Executive Licensing Panel - minutes

Centre 0325 (Bourn Hall Clinic Norwich)

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

1.2. The panel noted that Bourn Hall Norwich is part of a group that incorporates three other HFEA licensed centres; centre 0100 Bourn Hall Clinic, centre 0188 Bourn Hall Clinic (Colchester), centre 0363 Bourn Hall Clinic Wickford and a 'satellite' service at Bourn Hall Clinic, King's Lynn. All of these clinics are centrally managed and have common practices and procedures, in particular the quality management system (QMS).

1.3. The panel noted that, at the centre's renewal inspection in November 2018, eight 'major' and five 'other' areas of non-compliance or poor practice were identified. Given the significant areas for improvement identified, the executive held a management review meeting in accordance with the HFEA Compliance and Enforcement Policy to evaluate the centre's performance. The executive was concerned that the centre's processes for ensuring patients' consent was provided appropriately were inadequate and that 'welfare of the child' assessments were not robust. There had also been a 'near-miss' in relation to an error in consent to legal parenthood documentation which had not been identified by centre staff before the provision of treatment.

1.4. The panel noted that the executive recommended the renewal of the centre's treatment and storage licence for a period of three years, rather than the usual four and, that the executive would take into account the findings of the planned licence renewal inspections of the three other centres in the Bourn Hall group to determine when to conduct an interim inspection at this centre. The Executive Licensing Panel (ELP) endorsed the executive's recommendation and encouraged the inspectorate 'to consider that, lessons learned by other centres in the group, where there had been evident failings in the past, had not resulted in effective processes being in place regarding the taking and checking of consent at this particular centre.'

1.5. The panel noted that the targeted interim report presented also considered whether recommendations for improvement from the centre's previous inspection and from non-compliances identified during the inspections of the other centres in the Bourn Hall group have been fully embedded into the centre's current practices. This report is being considered by ELP together with the report of the renewal inspection of centre 0363 and an executive update on progress with implementation of recommendation made following the renewal inspection of centre 0100 in September 2019.

1.6. The panel noted that, in the 12 months to 30 November 2019, the centre had provided 433 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a small sized centre.

1.7. The panel noted that, HFEA held register data, for the year ending 31 October 2019, show the centre's success rates, in terms of clinical pregnancy, are in line with the national average.

1.8. The panel noted that, in 2018, the centre reported 4 cycles of partner insemination, with one pregnancy. 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 31 October 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be statistically lower than the 10% multiple live birth rate target.

1.10. The panel noted that a targeted unannounced inspection took place on 14 January 2020.

1.11. The panel noted that at the time of inspection there were four major areas of non-compliance concerning the QMS, premises and facilities, fees and legal parenthood. Since the inspection visit, the Person Responsible (PR) has given a commitment to fully implement all the recommendations made in the report, within the required timescales, and has confirmed the actions taken to date.

1.12. 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 the recommendations.

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

1.14. The panel noted that, progress with the required actions, and those following recent inspections of other centres in the Bourn Hall group, were followed up by the centre's inspector at the scheduled renewal inspection of centre 0363 (Bourn Hall Clinic Wickford), which took place on 25 and 26 February 2020. The report of the renewal inspection of centre 0363 and an update on progress with implementing recommendations following the renewal inspection of centre 0100 (Bourn Hall Clinic) in September 2019 are also for consideration by the ELP at this meeting.

1.15. The panel noted that the inspectorate recommended the continuation of the centre's treatment storage licence.

2. Decision

2.1. The panel raised particular concern about the ongoing issues relating to the collection of data at the centre, noting that similar non-compliances had been identified at previous inspections, hoping these would all be rectified in the near future.

2.2. The panel was satisfied with the centre's actions, to date, to address the non-compliances identified in the targeted inspection report, given the current restrictions due to Covid-19 pandemic.

