensure that the provider (and their staff) of the out-of-hours on-call service to the Bourn Hall group comply with the requirements of the HF&E Act 1990 (as amended), specifically in relation to confidentiality. The PR should ensure that actions are taken to address the concerns noted by the inspection team before resuming treatment activity. In view of the current suspension of treatment services due to the COVID-19 pandemic the centre's inspector will liaise with the PR to consider an appropriate timescale for completing this action.	The agreement bewteen East of England Ambulance service and bourn Hall will be reivewed and amended to ensure it complies with the confidentiality requirements of the HF& A Act (as amended) and detials the correct contact details of current staff members Timescale to be agreed by the PR and inspector post the COVID- 19 pandemic	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The centre's inspector will liaise with the PR to consider an appropriate timescale for implementing this recommendation, taking into account the period of time where treatments are suspended as a result of the COVID-19 pandemic. **Further action is required**
9. Consent to disclosure to researchers Two discrepancies were found between completed patient	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are	We have corrected the submissions identified	The executive acknowledges the PR's response and her commitment to fully implementing this

and partner disclosure consents and the related consent data submitted for inclusion on the register in 15 patient files audited. 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.*	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 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 26 May 2020. The PR should audit the effectiveness of changes introduced in this area of practice. In view of the current suspension of treatment services due to the COVID-19 pandemic the centre's inspector will liaise with the PR to consider an appropriate timescale for submitting this audit.	We wil 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 at an agreed date once fertility treatment services can recommence. We wil carry out an audit of the changes effectiveness and provide a summary report within the timescale as agreed by the PR and Inspector post the COVID-19 pandemic.	recommendation. The PR has confirmed that the incorrect submissions have been corrected. The centre's inspector will liaise with the PR to consider an appropriate timescale for submitting the review and audit of practice, taking into account the period of time where treatments are suspended as a result of the COVID-19 pandemic. **Further action is required**

10. Screening of patients The centre does not include consideration of circumstances when additional testing for HTLV-1 antibody testing may be required depending on whether the person originates from high prevalence areas or has sexual partners originating from those areas. SLC T50c.	The PR should ensure that all standard licence condition requirements relating to screening tests for patients and partners are incorporated in the centre's practices and are documented in the centre's SOPs. When responding to this report, the PR should provide a summary of the actions taken to ensure that consideration of circumstances when additional testing for HTLV-1 antibody testing may be required, is incorporated into the centre's practices. It is expected that the implementation of any corrective actions required will be completed by 26 May 2020. The PR should audit the effectiveness of changes introduced in this area of practice. In view of the current suspension of treatment services due to the COVID-19 pandemic the centre's inspector will liaise with the PR to consider an appropriate	We will review all SOPs, work insrutions and documents relating to screening of donors to ensure there is clear guidance and instuction as to when additional testing for HTLV-1 antibody is reqiured and at what stage in a patients treatment the test should be conducted Implementation of the corective actions wil be at an agred date once fertility treatments can recommence. We wil cary out an auditof the changes effectiveness and provide a summary report within the timscale as agreed by the PR and inspector post the COVID-19 pandemic.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided a summary of the actions that will be taken to address this non compliance, which will be fully implemented once treatments resume. The executive acknowledges the impact that the suspension of treatments and activity at the centre has on fully implementing this recommendation. The centre's inspector will liaise with the PR to consider an appropriate timescale for submitting the audit of practice, taking into account the period of time where treatments are suspended as a result of the COVID-19 pandemic. **Further action is required**

	timescale for submitting this audit.		
11. Record keeping During the inspection four sets of records of patients who had completed their consents to treatment via the electronic (e-consent) pathway were reviewed. The inspection team noted that in several cases the patients had watched some videos for as little as 3 seconds, not the full length of the video. In some cases, the patients had watched the entire video. However, there was no record that the clinician or nurse who had seen the patients had considered the short amount of time that the patients had spent watching the informational videos. SLC T32.	The PR should ensure that staff review audit logs of a patient's access to informational videos within the e-consent platform to determine if further steps are necessary to ensure patients have provided fully informed consent. The PR should review the centre's processes for documenting that the audit logs within the e-consent platform have been assessed. 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 26 May 2020. The PR should audit the effectiveness of changes introduced in this area of practice. In view of the current suspension of treatment services due to the COVID-19 pandemic the centre's inspector will liaise with the PR	We will review our processes, SOPs, work instruction and pathways to ensure staff are monitoring and documenting the checks of the audit logs and any concerned highlighted from the audit log is addressed and documented . A summary report will be provided on an agreed date once fertility treatments recommence We will carry out an audit of the changes effectiveness and provide a summary report within the timescale as agreed by the PR and inspector post the COVID-19 pandemic..	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided a summary of the actions that will be taken to address this non compliance, which will be fully implemented once treatments resume. The executive acknowledges the impact that the suspension of treatments and activity at the centre has on fully implementing this recommendation. The centre's inspector will liaise with the PR to consider an appropriate timescale for submitting the audit of practice, taking into account the period of time where treatments are suspended as a result of the COVID-19 pandemic. **Further action is required**

	to consider an appropriate timescale for submitting this audit.		

Reponses from the Person Responsible to this inspection report
Bourn Hall team would like to thank the inspector and her coleagues for the open and thorough approach taken to the inspection. As a group we are committed to continuous improvement and the recognition to this is greatly appreciated