Executive Licensing Panel - minutes

Centre 0100 (Bourn Hall Clinic) Renewal Inspection Report

Friday, 27 November 2015

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Juliet Tizzard (Chair) Joanne Anton Jessica Watkin	Director of Strategy & Corporate Affairs Policy Manager Policy Manager
Members of the Executive	Dee Knoyle	Secretary
External adviser		
Observers	Trisram Dawahoo	Digital Communications Manager

Declarations of interest

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

The panel had before it:

- 8th 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 this is a treatment and storage centre which provides a full range of fertility services. The panel noted that in relation to activity levels this is a large centre.

1.3. The panel noted that the centre has been licensed by the HFEA since 1991.

1.4. The panel noted that Bourn Hall Clinic is part of a group that incorporates two other HFEA licensed centres and a small number of satellite clinics that are all centrally managed and have common practices and procedures.

1.5. The panel noted that the Bourn Hall Clinic group includes centre 0325, Bourn Hall (Norwich), centre 0188, Bourn Hall (Colchester). These centres have common structures and functions and were all inspected within the last 10 months. The Executive undertook a trial approach to Bourn Hall Clinic's renewal inspection: activities which were common across the group, that had been found to be compliant in the course of the detailed review at the two sister clinics' renewal inspections, were not reviewed in detail. Local compliance with group policies and procedures was assessed by review of audits and observation of practice. Therefore, the report references centre specific activities and processes and most notably, includes follow up of the implementation of recommendations for improvement made in the course of previous inspections of clinics in the group.

1.6. The panel noted that, in advance of the inspection, the Person Responsible (PR) at all the clinics in the Bourn Hall Clinic group agreed that recommendations for improvements made following the renewal inspections of the other two clinics in the Bourn group, would be implemented across all centres. It was also agreed that, should non-compliance continue to be observed beyond the anticipated timescale for the implementation of corrective actions, that this may result in the escalation of the categorisation of the non-compliance. The report therefore represents the result of a focused inspection in recognition that there has been previous detailed scrutiny of many common practices and procedures.

1.7. The panel noted that in the 12 months to 31 July 2015, the centre provided 2156 cycles of treatment (excluding partner intrauterine insemination).

1.8. The panel noted that for IVF and ICSI, HFEA-held register data for the period 1 June 2014 to 31 May 2015 showed the centre's success rates were in line with national averages with the following exception:

- success rates following frozen embryo transfer in women aged under 40 were lower than average at a statistically significant level.

1.9. The centre's success rate in relation to frozen embryo transfers (FET) was discussed with the PR and centre staff during the inspection. The PR had been aware of this reduction in success rate and had been keeping this under regular review. The PR reported that the outcomes were related to the use of embryos frozen, in what appeared to be sub-optimal conditions, which the centre was not aware of at the time of freezing. The panel noted that the inspection team considered that no further recommendations should be made in relation to this area of practice as the PR was already monitoring and reviewing this issue.

1.10. The panel noted that in 2014, the centre reported 11 cycles of partner insemination with two pregnancies. This equated to an 18% clinical pregnancy rate which was consistent with the national average.

1.11. Between 1 June 2014 and 31 May 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 17%. This represents performance

that is likely to be greater than the 10% maximum multiple live birth rate target for this period. The panel noted that the multiple pregnancy rates for the other centres in the group were not significantly different from the target.

1.12. The panel noted that at the time of the inspection on 22 September 2015 one critical, six major and six other areas of non-compliance were identified. The panel noted that since the inspection the PR has committed to fully implementing all of the recommendations within the prescribed timescales.

1.13. The panel noted that the inspectorate recommended 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 within the prescribed timescales.

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 was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR has discharged their duty under section 17 of the HFE Act 1990 (as amended).

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

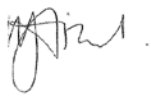
2.4. Despite the relatively high volume of non-compliances, the panel were encouraged by the PR's positive response to the inspection report and engagement with the inspectorate.

2.5. 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.

3. Chair's signature

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

Signature



Name

Juliet Tizzard

Date

7 December 2015

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: 22 September 2015

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), Shanaz Pasha, Louise Winstone, Neil McComb, Helen Crutcher.

Date of Executive Licensing Panel: 27 November 2015

Centre name	Bourn Hall Clinic
Centre number	0100
Licence number	L/0100/14/b
Centre address	Bourn, Cambridge, Cambridgeshire, CB23 2TN, UK
Person Responsible	Dr Michael Macnamee
Licence Holder	Dr Thomas Mathews
Date licence issued	01 April 2012
Licence expiry date	31 March 2016
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:
Bourn Hall Clinic is located on the outskirts of Cambridge and has held a treatment and storage licence with the HFEA since 1991. The current licence was varied to reflect a change of Licence Holder in February 2013.

The centre provides a full range of fertility services and provided 2156 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2015. In relation to activity levels this is a large centre. Other licensed activities of the centre include storage of gametes and embryos.

