Inspection Report

Date of Inspection: 21 March 2012
Purpose of inspection: Interim inspection of treatment and storage licence
Length of inspection: 8 hours
Inspectors: Sara Parlett (HFEA; Lead)
Bhavna Mehta (HFEA)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 4 February 2010 and 18 May 2012.

Date of Executive Licensing Panel: 1 June 2012

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice (CoP), to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim 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 Authority's Executive Licensing Panel (ELP) which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	Bath Fertility Centre
Centre Number	0139
Licence Number	L0139/12/c
Centre Address	Royal United Hospital Combe Park Bath BA1 3NG
Person Responsible	Mr Nicholas Sharp
Licence Holder	Mr David Walker
Date Licence issued	01/09/2008
Licence expiry date	31/08/2013
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

Bath Fertility Centre is a well established centre first licensed by the HFEA in 1994.

The centre occupies detached premises in the grounds of the Royal United Hospital which is managed by the Bath NHS Trust. Treatments are provided to both private and NHS funded patients.

The centre provided approximately 500 in vitro fertilisation (IVF) / intracytoplasmic sperm injection (ICSI) cycles last year.

The Person Responsible (PR) is a Consultant Obstetrician and Gynaecologist and has been in post since the centre's inception.

The centre plans to relocate to new premises at the end of 2012. A new unit is currently being built in Peasedown St John, approximately eight miles away. The PR is aware of the need to apply to the HFEA to vary the centre's licence to relocate to new premises. This application will be submitted to the ELP for consideration in due course.

The centre last had an interim inspection in February 2010. Interim inspections focus on HFEA core themes and the current themes are, with some exceptions detailed in the report, the same as those inspected against in 2010.

It was agreed with the Head of Inspection that this interim inspection would focus only on those themes that were not covered at the previous inspection, unless there was a specific reason to do so. The rationale for this is detailed in the main body of the report.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 February 2011 – 31 January 2012*
IVF	247
ICSI	249
Frozen embryo transfer (FET)	155
Donor insemination (DI)	41
Intrauterine insemination (IUI) (01/01/2011 – 31/12/2011)	40
Egg donation (non-egg share)	4

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

Outcomes*
For IVF/ICSI/FET, HFEA held register data for the period December 2010 – November 2011 show the centre's success rates are in line with national averages with the following exception: • The clinical pregnancy rate (CPR) for IVF in the over 38 years age group is above the national average at a statistically significant level. For the year 2011 the centre reported 40 cycles of IUI with two pregnancies. This is in line with the national average.

*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 licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to draw a conclusion on the continuation of the centre's licence.

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

The ELP is also asked to note that the centre was proactive in addressing several of the areas of non-compliance highlighted on inspection soon after the inspection visit took place.

Since the inspection visit the centre has provided evidence that the following recommendations have been fully implemented:

Major areas of non compliance

- To ensure that a robust notification system is in place to remind centre staff when consent to storage of licensed material is close to expiry, to ensure that samples destined to be allowed to perish do not remain in storage past the consented period.
- To ensure that the process for assisted hatching is validated.

Other areas of practice that require improvement

- To ensure that systems are in place to confirm that consent forms are completed appropriately prior to treatment.

The PR has given a commitment to fully implement the following recommendations:

Major areas of non compliance

- To perform an audit of the consent to disclosure in patient records against the consent decisions which have been submitted to the HFEA.

Other areas of practice that require improvement

- To ensure that:
    - Witness checks are recorded at the time of the procedure;

      and
    - There is consistency between the documented frequency for auditing the centre's witnessing quality indicator (QI) and the actual frequency of audit.
- To ensure that, prospectively, all patients are screened for Hepatitis B core antigen antibody (anti-HBc).
- To:
    - Review the centre's processes to ensure that donors are registered correctly with the HFEA;

      and

      Ensure that where errors in the data submitted to the HFEA are identified, these are cleared within two calendar months.

- To regularly review staff resource levels to ensure that there is sufficient time available for the laboratory manager to allocate to the quality management role.

The inspection team considers that, overall, there is sufficient information available to recommend the continuation of the centre's licence without additional conditions. In making this recommendation, it is noted that the PR has responded to all recommendations made in this inspection report.