2.3. The panel was satisfied the centre was fit to have its treatment and storage licence continued.

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

Targeted Interim Inspection Report

Centre name: Bourn Hall Clinic Norwich.
Centre number: 0325.
Date licence issued: 1 May 2019.
Licence expiry date: 30 April 2022.
Date of inspection: 14 January 2020.
Inspectors: Karen Conyers (lead), Polly Todd and Bernadette O'Leary (HFEA observer).
Date of Executive Licensing Panel: 21 April 2020.

Purpose of the report

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

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLCs).

The HFEA undertook a licence renewal inspection of this centre in November 2018. The Executive Licensing Panel (ELP) which considered the report of the inspection in February 2019 adjourned their decision regarding the renewal of the centre's licence pending updates being provided by the centre on progress with the implementation of recommendations. The executive provided the requested updates, and these were considered by ELP on 9 April 2019. The ELP endorsed the executive's recommendation to renew the centre's licence for three years, rather than the usual four, and that the timing of the interim inspection should be at the discretion of the executive.

This is a report of a targeted unannounced interim inspection together with our assessment of the centre's performance based on other information. The inspection was focused on reviewing all actions taken by the centre in response to the findings of the licence renewal inspection in November 2018, and recent inspections of other centres in the Bourn Hall group. The inspection also reviewed areas of practice which would usually be considered at an interim inspection. The current foci for an interim inspection are:

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

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

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

Summary for the Executive Licensing Panel

Summary for licensing decision

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

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

The ELP is asked to note that this report makes recommendations for improvement in relation to four major areas of non-compliance or poor practice.

Since the inspection visit, the Person Responsible (PR) has given a commitment to fully implement the following recommendations within the required timescales and has confirmed the actions taken to date. 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 the recommendations.

Major areas of non-compliance:

- The PR should ensure that non-compliant findings in the centre's audits are fully investigated, and that the actual root cause is identified so that effective corrective actions can be implemented.
- The PR should ensure that medical gases are stored in line with gas storage regulations when in use and/or being stored.
- The PR should ensure fees payable to the HFEA are made within the required timeframe.
- The PR should ensure that the centre's processes for recording marital and civil partnership status are robust.

Progress with these actions and those following recent inspections of other centres in the Bourn Hall group were followed up by the centre's inspector at the scheduled renewal inspection of centre 0363 (Bourn Hall Clinic Wickford) which took place on 25 and 26 February 2020. The report of the renewal inspection of centre 0363 and an update on progress with implementing recommendations following the renewal inspection of centre 0100 (Bourn Hall Clinic) in September 2019 are being considered by ELP together with this report.

Information about the centre

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

The centre provided 433 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 November 2019. In relation to activity levels this is a small centre.

Bourn Hall Norwich is part of a group that incorporates three other HFEA licensed centres; centre 0100 Bourn Hall Clinic, centre 0188 Bourn Hall Clinic (Colchester), centre 0363 Bourn Hall Clinic Wickford and a 'satellite' service at Bourn Hall Clinic, King's Lynn. All clinics are centrally managed and have common practices and procedures, in particular the quality management system (QMS).

At the time of the centre's renewal inspection in November 2018 eight 'major' and five 'other' areas of non-compliance or poor practice were identified. Given the significant areas for improvement identified, the executive held a management review meeting in accordance with the HFEA Compliance and Enforcement Policy to evaluate the centre's performance. The executive was concerned that the centre's processes for ensuring patients' consent was provided appropriately were inadequate and that 'welfare of the child' assessments were not robust. There had also been a 'near-miss' in relation to an error in consent to legal parenthood documentation which had not been identified by centre staff before the provision of treatment.

In view of this the executive recommended the renewal of the centre's Treatment and Storage licence for a period of three years, rather than the usual four and, that the executive would take into account the findings of the planned licence renewal inspections of the three other centres in the Bourn Hall group to determine when to conduct an interim inspection at this centre. The ELP endorsed the executive's recommendation and encouraged the inspectorate 'to consider that, lessons learned by other centres in the group, where there had been evident failings in the past, had not resulted in effective processes being in place regarding the taking and checking of consent at this particular centre.'

