Unannounced Inspection Report

Bourn Hall Clinic
0100

Date of Inspection: 5th February 2009
Date of Licence Committee: 20th April 2009

Centre Details

Person Responsible	Dr Mike Macnamee
Nominal Licensee	Mr Peter Brinsden
Centre name	Bourn Hall Clinic
Centre number	0100
Centre address	Bourn Hall Bourn Cambridgeshire CB23 2TN 01954 719111
Type of inspection	Unannounced.
Inspector(s)	Andy Leonard (Inspector, HFEA) Ellie Suthers (Inspector, HFEA)
Fee paid	N/A
Licence expiry date	L0100-13-a 31st March 2012
NHS/ Private/ Both	Private Centre; NHS and private patients

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About the Inspection:

This inspection visit was carried out by two HFEA inspectors on 5th February 2009 and lasted for 6.5 hours. The inspection was unannounced. It was performed to ensure that HFEA risk assessment was accurate. A small number of Centres is randomly sampled in this way for quality assurance purposes. The inspection team had no indication or evidence of any problems at the centre prior to inspection.

The purpose of the inspection is also to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are compliant with the EU Tissue and Cells Directive 2004/23/EC. An unannounced inspection focuses on key areas of activity and on issues which arose at the last inspection. Such unannounced inspections do not cover the breadth of issues which are investigated by licence renewal or interim inspections.

The report summarises the findings of the inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the HFEA licence Committee. The report is made available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the centre and Person Responsible

Centre 0100 was first licensed in 1991. The current licence was granted on 5th July 2007 and will expire on 31st March 2012. The centre is licensed for: in-vitro fertilisation (IVF); intracytoplasmic sperm injection (ICSI); insemination; treatment with donor gametes and embryos; processing of gametes and embryos; procurement and distribution of gametes and embryos. storage of eggs, embryos and sperm; mechanical and laser-assisted hatching.

The premises are based within a converted manor house and an adjacent purpose-built facility. The premises are extensive and provide an adequate, clean, private, well maintained and functional environment for patients and centre staff, and clinical and laboratory processes. It is a large, active centre, providing approximately 1450 treatment cycles in the last year. In 2006, the most recent year for which a full and confirmed data set is available for all centres, the live birth success rate for IVF/ICSI at the centre was within the top 15% of all UK centres[1]. The centre also has success rates for IVF/ICSI and donor insemination (DI) in the age groups <35 years and 35-37 years which are above the UK national average[1].

The Person Responsible (PR) is appropriately qualified to discharge his duties, as outlined in Section 17 of the HF&E Act (1990). He has completed the HFEA PR Entry Programme and was familiar with all clinical, nursing, laboratory, administrative and managerial aspects of the service. He is well supported by experienced staff and an established management team.

Centre activities[1] for the time period 1st November 2007 to 31st Oct 2008

ACTIVITY	CYCLES
In vitro fertilisation (IVF)	604 cycles
Intracytoplasmic sperm injection (ICSI)	687 cycles
Frozen embryo transfer (FET)	444 cycles
Donor insemination (DI)	30 cycles
Egg donation or share provider	19 cycles
Egg recipients or share recipient	7 cycles
Gamete intrafallopian transfer (GIFT)	NO
Research	YES (R0167)
Storage gametes/embryos	YES

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. 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.

Summary for Licence Committee

The inspection was unannounced. It was performed to ensure that HFEA risk assessment was accurate. A small number of Centres is randomly sampled in this way for quality assurance purposes.

The current licence L0100-13/a was granted on 5th July 2007 and will expire on 31st March 2012. The centre is licensed for: in-vitro fertilisation (IVF); intracytoplasmic sperm injection (ICSI); insemination; treatment with donor gametes and embryos; processing of gametes and embryos; procurement and distribution of gametes and embryos. storage of eggs, embryos and sperm; mechanical and laser-assisted hatching.