Details of Inspection findings

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. **Costed treatment plans** This theme was covered at the last inspection. However, it was noted that a copy of the costed treatment plan was present in the ten sets of patient notes audited on inspection (CoP Guidance 4.3). **Legal parenthood** This theme was covered at the last inspection. However, improvements since the last inspection relating to this theme are documented in section two of the report.
What they could do better. Nothing noted at the time of inspection.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. **Consent to disclosure** This theme was covered at the last inspection. However, at the time it was not standard practice to conduct an audit of patient consents to identifying information from the HFEA register being disclosed to researchers against that recorded on the HFEA register. Ten sets of patient notes were reviewed on inspection and appropriately completed consent to the disclosure of identifying information was in place in all cases, with one exception noted below. **Consent to storage** This theme was covered at the last inspection. However, it was considered proportionate to review the centre's database to determine if all gametes and embryos are currently in storage with appropriate consent. It was demonstrated, via review of the centre's database, that all embryos currently in storage have valid consent (HF&E Act 1990 (as amended) Schedule 3, Paragraph 8 (2)). All sperm samples currently in storage have valid consent, with one exception noted below (HF&E Act 1990 (as amended) Schedule 3, Paragraph 8 (1)). Ten sets of patient notes audited on inspection were found to include appropriately

completed storage consents.

What they could do better.

Consent to disclosure

In one set of notes audited on inspection, the patient's details on page one of the consent to disclosure consent form had not been completed, although all of the pages had been signed by the patient. The nurse manager explained that this may be because all patient information and consent forms are sent out to patients in one pack. The patient had completed these details on the first consent form and possibly considered that this was sufficient for all of the consent forms. The nurse manager took corrective action at the time of the inspection by first confirming the patient's identity by matching the signature and then completing the required information (General Direction 0007).

In one of the 18 registration forms audited, a discrepancy was noted where a patient had consented for research, but this consent decision was incorrectly entered on the HFEA register. This discrepancy was corrected at the time of inspection.

In two of the 18 registration forms audited, a discrepancy was again noted where a patient had consented for research, but this consent decision was not correctly recorded on the HFEA register. However, evidence was provided on inspection that the information submitted to the HFEA via the centre's database was consistent with that consented by the patient. This discrepancy will be further investigated by the Executive.

Consent to storage

The sperm samples of one patient are currently in storage without valid consent, having expired in November 2011 (HF&E Act 1990 (as amended) Schedule 3, Paragraph 8 (1)).

The centre's bring forward system for gametes and embryos in storage was described by the laboratory manager and was considered to be appropriate by the inspection team (CoP Guidance 17.18). The laboratory manager demonstrated that the bring forward procedure had been followed for this patient, but that the disposal of the sample at the end of the procedure had been missed. At the end of the inspection, the laboratory manager confirmed that these samples had been thawed and allowed to perish.

Multiple births

This theme was covered at the last inspection. However, because the centre indicated in their self assessment questionnaire (SAQ) submitted prior to inspection that they were unlikely to meet the current multiple birth rate target, this theme was covered.

For the 2010/11 time period the centre's multiple CPR for all IVF, ICSI and FET cycles for all age groups was 20%.

The centre's multiple CPR for 2010/2011 represents performance likely to be better than the target multiple birth rate of 20%.

What the centre does well.

On-going monitoring of the centre's multiple CPR suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15% (SLC T123).

The centre has a documented multiple birth minimisation strategy (MBMS), which includes how the centre identifies suitable cases for elective single embryo transfer (eSET). This includes criteria in relation to patient selection and embryo assessment (General Direction 0003, 5 (a)).

The PR has provided sufficient evidence to demonstrate compliance with General Direction 0003 in that:

- Staff were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates;
- Staff at the centre have audited their MBMS as part of the quality management audit programme. The laboratory manager explained that the last audit was performed in January 2012 and that they are planning to extend the eSET patient selection criteria, to include all women under the age of 40;
- Staff have maintained a log of women receiving multiple embryo transfers who meet the criteria for eSET, including the reasons for variation from the eSET policy and the pregnancy outcome. The laboratory manager stated that 88% of patients in 2011 who met the criteria for eSET had one embryo transferred. Evidence was seen during the patient notes audit that discussions are held with patients regarding the risks associated with multiple pregnancy (General Direction 0003, 7);
- The centre maintains a summary log of cases in which three embryos have been transferred (General Direction 0003, 1 (b)). The log demonstrated that 22 patients had three embryos transferred in 2011 and that all were over the age of 40 (CoP Guidance 7.5 (b)).