This is a report of a targeted interim inspection which also considered whether recommendations for improvement from the centre's previous inspection and from non-compliances identified during the inspections of the other centres in the Bourn Hall group have been fully embedded into the centre's current practices. This report is being considered by ELP together with the report of the renewal inspection of centre 0363 and an executive update on progress with implementation of recommendation made following the renewal inspection of centre 0100 in September 2019.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

HFEA held register data for the year ending 31 October 2019 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages

For the year 2018 the centre reported four cycles of partner insemination with one clinical pregnancy. This represents a clinical pregnancy rate which is comparable with the national average.

Multiple births[2]

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

HFEA held register data for the year ending 31 October 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

Areas of practice reviewed

Consent and 'welfare of the child' assessments

At the renewal inspection of this centre in November 2018 the inspection team identified a number of non-compliances in relation to the completion of consent forms and 'welfare of the child' assessments that had not been identified by the centre prior to provision of treatment or donation. Since the time of that inspection, similar issues in relation to consent forms were noted at the licence renewal inspection of centre 0188 in May 2019.

As a result of these findings the PRs of the Bourn Hall group appointed 'Quality Control (QC) Coordinators' to undertake additional checks of all documentation to ensure that any errors or omissions are identified prior to treatment. Furthermore, the Bourn Hall group has recently implemented an electronic consent platform which includes algorithms to address typographical errors such as incorrect dates of signing and incomplete sections of consent forms which were some of the issues identified previously. The inspection team was informed that this platform was introduced at centre 0325 in late 2019, and no issues in relation to the completion of consent and 'welfare of the child' assessments have been noted since that time.

The centre's most recent audits of consent forms were reviewed during the inspection, and the findings are discussed in the 'Quality management system' section below.

Screening of donors

Several issues in relation to the screening of donors were identified at the time of the inspections of this centre in November 2018 and centre 0188 in May 2019. Actions taken in response to those findings were reviewed at the time of the licence renewal inspection of centre 0100 in September 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

[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%.

regulatory requirements and recently released professional guidelines (UK guidelines for the medical and laboratory procurement and use of sperm, oocyte and embryo donors (2019)).

During the inspection the Medical Director was able to provide an update on progress with this overhaul and confirmed that the group has implemented the key changes recommended in the professional guidelines introduced in June 2019. Full implementation of all changes to processes are to be completed by 18 March 2020, and progress with this will continue to be monitored by the centre's inspector.

Quality Management System (QMS)

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

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: medicines management; infection control; legal parenthood; consent; witnessing.

The centre's procedures for auditing and acting on the findings of audits were reviewed and the following issues were noted (see recommendation 1).

- One of the findings in the centre's audit of records of treatments between 1 May 2019 and 30 September 2019 was an omission in a MT ('Men's consent to treatment and storage') form where section 6.2 'consent to the use of your embryos' had not been completed. The form was dated 1 July 2019 and the patients had undergone treatment. In another of the centre's audits of records of treatments between 1 May 2019 and 30 September 2019 (still being finalised), it was noted that there was an error in the date of signing of a WT ('Women's consent to treatment and storage') form, and in another case section 6.5 'posthumous birth registration' of the MT form has not been completed.

  Initially the inspection team was concerned that the 'QC check' had not been effective in identifying the errors and omissions in these cases. Soon after the inspection the PR reviewed these records and noted that in two cases there had been previous correctly completed consent forms on file and new forms were not necessary, and that the auditors had not reviewed the previous forms. The PR also informed the inspection team that 'The errors occurred prior to the training and employment of the QC Coordinator.' One of the actions following the identification of these errors was to provide staff with additional training in consent and completing the 'quality control' check, which was completed on 14 November 2019. Shortly after the inspection the centre's Head of Quality Assurance informed the centre's inspector that over the previous three months of 'QC' checks 94% of consent forms were completed correctly, and issues identified in the 6% of non-compliant forms were corrected prior to treatment.