It is a large, active centre providing approximately 1450 treatment cycles in 2007. In 2006, the live birth rate for IVF/ICSI in all patients at the centre was in the top 15% of all UK centres. In 2006, the centre had success rates for donor insemination (DI) in the age groups 35-37 years above the UK national average. Success rates for IVF/ICSI and DI in all other age groups were comparable with the national averages.

Sufficient numbers of appropriately qualified and competent staff are employed at the centre and there is an organisational structure in place which defines accountability, responsibility and reporting relationships. The Person Responsible is appropriately qualified to discharge his duties, as outlined in Section 17 of the HF&E Act (1990). He was familiar with all clinical, nursing, laboratory, administrative and managerial aspects of the service. He is well supported by staff and an established management team.

The centre is ISO 9001 accredited and operates an effective quality management system. The premises are based within a converted manor house and a purpose-built unit. The premises are extensive and provide an adequate, clean, private, well maintained and functional environment for patients and centre staff, and clinical and laboratory processes.

Review of patient records and consenting processes indicate that the patient consultations ensure patients are well informed about their treatment and have opportunities to ask questions of clinical staff before completing consent forms. Consent forms and welfare of the child assessments were all completed appropriately. Patient information content was not assessed at this inspection but was considered appropriate at the inspection in August 2007.

Clinical and laboratory practices were appropriate, with the exception of one issue, detailed below.

Improvements are needed in:

- Payment of HFEA invoices
- Validation of key equipment and processes
- Clearing errors on EDI entry

The inspection team recommend that progress in addressing these regulatory issues should be made within the timescales specified. From the evidence seen on the day of inspection, the inspectorate are satisfied with all other key areas of service provided by the centre.

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		X	
2. Quality of the service	X		
3. Premises and Equipment	X		
4. Information		X	
5. Laboratory and clinical processes		X	

Breaches of the Act, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
In the year to July 2008 the centre took an average 58 days to pay invoices to the HFEA, according to HFEA Finance Department. This is potentially a breach of Licence Condition A.13.3. The centre has received 5 invoices, which it disputes and has only part-paid, outstanding for more than 9 months	The Person Responsible should continue to liaise with the Finance Department to review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	Immediately Progress to be monitored at the time of the next inspection.
Some equipment and critical laboratory processes have not been validated, in breach of Standard licence condition A.11.11 and Code of Practice Standard S.7.8.3	That the centre completes the validation of critical equipment and procedures which impact on gamete and embryo quality and safety.	To be completed by 31st August 2009. Progress to be monitored in the course of the next inspection.
The centre has not complied with the HFEA policy on the collection, confirmation and publication of registry data, which was attached to Direction 2008/6. This requires weekly clearing of error reports generated by the electronic data interface (EDI), with the proviso that non-clearance for 2 consecutive months will be reported to a Licence Committee	That centre staff actively liaise with HFEA registry staff to ensure accurate data entry to the HFEA register and compliance with the HFEA policy on the collection, confirmation and publication of registry data.	Immediate To be assessed at next inspection

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations

None

Changes/ improvements since last inspection in August 2007

Recommendations	Action Taken
At the last inspection, a breach of confidentiality was noted at the ground floor patient reception station, where patients are asked to sign-in. Patients which undertake this process also view the names of all other patients attending on the same day.	The PR dispensed with the written patient entry log and organised that that patients are booked in on the receptionist's computer instead. The screen for this computer is not visible to patients.
The document control system needed to be applied across all paperwork	A document control system has been implemented across all centre documents.
Monitoring of air quality needed to be formalised.	Air quality assessment has been formalised in a defined procedure. Assessment is performed quarterly in the laboratory and clinical areas, with six monthly servicing of the air flow cabinets.
At the last inspection, it was noted that the incident management protocol was last updated in 2005 and needed to be reviewed to include HFEA requirements	The centre now has a compliant incident reporting procedure which was seen by the inspectorate
Risk assessment of a locking mechanism for an unsecured cryostorage dewar.	All dewars are now locked
Patient consent documents need to be updated to reflect reference to the current CoP 7 where appropriate.	Consent forms have been updated accordingly and are reviewed annually as required