Bourn Hall Clinic is part of a group that incorporates two other HFEA licensed centres and a small number of satellite clinics that are all centrally managed and have common practices and procedures. In view of the common structures and functioning of the centres within the Bourn Hall Clinic group and that the two other HFEA licensed clinics (centre 0325 Bourn Hall (Norwich), centre 0188 Bourn Hall (Colchester)) had been inspected within the last 10 months, the Executive undertook a trial approach to this centre's renewal inspection. Activities which were common across the group and had been found to be compliant in the course of the detailed review at the two sister clinics recent renewal inspections were not reviewed in detail. Instead local compliance with group policies and procedures was assessed by review of audits and observation of practice. This report therefore references centre specific activities and processes and most notably, includes follow up of the implementation of recommendations for improvement made in the course of previous inspections of clinics in the group.

In advance of the inspection the PRs of all the clinics in the Bourn Hall Clinic group agreed that recommendations for improvements made following the renewal inspections of the other two clinics in the Bourn group would be implemented across all centres. It was also agreed that should continued non-compliance be observed beyond the anticipated timescale for the implementation of corrective actions that this may result in the escalation of the categorisation of the non-compliance.

This report therefore represents the result of a focused inspection in recognition that there has been previous detailed scrutiny of many common practices and procedures.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 June 2014 to 31 May 2015 show the centre's success rates are in line with national averages with the following exception:

- success rates following frozen embryo transfer in women aged under 40 are lower than average at a statistically significant level.

The centre's success rate in relation to frozen embryo transfers was discussed with the PR and centre staff during the inspection. The PR had been aware of this reduction in success rate and had been keeping this under regular review. He reported that the outcomes were related to the use of embryos frozen in what now appears to be sub-optimal conditions which the centre had not been aware of at the time of freezing. As the PR was already monitoring and reviewing this issue the inspection team considered that no further recommendations should be made in

relation to this area of practice.

In 2014, the centre reported 11 cycles of partner insemination with two pregnancies. This equates to an 18% clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

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

Between 1 June 2014 to 31 May 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 17%: this represents performance that is likely to be greater than the 10% multiple live birth rate target for this period (see recommendation 2). The inspection team noted that the multiple pregnancy rates for the other centres in the group were not significantly different from the target.

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

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

Summary for licensing decision

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

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

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one critical, six major and six 'other' areas of non compliance.

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

Critical area of non compliance

- **The PR should ensure that CE marked medical devices are used where possible.**

Major areas of non compliance

- The PR should ensure that the multiple live birth rate target is not exceeded.
- The PR should ensure compliance with medicines' management regulations.
- The PR should ensure that all audits have documented corrective actions and timescales for implementation, that corrective actions are implemented in a timely manner, and that audits assess compliance with regulatory requirements.
- The PR should ensure that patients donating frozen embryos for research are offered the opportunity to receive counselling about the implications of their donation.
- The PR should ensure that proper information and clear consent forms are in place for patients considering donating their embryos to research.
- The PR should ensure that all licenced treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

'Other' areas that require improvement:

- The PR should ensure that witnessing practices are in accordance with guidance.
- The PR should ensure medical gases are stored in suitable premises.
- The PR should ensure that the premises are suitable for the activities to be performed.

- The PR should ensure that the clinical indication for use of any medications in a manner that is different to their intended purpose is documented in patient's records.
- The PR should ensure that the centre's standard operating procedure (SOP) for screening of gamete and embryo donors is compliant with regulatory requirements and reflects current practice.
- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.

Recommendation to the Executive Licensing Panel

The centre has one critical and six major areas of concern and significant improvement is required in order for the centre to reflect suitable practices.

The inspection team notes the success rates for frozen embryo transfer in women aged under 40 are below the national average and the centre's multiple clinical pregnancy rates are unlikely to meet the target. The PR should ensure that the Quality Management System (QMS) is used to best effect to monitor and improve their success rates, manage their multiple pregnancy rate and to continually improve the quality of the service offered to patients. The inspector will continue to monitor the centre's performance.

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 within the prescribed timescales.

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 into 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 Bourn Hall group clinics' 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.

This clinic was considered to be broadly compliant in the implementation of these procedures on the basis of review of the centre's records and observation of practice on the day of inspection.

What the centre could do better

Witnessing (Guidance note 18)
The centre does not witness the discard of sperm (see recommendation 8, Code of Practice guidance 18.4).

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 Bourn Hall group clinics' procedures for screening donors at the time of the renewal

inspections of centres 0325 and 0188 were partially compliant with HFEA requirements but recommendations for improvement were made and evidence of their implementation provided. These areas of practice were a focus of this inspection.

This clinic was considered to be locally compliant in the implementation of revised donor screening procedures on the basis of audit of the centre's records and discussions with centre staff.

Payments for donors (Guidance note 13; General Direction 0001)
The Bourn Hall group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records and discussions with centre staff.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The Bourn Hall group clinics' procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records and discussions with centre staff.

What the centre could do better

Screening of donors (Guidance note 11)
The Bourn Hall group's SOP for screening of donors did not reflect current practices (see QMS section below).

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)
This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection.

The centre's premises are broadly suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

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

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

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

Laboratory accreditation (Guidance note 25)
It is important that 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 for accreditation by Clinical Pathology Accreditation (CPA) (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

The Bourn Hall group clinics' laboratories and/or third party laboratories were partially compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard at the time of the renewal inspection of centre 0325 and recommendations for improvement were made and evidence of their implementation provided.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

Infection control
This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection.