The centre's patient information was reviewed and found to be detailed in describing the risks of multiple pregnancy (CoP Guidance 7.7).

What they could do better.

Nothing noted at the time of inspection.

Validation of critical equipment and processes

What the centre does well.

Validation was added as an inspection theme by the Authority after the centre's last inspection in 2010. This theme was therefore covered in full.

Process validation

The centre's critical processes have been validated, with one exception noted below. Validation records for use of a new culture media, vitrification, IVF and ICSI were reviewed. The validation approach used includes reference to relevant published studies, personal communications and retrospective evaluation of the centre's own data. The laboratory manager confirmed that laboratory key performance indicators are monitored frequently, complementing the validation evidence reviewed (SLC T72).

Equipment validation

Critical equipment has been validated. Validation records for a selection of critical equipment including two incubators, a heated stage and a laboratory refrigerator were reviewed on inspection. The validation approach used includes temperature mapping studies, pH monitoring and power failure simulations and was considered by the inspection team to be comprehensive. Evidence was provided that critical measuring equipment used in the validation process was calibrated against national standards (SLC T24).

Records of re-validation of two pieces of equipment after repair were also reviewed (SLC T25).

What they could do better.

Process validation

The validation of the process for assisted hatching has not been performed. The laboratory manager explained that this had been overlooked because assisted hatching is carried out rarely, with only two cases performed in the last year (SLC T72). Post inspection, the laboratory manager submitted evidence demonstrating that this process has now been validated.

Witnessing

What the centre does well.

Witnessing was inspected against at the last inspection. However, because misidentification of gametes and embryos is a key risk for the sector, this theme was covered in full.

The centre double checks the identification of gametes and embryos and the patient or donor to whom they relate at all critical points of the clinical and laboratory process (SLC T71).

The centre has documented SOPs describing the witnessing procedure for all critical points specified in CoP Guidance 18.4. Witnessing steps observed during the inspection were performed in accordance with both centre SOPs and CoP Guidance.

Ten sets of patient notes audited on inspection were found to include records of all required witnessing steps, including the date and time of the procedure, with three exceptions noted below. A record of witnessing of the transfer of embryos to the research licence held by the Centre for Reproductive Medicine, Coventry (HFEA licensed centre 0013, research project R0155) was also reviewed (SLC T71).

Evidence of comprehensive training and competence assessment for staff performing witnessing steps was seen on inspection (SLC T15 (a)).

The centre has established a QI for witnessing. The report of the last patient notes audit performed was reviewed on inspection and included the corrective action that had been identified and implemented. Process audits of staff performing laboratory procedures, including witnessing, were also performed in 2011 (SLC T35 and T36).

What they could do better.

The centre's documented QI monitoring SOP states that the frequency for auditing of the witnessing QI is quarterly, however the last patient notes audit was performed in February 2011 (SLC T35).

In three sets of patient notes audited on inspection, the record of the practitioner performing one of the required witnessing steps was absent (SLC T71). The centre's 'IVF embryology' worksheet includes a final 'witnessing check' box. At the end of each patient's treatment, the patient notes are reviewed to ensure that all witnessing steps have been appropriately recorded. In two of these cases, this final 'witnessing check' box had been checked.

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

Gamete and embryo donation was added as an inspection theme by the Authority after the centre's last inspection in 2010. This theme was therefore covered in full.

The centre does not currently have an active sperm or egg donor recruitment programme, but does import donor sperm from abroad for use in treatment and accepts known egg donors introduced by patients. The donor coordinator explained that known sperm donors had not been selected and assessed for some years.

The centre's donor assessment and screening procedures for egg donors are supported by a detailed SOP and checklists, compliant with SLC T52.

Six sets of egg donor records were audited on inspection. This sample of records provided evidence that:

- Donors are being selected on the basis of their age, health and medical history, provided in a questionnaire and through a personal history and medical examination performed by a clinician (SLC T52 (a));
- Donors are being selected in accordance with the screening requirements of SLC T52 and relevant professional bodies[1], with one exception noted below.

Evidence of staff training and competence assessment for the selection and screening of donors was seen on inspection (SLC T15 (a)).