Additional licence conditions and actions taken by centre since last inspection

None

Report of inspection findings

1. Organisation

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
The centre has been licensed since the introduction of HFEA licensing in 1991. The centre's quality manual contains an organisational chart with clear lines of responsibility and communication. The Person Responsible (PR) is the Head of the Assisted Conception Unit and in overall control of licensed activity, but devolves authority to experienced departmental leads in science, medicine, nursing, administration, pharmacy, research and quality assurance. The PR has completed the PR Entry Programme and appears in control of activities at the centre and to understand the regulatory framework imposed by the HFE Act (1990) and HFEA Code of Practice, 7th edition. The PR had ensured rapid action was taken in response to all breaches and recommendations in the report of the inspection in July 2007. The centre management team have responsibility for resource management in their areas and these are integrated to provide centre-wide resource management at fortnightly management team meetings, the minutes of which were observed on inspection. That activity levels are matched to resource levels is also considered at these meetings The inspectorate was advised that risk assessments for the premises and procedures are up to date. This was the case on the last inspection when risk assessments were observed by the inspectorate. The centre has a compliant incident reporting procedure which was observed by the inspectorate and also described in detail by a senior nurse. The protocol meets with HFEA requirements. Incidents are reported to the departmental manager and on to the PR, as the incident reporting officer, who decides if the incident is HFEA reportable. The Quality Assurance (QA) department logs the incident, undertakes investigation and discusses possible corrective and preventative actions with the relevant personnel. Such actions are

logged in the corrective and preventative actions log. Incidents, where required, are discussed at the next relevant departmental and management meetings and at the next Management Review meeting .An appropriate incidents log is maintained by the centre.

Verbal complaints are directed to a senior member of nursing staff or doctor, as required, and immediate resolution attempted by them. If this is impossible, the complaint is further investigated and a written response provided to the complainant. Written complaints are processed by the QA department and reviewed by the Medical Director; an immediate acknowledgement letter is sent, followed by a letter describing investigation and explanation. All complaints and their investigation and follow up actions are noted in the complaints log maintained by the QA department.

The centre has a formalised contingency plan with HFEA centre 0030 for service provision in the event of significant failure(s) at the centre. The centre also has a disaster recovery plan as part of the ISO 9001 system.

Integrated control of the centre is achieved through fortnightly management group meetings, the minutes of which were observed on inspection and are available to all staff. Departmental team meetings are generally held monthly, though nursing staff meet fortnightly. A daily clinical meeting is held to discuss upcoming cases. Minutes from meetings were provided to the inspectorate. They were considered to be well presented and detailed, providing clear descriptions of subjects discussed and actions required.

HFEA Alerts are received by the PR and disseminated to relevant departmental managers. Urgent action can be taken if required after discussion between them. HFEA Alerts are also discussed at the management team meetings as a standard agenda item, and are discussed if relevant at monthly departmental meetings.

Areas for improvement

This centre had on the 5th February 2009 5 partly-paid invoices outstanding for 9 months or more as a result of the invoiced number of cycles not being in agreement with the centre's records regarding the number of cycles undertaken. In the last year, the centre has taken on average 58 days to pay invoices according to HFEA Finance Department. This is greater than the 28 day payment period required by Licence Condition A.13.3. The PR understands the requirements of this licence condition but considers the 5 outstanding invoices are inaccurate and have been disputed with HFEA Finance Department. It is noted that the average payment time for undisputed invoices is 38 days. The PR will continue to liaise with HFEA Finance Department to resolve invoice payment issues.

Areas for consideration

None

Executive recommendations for Licence Committee

The Person Responsible should liaise with the HFEA Finance Department to review the arrangements for payment of invoices and ensure that there are no barriers to their prompt payment. Progress in this regard should be monitored at the time of the next inspection.