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

Medicines management
It is important that the centre has procedures in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

The Bourn Hall group clinics' procedures for management of medicines at the time of the renewal inspection of centre 0188 were partially compliant with guidance but recommendations for improvement were made and evidence of their implementation provided.

This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection. This clinic was considered to be partially compliant with guidance in the implementation of these procedures.

Pre-operative assessment and the surgical pathway
The Bourn Hall group has policies and procedures 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.

This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection. This clinic was considered to be locally compliant with guidance in the implementation of these procedures.

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy.

The Bourn Hall group clinics' 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.

This clinic was considered to be partially compliant in the implementation of these procedures as the centre's most recent data indicates that it is unlikely to meet the HFEA's multiple live birth rate target.

Procurement of gametes and embryos (Guidance note 15)
The Bourn Hall group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of the centre's audits of practice, an audit of the centre's records and discussions with centre staff.

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

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

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's audits of practice and discussions with centre staff.

Receipt of gametes and embryos (Guidance note15)
The Bourn Hall group clinics' procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's audits of practice and discussions with centre staff.

Imports and exports (Guidance note 16; General Direction 0006)
The Bourn Hall group clinics' procedures for import and export of gametes and embryos are compliant with HFEA requirements.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

Traceability (Guidance note 19)
The Bourn Hall group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

Quality management system (QMS) (Guidance note 23)
The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

The Bourn Hall group has a QMS in place that was broadly compliant at the time of the renewal inspection of centre 0188 and recommendations for improvement were made. Evidence of their implementation has been provided and some actions remain pending as the prescribed timescales are not yet due. These areas of practice were a focus of this inspection.

This clinic was considered to be partially compliant in the implementation of these procedures on the basis of review of the centre's records, procedures and discussions with centre staff.

Third party agreements (Guidance note 24)
The Bourn Hall group clinics' procedures are compliant with HFEA requirements for third party agreements.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's third party agreements and audits of suppliers.

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

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

Equipment and materials (Guidance note 26)
The Bourn Hall group clinics centres 0325 and 0188 were partially compliant with requirements to use CE marked medical devices at the time of the renewal inspections. This area of practice was a focus of this inspection and this clinic was considered to be partially compliant with the requirements to use CE marked medical devices.

This clinic was considered to be locally compliant with HFEA requirements to validate critical equipment. The Bourn Hall group has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The Bourn Hall group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff. The centre's renewal application indicates they propose to start a new activity of non-invasive assessment and the validation of this procedure was also reviewed on inspection.

Adverse incidents (Guidance note 27)
Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

The Bourn Hall group clinics' procedures for reporting adverse incidents were partially compliant at the time of the renewal inspection of centre 0188 and recommendations for improvement were made and evidence of their implementation has been provided. This area of practice was a focus of this inspection.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
The centre's medical gas cylinders are not kept in a purpose built cylinder store that allow the cylinders to be kept well ventilated (see recommendation 9, SLC T17 and Health Technical Memorandum.02-01: Medical gas pipeline systems Part B: Operational management).

Infection control
There is carpeting in several clinical areas (ward, embryo transfer room, scan room, phlebotomy room) and the flooring in the rooms used for sperm sample production is not seamless and there is no coving between the floor and the wall to prevent accumulation of dust and dirt in corners and crevices (see recommendation 10, SLC T2 and SLC T17).

Two large sharps bins were fixed to cupboards at a low level in areas that patients and children would attend. The inspection team was concerned that children or patients could be at risk of needle stick injury if they put their fingers in the sharps bin (see recommendation 10, SLC T2).

Medicines' management
The centre's register of controlled drugs included several entries that were overwritten after the identification of a previous error in drug balance levels. The inspection team acknowledges that the drugs could all be accounted for but was concerned that errors had not been corrected in accordance with regulations. In another entry, the time of administration of a drug was overwritten (see recommendation 3, SLC T2 and Misuse of Drugs Regulations 2001, schedule 20 (c) and 27). Compliance with regulatory requirements with regard to correction of errors in the controlled drugs register was identified as an issue at centre 0188 but the inspection team considered that these had been in higher risk areas than those identified during this inspection. During the inspection centre staff were able to demonstrate that learning from previous findings and

improvements to practice had been implemented across the group. However, the errors identified here had not been seen in the controlled drug registers at the other two centres.

The clinical indications for prescribing and treating patients with intralipids were not documented in their medical records (see recommendation 11, SLC T2 and Clinic Focus July 2015).

Multiple births (Guidance note 7; General Direction 0003)
Between 1 June 2014 to 31 May 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 17%. If there is no change to the centre's multiple pregnancy rate our analysis suggests that the 10% multiple live birth target is likely to be exceeded (see recommendation 2).