  The inspection team was concerned that whilst the audit accurately recorded that incorrect consent forms were in the patient's records; it was not until the audit was

discussed during the inspection that further investigations were undertaken. Only at this point was the PR able to satisfy himself that previous correctly completed consent forms were in place in two cases.

In one audit report, the root cause for the error in the consent form was noted as 'missed prior to treatment and QC check'. The inspection team did not consider this to be the root cause of the failure. A similar concern regarding the centre's ability to identify the actual root cause of non-compliances in audits was also noted during the inspection of centre 0188 in May 2019.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture, then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- leadership
- patient support
- extension of storage consent
- consent
- screening of donors
- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood

The centre has been effective in ensuring compliance with guidance issued by the HFEA, however the inspection team was concerned that the learning from findings at previous inspections has not yet been fully embedded, as discussed above and in the 'Legal parenthood' section below.

The inspection team noted that the success rate on the centre's website do not include live birth rate data per embryo transferred, and the PR confirmed that this will be implemented across the group by the end of March 2020.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

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

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

Staffing

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

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

Medicines management

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

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

Prescription of intralipid 'off label'

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

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

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

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

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

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

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

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

The CE mark status of the following medical devices was reviewed in the course of the inspection: culture media and plastic ware. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support
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.

Patient feedback
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 four patients have provided feedback in the last 12 months, giving an average 2.5 star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to.

The low level of feedback through the HFEA's website has been noted at 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's waiting room and toilets 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 centre's own most recent patient survey responses were reviewed. The survey included patients who had undergone treatment between August and November 2019, and a total of twenty-three responses were received from 120 electronic surveys that were issued. This is a 19% return rate, similar to that seen at other centres in the Bourn Hall group. The PR continues to consider ways to increase the amount of feedback from patients. 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 inspection team noted that of the respondents, 91% would recommend the centre to a friend or relative. There were several positive comments complimenting the support from staff, but there were negative comments relating to support after treatment, accessibility of the counselling service and clarity of costs. The PR confirmed that whilst the feedback is anonymous, patients are offered a chance to discuss their feedback with a member of staff should they wish, and that all feedback is reviewed at 'Operations Group' meetings where trends can be identified and any corrective actions planned.

No patients were available to speak to the inspectors during the inspection.

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

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

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is not compliant with the HFEA requirements for the following reasons.

- On the day of the inspection there was a free-standing oxygen cylinder in the recovery area that was not secured in line with medical gas storage regulations (see recommendation 2).
- Fees payable to the HFEA have not always been paid within the required timeframe (see recommendation 3). Since the time of the last inspection in November 2018 the centre has been issued with eight risk tool alerts related to the late payments of HFEA invoices, which is not compliant with the requirements of the Authority.

Compliance with recommendations made at the time of the last inspection

Following the licence renewal inspection in November 2018, recommendations for improvement were made in relation to eight 'major' and five 'other' areas of non-compliance or poor practice.

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

On-going monitoring of centre success rates

Since the last licence renewal inspection in November 2018 the centre has not received any clinical performance related risk tool alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA. There are currently no significant data submission issues at this clinic.

Legal parenthood

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

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the last inspection in November 2018, legal parenthood consenting processes were found to be partially compliant with requirements because one couple had completed the incorrect consent to legal parenthood forms, however no pregnancy resulted from their treatment, so it was considered a near-miss. During the inspection of centre 0188 in May 2019, four cases were identified where there was no consent to legal parenthood forms or anomalies in consent forms which directly impacted on children born or to be born. Details of these findings are described in the inspection report of that centre, however as a result of these cases the PR agreed to a voluntary cessation of treatments with donor sperm or embryos created with donor sperm until such time that the HFEA was satisfied that the centre's processes for obtaining consent to legal parenthood were robust. The voluntary cessation was lifted in August 2019. At the time of the inspection of centre 0100 in September 2019, the inspection team was able to conclude that the processes used to obtain legal parenthood consent at that centre were compliant with HFEA requirements.