Evaluation

One improvement required

Areas not covered on this inspection
Risk Management; Third Party Agreements

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
In 2007, the centre reported 1025 IVF/ICSI cycles, 423 frozen embryo transfers (FETs) and 38 donor insemination (DI) cycles. This is a slight increase on the activity in 2006 (995 IVF/ICSI cycles, 342 FETs and 15 DI cycles). In 2006, the live birth rate for IVF/ICSI in all patients at the centre was within the top 15% of all UK centres. For age stratified (<35 years; 35-37 years; 38-39 years; 40-42 years and >42 years) live birth data from 2004 – 2007 inclusive, the centre had success rates for DI in the 35 – 37 year age group significantly above the national average comparable with national averages. Success rates for IVF/ICSI and DI in all other age groups were comparable with national averages.
Areas of firm compliance
Outcome data is reviewed on a regular basis by the centre and is discussed at laboratory, clinical and quality management review meetings. The centre is ISO 9001:2000 certified and has a well developed quality management system. A new full-time Quality Manager has been appointed and will replace the existing incumbent in April 2009. A quality policy signed by the PR which defines the centre's quality objectives and commitment to good professional practice and patient needs is held within the quality manual and is available to staff and patients. The centre has a well developed quality manual available on the centre server and is organised and controlled by an electronic document control system which is in the process of being updated. The new system will allow release of documents to defined staff roles, it being defined within the system which procedures are relevant to each staff function. This allows easy organisation of audit of personnel for procedures which are essential to their function in the workplace. The quality manual contents and other procedures exhibited appropriate document control features and evidence of annual review. New/revised SOPs are notified to staff via the electronic document control system, discussed with relevant staff at monthly departmental meetings, then released to the quality manual by designated individuals. Quality management system (QMS) review and evaluation is performed every six months (November/December and May/June). A print-out of a slideshow presentation from the last

review in November 2008 and the associated minutes were made available to the inspectorate. A wide range of issues were discussed including quality indicators and centre performance, non-conformances, changes to the quality management system and quality policy, audit results and plans for the future, continual improvement plans, supplier performance, staff training and competency assessment, patient satisfaction and complaints, external quality control performance, data protection and health and safety. An analysis of audit of key performance indicators for individual clinicians and embryologists was also presented. Quality objectives are reviewed annually at the May/June review meeting. The inspectorate considered the review to be compliant with the requirements of the Code of Practice, 7th edition.

The centre has an active programme of audit organised and performed by the QA department. The results of audits are discussed with relevant heads of functions and feed into the six monthly QMS review meetings.

The centre had an incident in the laboratory in 2008. The incident was appropriately reported to HFEA and investigated and was discussed at the scientific group meeting and the management team meeting, then at the QMS review meeting. Patient information and research data regarding relevant clinical procedures and was reviewed, and a small change was made to the air quality monitoring protocol. This progression of events provides strong evidence of the functioning of an effective and compliant QMS at the centre.

Feedback from patients is obtained through patient questionnaire surveys which are permanently available. The feedback is evaluated monthly and considered at departmental team meetings, if relevant, and at the monthly management team meeting. Patient feedback is also reviewed at the 6 monthly quality management review meeting. Staff suggestions and feedback are considered at regular team meetings and at the monthly management team meeting.

Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered
Evaluation
No improvements required.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
The premises are based within a converted manor house and an adjacent purpose-built facility. On entry to the manor house through the front door (locked outside of service hours), there is a permanently staffed reception area and small waiting area, with access to toilets and a restaurant for staff and patients. The centre's licence, quality policy, healthcare commission certification and insurance were on display in reception. The remainder of the manor house building is occupied by offices for senior staff, meeting rooms and the centres administration team. The centre's clinical and laboratory facilities are in the adjacent facility accessed from the manor house via a corridor and cardkey activated doors. Ground floor windows in the laboratory were seen to have wire mesh covers on the exterior. The centre is also protected by closed circuit television. Centre security was considered to be appropriate. Out-patients are seen on the first floor of the facility, which contains a reception, comfortable waiting area, consulting rooms, scanning rooms, quiet rooms for patient discussions and counselling, staff offices and a drug training room. In-patients are seen on the ground floor, which contains two 4 bed recovery areas for egg collection and embryo transfer patients, respectively, as well as a treatment room. Emergency resuscitation equipment was present on the ground floor and the first floor which was subject to logged daily checks, in compliance with the centre's procedures and UK Resuscitation Council Guidelines[2]. Clinical areas were clean and appeared comfortable, appropriately equipped and staffed, and suitable for the centre's activities. The counselling room and production room were also considered comfortable, quiet and respectful of patient privacy and suitable for their current uses. The laboratory premises are adjacent to the theatre suite and comprise a changing room for embryologists, corridor, coffee room, offices for andrology and embryology, laboratory for andrology and ICSI, laboratory for IVF and a dewar store. The laboratory premises were considered compliant and providing appropriate premises for the centre's activities. An SOP is in place for air quality monitoring. It describes that air quality is monitored quarterly