The donor coordinator explained that in their experience egg donors do not want to be reimbursed for expenses or reimbursed for loss of earnings. The centre's log of egg donors was reviewed and demonstrated that no expenses had been reimbursed (General Direction 0001).

The centre imported donor sperm from America and Denmark in 2011. Evidence that these donors are screened and compensated in compliance with HFEA requirements was

[1] The 2008 UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors produced by BFS, BAS, ACE and RCOG.

provided on inspection (General Direction 0001 and 0006).

The centre maintains detailed records on its database and can provide donors with information regarding the number, sex and year of birth of persons born as a result of donation (HFE Act 1990 (as amended), Schedule 31ZD (3)).

What they could do better.

Screening for Hepatitis B Virus

The audit of both donor and patient notes on inspection demonstrated that screening for Hepatitis B virus by serological testing for Hepatitis B surface antigen (HBsAg) is performed. However, screening for anti-HBc was not routinely performed before October 2011, non-compliant with SLCs T50 and T52.

Centre staff explained that prior to the information released by the HFEA in October 2011, clarifying the screening tests required, they were not aware that this was necessary. Centre staff confirmed that since October 2011, screening of anti-HBc has been performed. This was demonstrated in one set of donor notes reviewed on inspection.

However, one set of patient notes reviewed demonstrated that patients, who had screening pre-October 2011 and subsequently returned for treatment post-October 2011, were not screened for anti-HBc (SLC T50).

It is acknowledged that the risk of transmission of Hepatitis B virus through treatment with gametes from partners who have screened negative for HBsAg, but who have not been subject to anti-HBc screening is likely to be low.

Embryo testing (if applicable)

What the centre does well.

Not applicable. This centre is not licensed for embryo testing.

What they could do better.

2. Changes / improvements since the previous inspection on 4 February 2010.

Area for improvement	Action required	Action taken as evidenced during this inspection
The centre's witnessing is contemporaneous, but the recording of the checks is, during embryo transfer, conducted at the end of a procedure, albeit still as part of the procedure compliant with SLC T71. The centre's witnessing audit and inspectorate review of witnessing in patient records indicate that occasional witnessing signatures and/or timings were missing, contrary to SLC T71. The small delay while a procedure is completed may disturb occasionally the recording of the check.	SLC T71 states that witnessing checks must be completed and recorded at the time the clinical or laboratory process/procedure takes place. Corrective actions detailed in the centre's witnessing audit include that all staff should be told to sign the witness sheet at the time of witnessing and that the witnessing sheets should be checked before filing to ensure witnessing checks are complete. The inspectorate concurs with the first action and also recommends: 1) The processor must be responsible for ensuring the witness signature is collected. 2) The PR may wish to consider performing the check that all witnessing signatures are in place just before embryo transfer, rather than when the	Evidence was submitted to the Executive after the last inspection indicating that all staff were advised that this recommendation had been implemented and that all witnessing should be recorded at the time of the procedure. The centre's 'IVF embryology' worksheet has been revised to include a check step performed at the end of treatment to ensure that all witnessing records are in place. Refer to page 11 of the report for further discussion. **Further action is required.**

Area for improvement	Action required	Action taken as evidenced during this inspection
	witnessing sheet is filed.	
The frequency and method of QI monitoring for witnessing is not documented in the quality manual, contrary to SLC T35. Retrospective annual witnessing audits are currently performed but this is not stated.	The PR must ensure that the frequency and method of quality indicator monitoring for witnessing are stated in the quality manual, and applied, to comply with SLC T35.	Refer to page 11 of this report. **Further action is required.**
No procedures related to legal parenthood could be provided which ensure that: 1) Treatment is not provided when a person has withdrawn their consent to be the second parent of a child without telling the women being treated (the first parent) that the consent has been withdrawn, contrary to SLC T64 (b). 2) When a patient has withdrawn her consent to a nominated second parent being treated as the legal parent, or has more recently consented to a different person being the legal parent, that the original second parent is notified in writing of the withdrawal of consent, contrary to SLC T65.	The PR should ensure that the centre's procedures and practice related to addressing legal parenthood, e.g. consenting procedures, are modified to ensure procedures and practices are compliant with SLC T64(b) and T65.	A revised checklist used for donor recipients was submitted after the last inspection. This includes a check that consent to be the second parent has not been withdrawn. The use of this checklist was seen in recipient notes reviewed on inspection. **No further action is required.**
The inspectorate notes that a breach of licence conditions from the last inspection report, concerning competency	The PR is reminded of HF&E Act (1990) as amended, Section 17, paragraphs	After the last inspection, the inspection team considered that the PR had taken appropriate actions in response to the report, indicating