To provide assurance of the continued compliance and effectiveness of this centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Seven 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 obtain consent legal parenthood consent at this centre are compliant with HFEA requirements, however the following concern was noted.

- In one record there had been a change in the patient's surname to her partner's surname indicating that they may have married or entered a civil partnership since their previous treatment, and a PBR form ('Your consent to being registered as the legal parent in the event of your death') had been completed prior to their subsequent treatment. However, there was no evidence confirming the change of

marital or civil partnership status e.g. marriage certificate or similar, record of a discussion etc. Centre staff informed the inspection team that there is a process in place for patients to document changes in their details, but there was no evidence of this document in this case. Whilst the PBR is the correct form to be used for couples that are married or in a civil partnership, the inspection team was concerned that there is a risk that the legal parenthood status of a child could be impacted if marital / civil partnership status is not established and as a result the correct documentation is not completed before treatment (see recommendation 4).

Shortly after the inspection the PR confirmed that the couple were married and had provided evidence to confirm their marital status.

Similar issues in relation to ensuring robust recording of marital and civil partnership status were raised at the previous inspections of centre 0188 May 2017 and May 2019. Therefore, the inspection team was concerned that actions taken to address previous findings had not been effective.

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.

Whilst the centres within the Bourn Hall group have been subject to some regulatory scrutiny, 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. However, the PR is encouraged to fully engage with all aspects of the centre team's work to ensure effective leadership is consistently demonstrated.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None identified			

‘Major’ 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 child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise a combination of several ‘other’ areas of non compliance, none of which on their own may be major but which together may represent a major area of non compliance.

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

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. QMS As described in the body of the report, actions taken in response to audit findings were not satisfactory because further investigations were not undertaken, and that in some instances the actual root cause of the non-compliance was not identified. SLC T32 and T36.	The PR should ensure that non-compliant findings in the centre’s audits are fully investigated, and that the actual root cause is identified so that effective corrective actions can be implemented. The PR should ensure that immediate actions are taken to address the issues noted (which have been raised in previous inspections) and provide a summary of the actions taken when responding to this report.	At the time of the inspection one of the audit reports viewed was in progress and had only just been completed by the auditor, therefore the finding and root cause had not been discussed with the auditee. We will only provide audit reports to the inspectors that have been completed in future. We agree that there was one root cause that was not adequate and we are going to conduct 'root cause analysis' training in 2020. We will review the audit reports and ensure suitable	The executive acknowledges the PR’s response. The executive noted that one of the audit reports was not yet finalised, however it remains concerned that the person asked to complete the ‘root cause’ section of the report did not appear to have an understanding of what constitutes an actual root cause. It is expected that staff designated responsibility for ascribing a ‘root cause’ will have had training before undertaking this activity.

	As similar issues have been highlighted during several inspections of the Bourn Hall group, the PR should 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 should advise the centre's inspector of the timescale for achieving this when responding to this report.	root causes and corrective actions have been identified. With regards to commissioning a review of the centres auditing,we feel this is unnecessary as we are already audited annually by independent bodies, which includes a review of our audits and audit process: 1) An independent qualified IRCA Lead Auditor conducts an annual audit of our QMS 2) UKAS annually assess our Laboratory and Andrology services for ISO 17025 accreditation 3) We are audited annually for our certification to ISO 9001:2015 and ISO 27001:2013 All auditors are trained and their competencies reviewed annually.	The executive notes that 'root cause analysis' training is to be completed in 2020. The executive urges the PR to implement this training as soon as possible. The executive notes that the PR considers that the recommendation to commission an independent review of the centre's auditing and audit review processes is unnecessary because they are already audited annually by other external bodies. The most recent audit conducted by a lead IRCA auditor (in December 2019) was reviewed during the inspection of centre 0363 on 25 and 26 February 2020. The findings of that inspection are being considered by this ELP. Following the findings on recent inspections across all centres in the Bourn group 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 executive will liaise with both PRs of the Bourn Hall group centres to confirm a timescale for completing this. **Further action is required.**
2. Premises and facilities On the day of the inspection there was a free-standing oxygen cylinder in the recovery area that was not secured in line with medical gas storage regulations. The lead nurse confirmed that the cylinder had been removed from the area immediately on the day of the inspection. DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Part B	The PR should ensure that medical gases are stored in line with gas storage regulations when in use and/or being stored. When responding to the report the PR should confirm that all gases are now stored securely. The PR should review the centre's processes for ensuring that medical gases are stored in line with gas storage regulations when in use and/or being stored to	The oxygen cylinder that was free-standing was empty. It had been recently replaced by a full one that was stored in line with the gas storage regulations. All gases are stored securely. All staff have received medical gas training, and have been reminded of the gas storage requirements.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR states that the free-standing oxygen cylinder was empty. However, the executive notes that guidance on the safe handling of medical gases does not distinguish between full or empty cylinders. It is expected that staff handling medical gases treat empty cylinders with the same precautions as full ones, as it