Quality management system (QMS) (Guidance note 23)
Corrective actions identified in audits of practice at this centre have not been implemented in the prescribed timescales (13 from 2012/2013, seven from 2014 and four from 2015).The majority of the centre's audits have clearly defined corrective and preventative actions and timescales for implementation, however a large audit of several key quality indicators (QI) was not in this standard format and the report did not include corrective actions and timescales for implementation. The QIs evaluated included accuracy and completeness of consent forms, welfare of child assessments, consent to legal parenthood and consent to disclosure to researchers. The inspection team acknowledges that some of these QIs are also evaluated within other audits and that the clinic's QMS team had already identified this as an issue and planned to use their standard report format for future audits. However, the inspection team was concerned that some significant findings in the audit had not been followed up, for example there was an annotation relating to a welfare of the child assessment form in which it was unclear whether there were or were not any concerns about the welfare of the child (see recommendation 4, SLC T36).

The centre's own audit of witnessing did not identify the failure to witness at the time of disposal of sperm suggesting a failure of the audit to review compliance with regulatory requirements and guidance even though this objective is included in the audit scope. A similar recommendation with regard to reviewing audit practice against regulatory requirements was made following the inspection at centre 0188. The inspection team acknowledges that this recommendation was made only four months before the inspection at this centre and has been assured that implementation is underway and will be completed in the prescribed timescale (see recommendation 4, SLC T36).

During the inspection nursing staff were able to describe their current practices for screening gamete donors which were compliant with requirements. Recommendations for improvement were made with respect to screening of egg donors following the inspection of centre 0188. Since that inspection practices have been reviewed and revised across the group and were found to be compliant; however the SOP directing screening activity did not reflect these revised practices (see recommendation 12, SLC T33b).

Equipment and materials (Guidance note 26)
The following medical devices used by the centre are not CE marked: vitrification kit (see recommendation 1, SLC T30). The inspection team noted that this centre had implemented the recommended action identified following the inspections of centres 0325 and 0188 to seek a CE marked alternative for a non-CE marked culture medium.

However, this centre was found to be using this non-CE marked product when CE marked alternatives are available and in use in the other centres within the group.

Staff engaged in licensed activity

Person Responsible (PR)

Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (T/1055/7).

Staff (Guidance note 2)
The Bourn Hall group 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 Bourn Hall group clinics' procedures to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA requirements.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

Safeguarding
The Bourn Hall group clinics' procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection. The centre's procedures are locally compliant with safeguarding guidance.

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

This area of practice is considered to be largely centre specific and was focussed on in this inspection.

During the inspection visit the inspector spoke to a couple who provided feedback on their experiences. A further 36 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 24 of the individuals providing additional written feedback to the HFEA commenting that they have compliments about the care that they received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The Bourn Hall group clinics' 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 locally compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The Bourn Hall group clinics' procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing

relevant consent and prior to consenting to legal parenthood. However this clinic was considered to be partially compliant in the implementation of these procedures with respect to patients donating frozen embryos for research.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The Bourn Hall group clinics' 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/or sperm providers donating for benefits in kind
- egg and/or sperm providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg or sperm provider and recipient(s) (where relevant).

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

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

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

Complaints (Guidance note 28)
The Bourn Hall group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

Confidentiality and privacy (Guidance note 30)
The Bourn Hall group clinics' procedures to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors were partially compliant with HFEA requirements at the time of the renewal inspection of centre 0188 but recommendations for improvement were made and evidence of their implementation provided.

These areas of practice were a focus of this inspection and this clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

What the centre could do better

Counselling (Guidance note 3)
While patients donating fresh embryos are offered counselling, those donating frozen

embryos to research are not given a suitable opportunity to receive proper counselling about the implications of their donation (see recommendation 5, SLC R18).

Information

What the centre does well

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

The Bourn Hall group clinics' procedures for providing information were partially compliant with HFEA requirements at the time of the renewal inspections of centres 0325 and 0188 but recommendations for improvement were made and evidence of their implementation provided. These areas of practice were a focus of this inspection and this clinic was considered to be partially compliant in the provision of information with regard to donation of embryos to research.

What the centre could do better

Information
The consent form for patients donating embryos to research includes the following statement which the patient must initial to confirm their agreement: 'I/we understand that my / our donated tissue, or residues of the tissue will be stored for a maximum of 5 years.' The inspection team was not clear what this means and centre staff were not able to clarify the intention of this statement in the consent form (see recommendation 6, SLC T58).

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

What the centre does well

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

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

Legal Parenthood (Guidance note 6)
The partners of women treated with donated gametes or embryos, where the couple are neither married nor in a civil partnership, must give their consent in order to become the legal parent of any child born. If this consent is not properly taken, it can have serious consequences, such as the partner having to adopt any child born in order to become the

legal parent.

The Bourn Hall group clinics' procedures for obtaining consent to legal parenthood are compliant with HFEA requirements. This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

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. During the inspection we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and that corrective actions had been identified and taken.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
It is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

The Bourn Hall group clinics' procedures for taking consent to disclosure to researchers were considered broadly compliant at the time of the renewal inspection of centre 0188. Recommendations for improvement were made and evidence of their implementation provided.

This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection. This clinic was considered to be broadly compliant in the implementation of these procedures on the basis of review of the centre's records and data submitted to the HFEA.

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 in 40 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. 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 consent. The inspection team noted that none of these discrepancies were found on five patient/partner consents taken after April 2015. The centre's own audit of consent to disclosure to researchers also identified a discrepancy between the patient files and the data submitted to the HFEA (see recommendation 13, CH(10)05 and General Direction 0005).