[2] Cardiopulmonary Resuscitation Standards For Clinical Practice And Training, A Joint Statement from The Royal College of Anaesthetists, The Royal College of Physicians of London,The Intensive Care Society, The Resuscitation Council (UK), revised June 2008

in the laboratories and 'clean' clinical areas. Testing is performed by an external contractor and involves airborne particle and bacterial counts, and air flow rates and pressure differentials across the HEPA filters in the air cleansing system. Settle plates and contact plates have also recently been added to develop the protocol. The last full air quality assessment, dated 26th June 2008, was provided to the inspectorate. It showed that air quality in the laboratory is compliant with the requirements of the Code of Practice, 7th edition, being grade C or better in the air flow hoods and Grade D or better in the background air. The air quality monitoring methods are validated by the external contractor according to ISO standards

Laboratory equipment showed evidence of regular servicing and portable electrical appliance testing, and a procedure is in place for equipment servicing and maintenance. All equipment servicing and repairs are logged and key items have been risk assessed; risk assessments identify what to do with an item when it is faulty. The laboratory is equipped with a regularly tested and serviced emergency power supply, to maintain laboratory function in the event of failure of the national grid supply.

The laboratory has a complex environmental monitoring system which records parameters related to the temperature and humidity in the laboratories as well as the function of incubators, storage dewars, fridges, the oxygen level monitors and the air cleaning system. Critical parameter data are continually recorded to a laptop in the laboratory and automatically backed up for long term storage to a remote server at the centre. Non-conformities are highlighted in the log and initiate an immediate warning siren in the laboratory, a warning in the centre maintenance department and a dial out warning to those on the on-call list, which includes the Head of Science. The system has to be responded to in-order to deactivate the warning. The system allows analysis of historic data sets for key parameters to investigate non-conformity patterns. The system functions as an effective non-conformities log for key items of equipment and the environmental parameters they control, as well as satisfying the requirement for logging of key parameters influencing the quality and safety of gametes and embryos. Daily monitoring of temperatures of hot blocks and heated stages is also recorded in a log book and the centre are developing a more detailed validated method for doing this.

The main dewar store is accessed from the ICSI/andrology laboratory though three large dewars are kept in the ICSI/andrology laboratory. Given the security of the locked laboratory, the inspectorate consider the situation compliant. All dewars are connected to the environmental monitoring system which logs temperatures and liquid nitrogen levels and provides emergency call out in the event of non-conformities. The dewar store and ICSI/andrology laboratory are also fitted with low oxygen monitors connected to the environmental monitoring system. The storage facilities were considered by the inspectorate to be compliant with Code of Practice requirements.

Centre staff are provided with changing room facilities with showers, toilets and lockers, as well as a dining room. The staff facilities were compliant with Code of Practice, 7th edition, requirements.

Cleaning in the centre is provided by contract cleaning staff and the centre appeared clean and tidy on the day of inspection.

The centre premises are inspected for health and safety purposes and all areas have been risk assessed in the last year.