Operational management (2006) section 8.	consider why this non-compliance had occurred. A summary report of the findings of this review including corrective actions, with timescales for implementation, should be provided to the centre's inspector when responding to this report.		is likely that some gas remains and could still be a potential safety risk. The PR has confirmed that all staff have received medical gas training and have been reminded of the gas storage regulations. **No further action is required.**
3. Fees Fees payable to the HFEA have not always been paid within the required timeframe. SLC T9d and CH (10)02). *This is noted as an issue across all centres in the group.*	The PR should ensure fees payable to the HFEA are made within the required timeframe. Actions already taken to address this issue do not seem to have been effective therefore the PR should investigate the group's processes for the payment of fees due to the HFEA to identify where there is an obstruction to ensuring that these are made in the required timeframe. A summary of the findings of that investigation, including an immediate plan of actions to be taken to resolve this ongoing issue across the group, should be provided	As previously discussed with the HFEA, late payments from the NHS continues to be the obstruction, however, we will endeavour to pay future invoices promptly. The finance department have been repeatedly reminded of this issue.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. As acknowledged by the PR this issue has been raised previously and he has repeatedly reminded the finance department. Progress with this was followed up by the centre's inspector at the inspection at centre 0363 on 25 and 26 February 2020. The findings of that inspection are being considered by this ELP.

	when responding to this report.		The executive notes that since January 2020 no further risk based assessment tool alerts in relation to finance have been issued to any of the centres in the Bourn Hall group. The centre's inspector will continue to liaise with the PRs of the Bourn Hall group to ensure that HFEA invoices are paid within the timescales specified by the Authority. **No further action is required at this time.**
4. Legal parenthood In one record reviewed there had been a change in the patient's surname to partner's surname indicating that they may have married or entered a civil partnership since their previous treatment, however there was no evidence confirming the change of marital or civil partnership status. CoP 6.7.	The PR should ensure that the centre's processes for recording marital or civil partnership status are robust. Actions already taken to address these issue highlighted at a previous inspection of the group do not seem to have been effective, therefore the PR should advise the centre's inspector what further actions are going to be taken to ensure that staff follow the centre's processes for accurately recording marital or civil partnership	We have reviewed the SOP/ Work Instruction and form regarding the change of patients marital status and have identified amendments to be made. These will be updated by 28 February 2020.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Progress with this was followed up by the centre's inspector at the inspection at centre 0363 on 25 and 26 February 2020, and it was noted that the amendments to the procedure, work instruction and form had been completed. The findings of that inspection are being considered by this ELP.

	status. A summary of the actions taken should be provided when responding to this report. Within three months of this, the PR should carry out an audit of practice to ensure that the corrective actions implemented have been effective. A summary report of the findings of the audit should be provided to the centre's inspector by 14 May 2020.		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 the audit of practice. **Further action is required.**

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement are any areas of practice in which failings occur, which cannot be classified as either a critical or major area of non compliance, but which indicate a departure from statutory requirements or good practice.

An ‘other’ area of non compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None identified.			

Additional information from the Person Responsible
I appreciate the constructive input of the inspection team.