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The Bourn Hall group clinics' procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities:

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records and discussions with centre staff.

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
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 Bourn Hall group clinics' procedures for screening patients were partially compliant with HFEA requirements at the time of the renewal inspections of centres 0325 and 0188 but recommendations for improvement were made and evidence of their implementation provided. These areas of practice were a focus of this inspection.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

Storage of gametes and embryos (Guidance note 17)
The Bourn Hall group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The Bourn Hall group clinics' 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.

This clinic was considered to be locally compliant in the implementation of these procedures on the basis of discussions with centre staff.

What the centre could do better

Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The Bourn Hall group clinics' procedures for keeping records at the time of the renewal inspection of centre 0188 were partially 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. Recommendations for improvement were made and evidence of their implementation provided.

This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection. This clinic was considered to be locally compliant in the implementation of these procedures on the basis of review of the centre's records, audits of practice and discussions with centre staff.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
It is important that a centre's procedures for submitting information about licensed activities to the Authority are compliant with HFEA requirements to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The Bourn Hall group clinics' procedures for submitting information about licensed activities were partially compliant at the time of the renewal inspections of centre 0325 and 0188. Recommendations for improvement were made and evidence of their implementation provided.

This area of practice is considered to be largely centre specific and local compliance was focussed on in this inspection. This clinic was considered to be partially compliant in the implementation of these procedures on the basis of review of the centre's records and data submitted to the HFEA. The HFEA register audit team found some evidence of problems with the timeliness and accuracy of this centre's submission of data to the HFEA's register of information.

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
2% (1/62) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005 and at the time of the inspection there were four instances of treatments involving the use of donated gametes where the donor does not appear to be registered with the HFEA. The audit team also identified two missing early outcome forms (see recommendation 7, SLC T41 and General Direction 0005).

Section 3: Monitoring of the centre's performance

Following the interim inspection of this centre in 2013 recommendations for improvement were made in relation to one area of major non compliance and four 'other' areas of non compliance. The PR provided information and evidence that the recommendations were fully implemented within the prescribed timescales. However some similar findings have been identified again following inspections of the centre's sister clinics: timeframes for screening and the use of non-CE marked medical device, albeit for different products.

Following the renewal inspection of centres 0325 (December 2014) and 0188 (May 2015) the PRs provided information and evidence that recommendations were fully implemented within the prescribed timescales. Pending actions will be followed up by the centre's inspector when due. However similar findings have been identified at this inspection with respect to the use of non-CE marked medical devices and corrections of errors in the controlled drugs register suggesting that learning in respect to these practices has not been implemented effectively across the group.

On-going monitoring of centre success rates

In 2015, the centre was asked to review practices with regard to multiple pregnancy rates. The PR responded to the request and during discussions at the time of the inspection, provided a commitment to keep this area of practice under review.

Areas of practice requiring action

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

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Equipment and materials 1. The following medical devices used by the centre are not CE marked: vitrification kit. SLC T30. It is noted that the HFEA's assessment framework recommends classification of this as a 'major' non compliance but in consideration that a similar	The PR should ensure that CE marked medical devices are used where possible. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients, however. In view of the previous findings and recommendations to the group it is expected that all medical devices should be CE	Noted and accepted We acknowledge that part of the vitirification kit in use is not CE marked and will implement changes to ensure that the devices used are fully compliant. There are concerns that implementing major changes	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided assurance that the recommended actions will be implemented but has requested an extension to the timescale for implementation so that careful evaluation of

recommendation was made with regard to use of non-CE marked medical devices at centres 0325 and 0188 and recommended action to use only CE marked medical devices wherever possible has not been fully implemented this has been graded as a critical non compliance.	marked by 22 December 2015. It is unlawful for manufacturer's to make non CE marked medical devices available for human application and in consideration of this the PR should also submit a notice to the Medicines and Healthcare Products Regulatory Agency (MHRA) in accordance with guidance issued in the April 2013 HFEA Clinic Focus article.	without careful evaluation to ensure the best outcomes for patients may pose a risk. We propose to evaluate / implement changes by June 2016 and hope this timeframe is acceptable. Please refer to Note 1 below for additional information relating to this finding. PR will submit a notice to the MHRA as requested	the alternative vitrification product(s) can be carried out. In view of the PR's assurances, the Executive accepts the proposed implementation date and requests confirmation that all medical devices in use are CE marked by 30 June 2016. The Executive also acknowledges the PRs confirmation that he will submit the notice to the MHRA and that they will not use non CE marked medical devices in future as stated below. Further action is required.

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Multiple births 2. Between 1 June 2014 to 31 May 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 17%. If there is no change to the centre's multiple pregnancy rate our analysis suggests that the 10% multiple live birth target is likely to be exceeded. The inspection team acknowledges that the PR has been keeping this area of practice under regular review.	The PR should review their multiple births minimisation strategy to ensure that the 10% multiple live birth rate target is not exceeded. The PR should provide the centre's inspector with an update by 22 December 2015 and quarterly updates thereafter on the review and the implementation of any corrective actions required to improve the effectiveness of the centre's multiple birth minimisation strategy.	The multiple clinical pregnacy rate (CPR) has been flagged by HFEA in recent months and, as akcowledged in this finding, is reviewed monthly at management team meetings. The Clinic is aware of the data up to May 2015 and can confirm that Q3 data has shown a reduction in multiple CPR (14.5%) . The algrothym for the number of embryos required to proceed to blastocyst culture has been updated to facilitate a reduction in multiple CPR. In	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided the requested update on the centre's review of their multiple birth minimisation strategy and a summary of the corrective actions implemented. The Executive awaits the next quarterly update in February 2016. Further action is required.