Areas for improvement
None
Areas for consideration
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Storage of records
Evaluation
No improvements required.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
The centre sees both NHS and privately funded patients. After initial contact with the centre, patients are sent a comprehensive patient information and consent form pack regarding treatments at the centre, and a date for their first consultation. They are also provided with dates for treatment information seminars held at the centre fortnightly which they are urged to attend. At first consultation they are reviewed by a clinician and treatment options are discussed and the couple's questions answered and the consent forms signed. They are then seen by a fertility nurse who organises their treatment pathway and answers any further questions. Counselling is also discussed in patient information and by the fertility nurse with the couple. Counselling can be arranged at the centre, or via one of three independent counsellors at their premises. The centre tries to ensure that couples are seen by the same fertility nurse throughout their treatment. The centre has a procedure to ensure that all necessary information is provided to patients and that they have an opportunity to ask questions, prior to consent forms being signed. This involves an information checklist which is kept in patient records, on which it is indicated that specified information has been supplied verbally and/or in writing. Review of 5 sets of donor and recipient records indicated consent forms had been appropriately completed. The centre has a Welfare of the Child procedure in place which ensures that the assessment is completed and reviewed and that consent for disclosure is taken. Welfare of the Child and consent for disclosure forms are normally completed, and the issues discussed, at the first nurse consultation. Review of 5 sets of donor and recipient records indicated Welfare of the Child (WoC) assessment had been appropriately completed. Access to patient records is effectively controlled. They are stored in the Nurse Coordinators office which has cardkey access restricted to defined groups of centre staff. Patients can obtain a copy of their patient records by written application to the centre, signed by both patients. Records in clinical use were also seen on the day of inspection to be securely held by centre staff.
Areas for improvement
The last HFEA operational audit visit in December 2007 found a data error rate of 3%, albeit most were in non-essential fields, and a late reporting rate of 6%. The HFEA Registry reported some concern however that the centre have not complied with the HFEA policy on

the collection, confirmation and publication of registry data, which was attached to Direction 2008/6. This requires weekly clearing of error reports generated by the electronic data interface (EDI), by which the centre log patients on the HFEA register, with the proviso that non-clearance for 2 consecutive months will be reported to a Licence Committee. This was discussed in detail with centre staff, who related that forms which passed an on-site validation test, were failing a HFEA-based validation test after being transmitted from the centre. Error reports indicated data fields had not been completed which were shown to the inspectorate to have been completed on the transmitted forms. The possibility was raised that data was being corrupted during transfer which made it difficult for the centre to comply with Direction 2008/6, even though they were working hard to do so.
Areas for consideration
None
Executive recommendations for Licence Committee
That centre staff continue to actively liaise with HFEA registry staff to ensure accurate data entry to the HFEA register and compliance with HFEA policy on the collection, confirmation and publication of registry data, which was attached to Direction 2008/6.
Areas not covered on this inspection
Patient information content
Evaluation
One improvement required

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

Registered doctors	5
Registered nurses	12
Non NMC registered nurses/health care assistants	4.4
Registered scientists	2.6
Scientists working towards registration	3
Laboratory support staff	0
Counsellors	3
Support staff (receptionists, record managers, quality and risk managers, etc).	9.4

Summary of laboratory audit
The centre performs a rolling audit of sperm and embryo storage dewars which ensures that all dewars are audited at least every two years. The Head of Science told the inspectors that the audit was up to date and had documented evidence of this. He also said that conflicts were seldom found and, if found, were immediately investigated and resolved. The procedures and audit were considered compliant by the inspectorate.
Summary of spot check of stored material
No spot check of stored material was carried out on this unannounced inspection
Areas of firm compliance
New staff and those returning from career breaks, follow a specified induction programme which includes confidentiality, welfare of the child and patient dignity/respect, as well as more specific areas which are department related, manual handling, health and safety and fire training. Staff interviewed verified the induction process, which they felt was effective. All staff undergo annual mandatory training in manual handling, health and safety and fire

training. Clinical staff are trained annually in basic life support; some complete advanced life support training. Continual professional development (CPD) was discussed with a nurse and a laboratory staffer. Both were happy that the centre supported their CPD, which involved a mix of in-house training, professional body CPD activities and conference attendance. Junior staff are encouraged to undertake certified training courses (e.g. Association of Clinical Embryologist, ultrasound scanning qualifications) and membership of professional bodies.