Area for improvement	Action required	Action taken as evidenced during this inspection
assessment, has yet to be corrected.	1(b),1(d), 1(e), which require the PR to secure that proper equipment and suitable practices are used, and that licence conditions are complied with, in the course of providing licence treatment. It is recommended that the PR considers whether the time allocated to the role allows him to fulfil his HF&E Act 1990 (As amended), Section 17 requirements.	that he is fulfilling his statutory duties as defined in the HF&E Act 1990 (as amended), Section 17, paragraphs 1(b), 1(d), 1(e). **No further action is required.**
Competency assessment plans are documented for nursing and embryology staff, but have only been fully implemented for embryology staff. For example, competency assessment of staff taking consent has not been documented, including whether they are competent to inform patients regarding parenthood legislation. No competency assessment plans were seen for clinical staff or other staff groups (e.g. administration). The frequency of competency assessment for each of the key activities carried out by each staff group, has not been documented. The centre is therefore non-compliant with	To ensure compliance with SLC T12 and T15a, the PR must ensure that on-going competency assessment plans are prepared for each staff group. These plans should identify the key activities which require competency assessment for each staff group, and the method and frequency of assessment. Competency assessments should be performed and recorded in an appropriate manner. The results of the assessments should be	The centre's revised quality manual states that the assessment of key competencies for all staff will be carried out annually (SLC T12). Records of competence assessments for several members of staff, including embryologists, clinical and administrative staff, were reviewed on inspection and were considered to be comprehensive. Clinical competence assessments reviewed included regular mandatory Trust training and licence specific competencies including welfare of the child assessment, provision of patient information and obtaining consent (SLC T15 (a)). **No further action is required.**

Area for improvement	Action required	Action taken as evidenced during this inspection
SLC T12 and T15a.	reviewed and corrective actions, e.g. retraining, taken as necessary. These processes should also be appropriately recorded. Competency assessment should be repeated at the frequency specified in the quality manual.	
The centre still needs to develop QI monitoring and review for counselling, the provision of information to patients, consenting, WoC assessment, donor selection, witnessing, traceability, the quality management system and HFEA data submission, to be compliant with SLC T35.	To ensure compliance with SLC T35, the PR should review activities at the centre and ensure that required standards of quality and safety, in the form of QIs for all activities authorised by the licence and other activities carried out in the course of providing treatment services that do not require a licence, are established. The activities monitored should include those described above, though the PR may choose to include others. The PR should also ensure that the monitoring mechanisms, audit frequencies and responsibilities for the QIs are documented, to comply	The centre's QI monitoring SOP was reviewed on inspection and includes QIs for all activities authorised by the licence. Refer to page 11 of the report for further QI development required. **Further action is required.**

Area for improvement	Action required	Action taken as evidenced during this inspection
	with CoP Guidance 23.19 – 23.22. To facilitate the development of quality indictor monitoring and audit, the PR should ensure adequate resources are available to establish and maintain the quality management system, as required by CoP Guidance 23.3. Specifically, the PR needs to ensure that the LM is able to devote enough time to the QM role to successfully establish appropriate quality indicator monitoring at the centre.	
The procedures associated with counselling provision; provision of information to patients; consenting; welfare if the child; donor selection; gamete and embryo procurement, processing and transport; gamete and embryo storage; witnessing; traceability; and patient confidentiality have not been recently audited against HFEA regulatory requirements. This is a breach of SLC T36.	To comply with SLC T36, the PR should have these procedures audited against HFEA regulatory requirements to ensure compliance. Non-conformities and corrective actions should be documented. Procedures should in future be reviewed regularly against the HFEA regulatory requirements to ensure compliance is	A sample of audit reports was reviewed on inspection. These included audits of laboratory procedures, clinical procedures, counselling, consent and selection and recruitment of donors. Findings and corrective actions were seen to be documented (SLC T36). **No further action is required.**