Code of Practice guidance note 7.1 (referring to General Direction 0003).		addition, data relating to frozen embryo transfer success rates is under evaluation as hgher success rates arising from these cycles may be contributing to the multiple CPR. Updates will be provided quarterly as requested - First one to be provided in February 2016	
Medicines management 3. The centre's register of controlled drugs included several entries that were overwritten after the identification of a previous error in drug balance levels. The inspection team acknowledges that the drugs could all be accounted for but were concerned that errors had not been corrected in accordance with regulations. In another entry, the time of administration of drug was overwritten.	The PR should ensure compliance with medicines' management regulations. The PR should undertake a further review of medicines management procedures and in particular consider the training requirements for all staff involved in handling controlled drugs. 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 22 December 2015.	Noted and accepted Review to be completed and a summary will be provided as requested	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Further action is required.

Misuse of Drugs Regulations 2001, schedule 20 (c) and 27. SLC T2. It is noted that the HFEA's assessment framework recommends classification as an 'other' non compliance but in consideration that a similar recommendation was made with regard to alterations in the controlled drugs register following inspection at centre 0188 this has been graded as a major non compliance.	Within three months, the centre should carry out an audit of medicine management procedures to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 22 March 2016.	Audit to be completed and a summary will be provided as requested	
Quality management system 4. Corrective actions identified in audits have not been implemented in the prescribed timescales (13 from 2012/2013, seven from 2014 and four from 2015). The majority of the centre's audits have clearly defined corrective and preventative	The PR should ensure that all audits have documented corrective actions and timescales for implementation, that corrective actions are implemented in a timely manner, and that audits assess compliance with regulatory requirements. The PR should review the	Noted and accepted 2012 CAPA have now been	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Further action is required.

actions and timescales for implementation, however a large audit of several key QIs was not in this standard format and the report did not include corrective actions and timescales for implementation. The centre's own audit of witnessing did not identify the failure to witness at the time of disposal of sperm suggesting a failure of the audit to review compliance with regulatory requirements and guidance even though this objective is included in the audit scope. A similar recommendation with regard to reviewing audit practice against regulatory requirements was made following the inspection at centre 0188. The inspection team acknowledges that this recommendation was made only four months before the inspection at this centre	findings of audits performed since the last inspection and ensure that overdue corrective actions from 2012, 2013 and 2014 are reviewed and/or implemented by 22 December 2015. The PR should conduct a further review of the centre's audit practices in particular the recording and implementation of corrective actions and the auditing of practices against regulatory requirements. 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 22 December 2015. The PR should review the findings of audits performed since the last inspection to ensure that any corrective actions identified have been fully implemented. A summary of the findings of this review including any corrective	completed. A review of 2013 / 2014 CAPA will be completed within the timeframe requested. Review to be completed and a summary will be provided as requested Review to be completed and a summary will be provided as requested	

and has been assured that implementation is underway and will be completed in the prescribed timescale SLC T36.	actions identified and timescales for implementation should be provided to the centre's inspector by 22 March 2016.		
Counselling 5. While patients donating fresh embryos are offered counselling, those donating frozen embryos to research are not given a suitable opportunity to receive proper counselling about the implications of their donation. SLC R18.	The PR should ensure that patients donating frozen embryos for research are offered the opportunity to receive counselling about the implications of their donation. The PR should advise the HFEA of the actions taken to ensure this is done when responding to this report. Within six months, the centre should carry out an audit of the offer of counselling to patients donating frozen embryos to research to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 22 March 2016.	Noted and actions detailed in Note 2 below have been initiated. Audit to be completed and a summary will be provided as requested	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Further action is required.

Information 6. The consent form for patients donating embryos to research includes the following statement which the patient must initial to confirm their agreement:: 'I/we understand that my / our donated tissue, or residues of the tissue will be stored for a maximum of 5 years.' The inspection team were not clear what this means and centre staff were not able to clarify the intention of this statement in the consent form. SLC T58.	The PR should ensure that proper information and clear consent forms are in place for patients considering donating their embryos to research. The PR should review the consent form against regulatory requirements and ensure that it is clear to the patient what they are providing their consent for if donating their embryos to research. A copy of the updated form and any other revised patient information (indicating the changes made) should be provided to the centre's inspector when responding to this report.	Noted - please see above and Note 2 below A copy of the draft revised document is appended. This has been provided to HFEA by the collaborating centre and will be submitted to their LREC for approval before being implemented into routine use at Cenre 0100.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The Executive requests that the PR informs the centre's inspector when the revised form has been implemented. Pending the introduction of new consent forms, the PR is advised to ensure that centre staff who are asking patients to give consent using this form are able to explain the meaning of the statement. Further action is required.
Obligations and reporting requirements 7. 2% (1/62) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should confirm that treatments identified as not	The missing donor registration information has been submitted by the EDI and notified to HFEA: XXXXX – the 1993 records show the donor was XX rather than XX and the donor centre	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Further action is required.