The centre has developed a detailed competency assessment programme. All staff have a job description which defines their core roles and the documented procedures by which they are performed. Annual appraisals are performed for all staff which include assessment of staff competency in their core roles and procedures. Competency assessment is linked to defining training needs through discussion at annual appraisal. The outcome of annual appraisal is logged for each staff member on a computer database. Embryology and medical staff competency is also monitored by comparison of key performance indicators between staff during the year.

Review of 5 sets of donor records indicated donor screening was performed according to professional body guidelines active at the times of donation. The PR immediately updated the screening protocol when the new joint professional body (ACE, BFS, ABA) donor screening guidelines were released in December 2008, and this is now used at the centre.

The centre performed 3, 5 and 5 three embryo transfers in 2005, 2006 and 2007, respectively, all in women aged 40 or over. The centre have established a protocol for selection of patients for elective single embryo transfer and provided it to the HFEA. They have also developed a log of non-compliances with that policy. These actions indicate compliance with Direction 2008/5.

A member of medical staff is contactable 24 hours a day, 7 days a week, via the centre number or an emergency number, both provided in patient information.

The centre only uses CE marked consumables and each new brand of consumable used is sperm motility tested to ensure its safety, even though CE marked. The centre has established traceability procedures; records are maintained for all plasticware and culture media on the centre's patient information management system, which lists batches and the dates on which they are changed. The incubator used for oocyte/embryo culture for each patient is logged.

All vessels in which gametes and embryos are contained are labelled with the patient and partner's names and dates of birth, and the patient's unit identification number. This facilitates compliant traceability and witnessing in the laboratory.

The Head of Science has risk assessed the manual witnessing procedure used within the centre. The centre clinical and embryology staff are all trained in witnessing procedures as part of their induction and training. Witnessing was observed during the inspection and, in the opinion of the Scientific Inspector, was compliant with the requirements of the HFEA Code of Practice, 7th edition.

The compliance of embryo and gamete storage premises was discussed in Section 3. The centre has comprehensive paper and electronic logs of samples in store and operates an appropriate bring-forward system. Separate dewars are used for quarantined and non-

quarantined samples.
Areas for improvement
The centre informed the inspectorate that they have developed a validation master plan which identifies key equipment and processes which require validation. Some equipment has been validated, e.g. dry shippers, incubators and the emergency power supply, but other critical items of equipment have not yet been validated, though risk assessments have been performed. Key processes have not been validated. The incomplete formal validation of critical equipment and processes is a breach of standard licence condition A.11.11 and Code of Practice, 7th edition, Standards S.7.8.3. The Head of Science explained that considerable progress had been made regarding validation but that the centre had then had to wait for the delivery of the Association of Clinical Embryologists validation package, developed in partnership with the HFEA, to formally document equipment and process validation. This package has only recently been released.
Areas for consideration
None
Executive recommendations for Licence Committee
It is recommended that the centre complete its master validation plan now that the Association of Clinical Embryologists validation package has been release
Areas not covered on this inspection
Counselling
Evaluation
One improvement required.

Report compiled by:

Name Dr Andrew Leonard

Designation Scientific Inspector, HFEA

Date 2nd March 2009

Appendix A: Centre staff interviewed

PR, Head of Science, Nursing Coordinator, Deputy Head of Science

Appendix B: Licence history for previous 3 years

Status	Licence	Type	Active From	Expires
Active	L0100/13/a	Treatment with Storage	05/07/2007	31/03/2012
Replaced by New Version	L0100/12/a	Treatment with Storage	01/04/2007	31/03/2012
Expired	L0100/11/b	Treatment with Storage	01/01/2006	31/03/2007
Replaced by New Version	L0100/11/a	Treatment with Storage	01/09/2005	31/03/2007
Replaced by New Version	L0100/10/b	Treatment with Storage	28/01/2005	31/03/2007
Replaced by New Version	L0100/10/a	Treatment with Storage	01/04/2004	31/03/2007

L0100/13/a
No Conditions or Recommendations on Licence
The centre had been granted an inspection holiday in April 2008 – March 2009 due to being assessed as low risk.