Area for improvement	Action required	Action taken as evidenced during this inspection
	maintained.	
Home production of sperm occurs in occasional cases and is documented in patient records. The patient is used as a witness for the identifiers on the sperm pot on arrival at the centre. The patient does not sign however that he produced the sperm, the date and time of production or that the sperm has not been interfered with in any way, non-compliant with CoP Guidance 15.7 (b) – (d).	The PR should ensure the procedure for dealing with home production includes that it is documented in the records that the provider produced the sperm, the date and time of production and that the sperm has not been interfered with, to be compliant with CoP Guidance 15.7 (b) – (d). The PR should ensure home procurement documentation is modified to allow the collection of these statements.	A revised sperm sample form was submitted to the Executive after the last inspection. This had been modified to include the information required by CoP Guidance 15.7 (b) – (d). The audit of ten sets of patient notes on inspection demonstrated that this revised sperm sample form is in use. **No further action is required.**
The PR should note that it is unlawful to procure gametes outside of premises covered by a HFEA licence or a third party agreement (TPA) with a HFEA licensed centre (SLC T1). If the PR wishes to perform egg collections in the main hospital operating theatre, the centre must develop a TPA with the operating theatre manager, which is compliant with the requirements detailed in SLC T114 and T116.	If any egg collections are to be performed in the main hospital operating theatre, the PR should develop a TPA with the operating theatre manager to allow this to occur in compliance with SLC T1. The TPA should include the requirements detailed in SLC T114 and T116.	An appropriate template TPA with the main hospital operating theatre was submitted to the Executive after the last inspection. The final signed version of the TPA was seen on inspection. **No further action is required.**
The storage consent form sent to patients with embryos in storage and associated	The PR should ensure that the centre's patient information	The centre's embryo storage review procedure and patient information have been updated to

Area for improvement	Action required	Action taken as evidenced during this inspection
information, and the general information regarding IVF and ICSI provided to patients before treatment, does not include: 1) The possibility of extension of embryo statutory storage up to 55 years in the event that a medical practitioner signs to the effect that one of the gamete providers, or the women to be treated if donor gametes were used to produce the embryos, is, or is likely to become, prematurely infertile. 2) The one year cooling off period in the event of consent for embryo storage being withdrawn by one of the gamete providers. This cooling off period does not however allow embryo storage beyond the statutory storage period.	and procedures are updated to include the possibility of: Extension of embryo statutory storage up to 55 years in 10 year steps in certain situations; A one year cooling off period in the event of consent for embryo storage being withdrawn by one of the gamete providers.	include this information. Refer to page 8 of the report for further action required relating to the storage review procedure. **Further action is required.**
The TPA with the courier does not include that the courier contracts to maintain the specified conditions during gamete or embryo transport, non-compliant with HF&E Act 1990 (as amended), Schedule 3A(11).	The PR must ensure that the TPA with the courier is revised to include that the courier will contract to maintain the specified conditions of transport during transit, to comply with HF&E Act 1990 (as amended), Schedule 3A(11).	An appropriate template TPA with the courier was submitted to the Executive after the last inspection. The final signed version of the TPA was seen on inspection. **No further action is required.**
Documents reviewed on inspection were	Documents should be	A revised document control procedure was

Area for improvement	Action required	Action taken as evidenced during this inspection
well presented and appropriately detailed. A small number were not annually reviewed, for example the protocols for transportation and temperature monitoring of dewars, non-compliant with CoP Guidance 31.6.	reviewed, revised and reapproved at a frequency that ensures they remain fit for purpose. The maximum interval between reviews should be 12 months. The QM should review documents within the QMS for compliance with this guidance and take action to correct non-compliances.	submitted to the Executive after the last inspection and included the requirement to review all patient information and procedures annually. A number of documents were seen on inspection, including the protocols for transportation and temperature monitoring of dewars. All had been reviewed within the last year. **No further action is required.**
The laboratory manager reported that samples are labelled with the patient's initial and surname and the clinical number. Straws used for cryostorage are additionally labelled with the date of birth. The sample labelling convention is potentially non-compliant with SLC T101, which requires that all samples should be labelled with at least the patient's **full** name and a unique identifier; the date of birth being acceptable as such (CoP Guidance 18.21).	The PR should consider whether the patient's initial and surname constitute the patient's full name, i.e. whether the centre's labelling convention is compliant with SLC T101.	The PR considers that the patient's initial, surname and clinical number provide unique identification of all samples and that the labelling convention is compliant with SLC T101. Lack of space prevents the complete first name being written on the label, thus only the initial and surname are used. The four digit clinical number is unique to each individual patient. The inspection team notes that the centre has practices in place for dealing with patients with similar names having treatment at the same time. SLC T101 states that if at some stages it is not possible to label the dishes or tubes with the patient/donor name, then it must be ensured that the patient/donor code used is uniquely