and at the time of the inspection there were four instances of treatments involving the use of donated gametes where the donor does not appear to be registered with the HFEA. The audit team also identified two missing early outcome forms. SLC T41 and General Direction 0005.	reported at the time of the inspection have been reported to the HFEA when responding to this report. The cases of treatments using missing unregistered donors should be reviewed action taken to remedy the errors immediately. The PR should review the systems and processes used for licensed treatment data submission to identify the reasons for the various issues so that these can be identified and addressed. The review should also include consideration of any learning implemented in other centres across the group. 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 22 December 2015. The PR should conduct an audit six months after implementing any changes to confirm that any changes	was XXX rather than XXX. A pdf of the donor information form used at the time has been provided to the registry team. It is considered that the register data may be incorrect as a result of the "historical audit project". We have requested the registry team review the records to see if XX is registered at XXX and, if yes, if the register entry for XXXXX could be amended to reflect the donor that was used. XXXXX – Records indicate this is an egg share recipient from XXXXX and the V10 form has been validated and sent (29/10/2015) XXXXX – Our records show that the donor is registered but as XXXXX following a request from HFEA that the country code be added to the donor number. The form has been re-collected and sent. Review to be completed and a summary will be provided as requested	

	made to systems and processes are having the desired effect. A summary report of the findings of the audit should be provided to the centre's inspector by 22 June 2016.	Audit to be completed and a summary will be provided as requested. Note from centre's inspector: the patient codes included above have been replaced by Xs to remove any risk of identification.	

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Witnessing 8. The centre does not witness the discard of sperm. Code of Practice guidance 18.4	The PR should ensure that witnessing practices are in accordance with guidance The PR should advise the centre's inspector of measures taken to ensure that this happens by 22 December 2015.	A witnessed discard step is in the process of being added to the relevant documents . The Head of Science has issued an instruction to ensure this is adopted group wide.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Further action is required.
Safety and suitability of premises and facilities 9. The centre's medical gas cylinders are not kept in a purpose built cylinder store that allow the cylinders to be kept well ventilated. SLC T2 and SLC T17. Health Technical Memorandum.02-01: Medical gas pipeline systems Part B: Operational management	The PR should ensure medical gases are stored in suitable premises. The PR should assess the risks with respect to the current storage of medical gases. The completed risk assessment and findings, with a corrective action plan and timescales for implementation should be provided to the centre's inspector by 22	As advised at the time of the inspection, a risk assessment by BOC has been commissioned and is scheduled for 08 / 09 December 2015. We will make every effort to ensure that the documentation	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Further action is required.

	December 2015.	is provided within the timescale requested or very soon afterwards if this is not feasible (reliant on external contractor avaialbility).	
Infection control 10. There is carpeting in several clinical areas (ward, embryo transfer room, scan room, phlebotomy room) and the flooring in the rooms used for sperm sample production is not seamless and there is no coving between the floor and the wall to prevent accumulation of dust and dirt in corners and crevices. Two large sharps bins were fixed to cupboards at a low level in areas that patients and children would attend. The inspection team were concerned that children or patients could be at risk of needle stick injury if they put their fingers in the sharps bin SLC T2 and T17.	The PR should ensure that the premises are suitable for the activities to be performed. The PR should ensure that the flooring in clinical areas of the centre is of the correct design and style to meet infection control standards by 22 March 2016. The PR should conduct a risk assessment of the positioning of sharps bins throughout the centre. The completed risk assessment and findings, with a corrective action plan and timescales for implementation of actions taken to minimise the risks to patients and visitors should be provided to the centre's inspector by 22 December 2015.	While we acknowledge this aspect of the finding we wish to advise the following: an operating theatre is used for embryo transfer and is compliant with requirements. The ET room mentioned here is a waiting room for patients undergoing ET rather than a clinical procedure room. As patients are not receiving any treatment here nor required to change out of their own clothing, we consider this not to be an IC risk. The phlebotomy room usage has been changed and is now only used for discussions. We note the timeframe for the actions for the ward / scan room and sperm sample produciotn areas.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Further action is required.

		Low level sharps bins have been repositioned to a higher level. The risk assessment and associated action plan for the positioning ofsharps bins will be completed within the timeframe requested.	
Medicines' management 11. The reasons for which patients are prescribed intralipids were not documented in their medical records. SLC T2. Clinic Focus July 2015.	The PR should ensure that the clinical indication for use of any medications in a manner that is different to their intended purpose should be documented in patient's records. The PR should review the medical records for patients who have been treated with intralipids since they were introduced to clinical use in the centre to ensure that clinical indications have been documented. 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 22 December 2015.	A review has been completed and formal records of clinical indication substantiating the use of intralipid infusion were not found. As a result of this review a mechanism to capture the required information will be implemented. It is anticipated this will be avaialble from 01 February 2016.	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of the findings of the review due by 22 December 2015. In view of the timescales for implementation provided, the Executive accepts the PR's request to provide a summary report of the audit findings to the centre's inspector by 31 May 2016. Further action is required.