LICENCE COMMITTEE MINUTES
21 November 2007
Bourn Hall Clinic (0100)
Interim Inspection

1. The papers for this item were presented by Wil Lenton, HFEA Inspector. Mr Lenton informed the Committee that the centre has been licensed since 1991 and provides approximately 1200 treatment cycles last year. The centre has a good history of regulatory compliance and has been ISO accredited since 2005, with a well developed quality management system.

2. Mr Lenton further informed the Committee that the interim inspection visit to this centre took place on 24 July. He discussed the inspection report with the Committee and summarised the regulatory issues listed at page 8 of the inspection report. One of these related to the fact that when patients arrive at the centre they are shown a list containing the names of all patients expected that day. Mr Lenton informed the Committee that the centre has now changed its practice for signing in patients. Mr Lenton read from the Person Responsible's response to the inspection report and confirmed that on the basis of this

response he is satisfied that the centre is in the process of addressing all of the breaches identified by the inspection team.

3. The Committee agreed that the centre's licence should continue with no additional conditions.

LICENCE COMMITTEE MINUTES
2nd May 2007
Bourn Hall Clinic (0100)
EUTCD variation

1. The papers for this item were presented by Tahir Hussain, HFEA Inspector. Mr Hussain informed the Committee that the centre's risk rating, reflecting the degree of compliance with EUTD requirements, was 3%, in the low range.

2. The Committee noted that the centre is working towards full compliance with the requirements of the EUTD and that progress will be assessed at the next inspection visit to the centre.

3. The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

LICENCE COMMITTEE MINUTES
22nd November 2006
Bourn Hall Clinic (0100)
Renewal Inspection

1. The papers for this item were presented by Vicki Lamb, HFEA Inspector. Dr Lamb informed the Committee that this centre had a good history of regulatory compliance. The inspection team had identified one breach of the Human Fertilisation and Embryology Act 1990, which was a sperm sample being stored after the expiry of the consent to storage. The centre has since addressed this event and the reasons for it. On the day of the inspection visit, the inspection team spoke to patients and to staff. The patients, in particular, said that they were very satisfied with the treatment they were receiving. The inspection had been very positive and the inspection team recommended the licence be renewed for a period of five years.

2. The Committee decided to renew the centre's licence for a period of five years with no additional conditions.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO INSPECTION REPORT

Centre Number 0100

Name of PR Dr Mike MacNamee

Date of Inspection 5th February 2009

Date of Response 12th March 2009

Please state any comments regarding the inspection and actions you have taken or are planning to take following the inspection with time scales

The PR will continue to liase with the HFEA Finance Department to review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices: on-going.

The outstanding critical equipment and processes will be validated: by 31st August 2009.

All relevant staff to attend appropriate refresher training in HFEA registry requirements: by 30th June 2009.

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

None

HFEA Licence Committee Meeting

20 April 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 6

Bourn Hall Clinic (0100), Unannounced Inspection

Members of the Committee:	
Anna Carragher, Lay member – Chair Jennifer Hunt, Senior Fertility Counsellor, IVF Hammersmith Hossam Abdalla, Clinical Director, Lister Clinic	Committee Secretary: Kristen Veblen, assisted by Claudia Lally Legal Adviser: Sara Ellson, Field Fisher Waterhouse

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item

The following papers were considered by the Committee:

- papers for Licence Committee (35 pages)
- no tabled papers.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

1. The Committee noted that the inspection of this Centre took place on 5 February 2009. The inspection report a number of identified areas for improvement:
   - non-payment of some invoices
   - non-validation of equipment
   - non-compliance with HFEA policy on collection, confirmation and publication of registry data.

2. The Committee noted the findings of the report and the statement by the Person Responsible setting out all the work being done in addressing the identified areas for improvement and agreed they were satisfied with the actions undertaken.

3. The Committee also noted from the evidence on page 10 of the report that very full action had been taken following the previous inspection.

4. The Committee agreed that the Centre's licence should continue with no additional conditions.

Signed..... Date.....
Anna Carragher (Chair)