	Within three months, the centre should carry out an audit to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 22 March 2016.	In light of the above, we request that the audit takes place three months after the implementation date (i.e. May 2016) and the summary report be provided by 31 May 2016.	
Quality management system 12. During the inspection nursing staff were able to describe their current practices for screening gamete donors. However the centre's SOP in place on the day of inspection did not reflect current practice. Compliance with regulatory requirements of screening of egg donors was identified as an issue at centre 0188. Since that inspection practices have been reviewed and revised across the group and were found to be compliant; however the SOP did not reflect these revised practices.	The PR should ensure that the centre's SOP for screening of gamete and embryo donors is compliant with regulatory requirements and reflects current practice. A copy of the updated SOP (indicating the changes made) should be provided to the centre's inspector when responding to this report. The PR should ensure that all relevant staff across the group are updated and provided with suitable training in the updated policies, procedures and SOP. Confirmation of staff training should be provided to the centre's inspector by 22	Please see copy appended Confirmation will be provided as requested	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a copy of the updated SOP as requested. Further action is required.

SLC T33b.	December 2015.		
Disclosure of information, held on the HFEA Register, for use in research 13. Two discrepancies were found in 40 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. The centre's own audit of consent to disclosure to researchers also identified a discrepancy between the patient files and the data submitted to the HFEA. CH(10)05 and General Direction 0005.	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register. The PR should confirm that the incorrect submissions identified have been corrected when responding to this report. The PR should review the centre's systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure 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 22 December 2015.	The incorrect submissions have been corrected. Review to be completed and a summary will be provided as requested	The Executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Further action is required.

	The PR should conduct an audit six months after implementing any changes to confirm that any changes made to systems and processes are having the desired effect. A summary report of the findings of the audit should be provided to the centre's inspector by 22 June 2016.	Audit to be completed and a summary will be provided as requested	

Reponses from the Person Responsible to this inspection report

We are delighted to be working with the HFEA as a pilot scheme for group-wide inspections and hope that this initiative continues. We found the inspection to be thorough and conducted in a professional manner. We understand the reasoning behind the escalation of findings that have previously been made at the other centres within the Group. Bourn Hall Clinic staff feedback regarding the inspection process is that we observed several areas where there was duplication of requests for information by the inspection team.

Note 1 - Finding 1 CE marking.

The Clinic staff are aware of the standard licence condition requirement to use only CE marked medical devices wherever possible. The findings at Centres 188 and 325 that related to the use of non-CE marked culture media have been acted upon across the group; CE marked media will be in use at all centres by 22 December 2015, as required by the inspectorate. We believe this demonstrates our commitment to this requirement.

In respect to the use of non CE marked devices contained within the vitirification kits currently in use at the centre, we wish to provide the following information:

In 2013 , having had disappointing results with vitrification using a CE marked product, a due diligence excercise was undertaken to identify a new method. This was a rigorous and lengthy process that included literature reviews, visits to successful units both in the UK and overseas and lengthy peer to peer discussions.

It was concluded that vitrification offered our patients a better chance of success than conventional slow freezing and the Kitazato method was considered to be the best option. Evaluation of the Kitazato vitrification kit was initiated, however during this period an improved Kitazato method was launched by one of the original inventors under the name Cryotech. At this point neither system was CE marked, nor was there a similar CE marked alternative, therefore the HFEA "wherever possible" clause was considered applicable. From the outset Cryotech gave assurances that CE marking was in progress, and, as no such commitment was received from Kitazato the Cryotech methodology was adopted.

The training and evaluation process included attendance at workshops both in Barcelona and London and hands on training for every embryologist from Cryotech's technical director. After a 2 year process we concluded that the method was fit for purpose and was introduced into clinical use at our Cambridge clinic in January 2015.

The CE marking process is still ongoing and is currently only awarded to the vitrification device itself; the soluitions used in conjunction with the vitrification device are not yet CE marked, however we believe this demonstrates Cryotech's commitment to achieve this requirement.

In the interim period Kitazato have achieved CE marking for their device and for one version of vitrification solutions. We propose to adopt the use of the Kitazato solutions with the Cryotech device however this will require evaluation and changes to our practices, procedures and suppliers. These changes cannot be made without full and rigorous training, assessment and review recognising our patient's best interests are paramount.

We have reviewed the work entailed and believe that we can complete a switch over to CE marked solutions by 30 June 2016. In addition we wish to confirm that we will not switch to using non CE marked products in the future and let you know of any such plans under consideration.

Note 2 - Finding 5 / 6 - Counselling / Information

The same issues were raised during our Collaborators' HFEA inspection, which took place the week following this inspection. Centre 0100 is working in conjunction with the collaborating centre and HFEA / LREC to ensure that updated documents are

available to patients wishing to donate embryos to research. A copy of the draft information sheet / consent form is appended for information only.

It is recognised that the review / approval process for this new document may take some time and in the interim period it is proposed that the existing documents continue to be used. The offer of counselling to all patients expressing an interest in donating to research will be made by the reasearch co-ordinator in writing by means of a cover letter and a copy of the counselling patient information sheet. The offer of counselling will also be noted in the patients records.