Area for improvement	Action required	Action taken as evidenced during this inspection
		identifying. The inspection team is satisfied with the PR's decision that the centre's practice is compliant with this requirement. **No further action is required.**
The equipment maintenance and repair procedure does not include the need for revalidation of equipment returning from repair, contrary to SLC T25.	The PR should ensure the equipment maintenance and repair procedure details that all equipment returned to the centre after repair is revalidated before being used in licensed activities, to ensure centre practice is compliant with SLC T25.	The centre's revised quality manual was submitted to the Executive after the last inspection and includes the need to revalidate equipment following repair. **No further action is required.**
The centre does not have a procedure for the control of confidential documents which included measures for establishing/maintaining data security and accuracy and resolving discrepancies, as required by SLC T44 (a) and (b).	The PR should review the centre's procedures and ensure they are compliant with all requirements of SLC T44.	The centre submitted a procedure for the control of confidential documents to the Executive after the last inspection. This includes measures for establishing/maintaining data security and accuracy and resolving discrepancies. **No further action is required.**
HFEA Registry reported that the centre have few errors in their registry data, except in May – Nov 2008, when registrations were filed without passport or NHS numbers. These errors need to be cleared to comply with General	The PR should continue to work with the HFEA registry to ensure that information submitted to the registry is accurate and that any errors within it are corrected in a	Centre staff stated that these historic errors had been resolved. The HFEA registry has confirmed this. **No further action is required.**

Area for improvement	Action required	Action taken as evidenced during this inspection
Direction 0005.	timely manner, compliant with General Direction 0005.	

3. Areas of concern

The analysis of the centre's SAQ and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
Submission of Data From 1 February 2011 to 31 January 2012, six outcomes for treatments that involved donor gametes were submitted. Four of these were with donors that are not registered with the HFEA. Seven historic donor treatments also have missing donor registration forms. General Direction 0005.	On inspection, the laboratory manager identified the donors that were not registered with the HFEA by running an error report from EDI. The laboratory manager explained that these donor gametes had been transferred from another licensed centre and that it is likely that the donors are registered with the HFEA, but that discrepancies with the donor code naming convention had caused the errors. Post inspection, the HFEA registry team has confirmed that all but one of the recent errors has been resolved and that the centre is actively working to resolve the historic errors.	**Further action is required.**
Staff complement It was noted at the last inspection that the laboratory manager is also the quality	The laboratory manager explained on inspection that the laboratory team was not at full staff complement. The centre is	**Further action is required.**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
manager. It was recommended that the PR ensures that the laboratory manager has sufficient time in the future to perform the quality manager role, to comply with CoP Guidance 23.3.	currently recruiting for a new embryologist and they also plan to recruit a trainee embryologist. As such, the laboratory manager explained that she does not currently have sufficient time to carry out the quality management role. As a short term measure, to ease the current weekend work requirements for the laboratory staff, the centre is planning to re-organise patient treatment to allow for alternate week egg collections. The laboratory manager explained that the centre previously used this system and was confident that it could be re-introduced easily. Long term, once recruitment and training of the new embryologist has been completed, this may give the time required for the quality management role.	
SAQ – Guidance Note 3: Counselling Is the centre's counsellor: • Accredited under the British Infertility Counselling Association (BICA) accreditation scheme (CoP Guidance 2.12 (b)).	The nurse manager explained that the centre's counsellor has many years experience as a fertility counsellor and has previously sat on the BICA Board. The PR stated that the counsellor's competence has been proved to his satisfaction, for example via performance assessment during annual appraisals.	**No further action is required.**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
• Can the counsellor provide evidence of working towards accreditation through the BICA accreditation scheme (CoP Guidance 2.12 (b)).	However, as the counsellor is very close to retirement, centre staff consider it would be disproportionate to request that the counsellor work towards BICA accreditation. The nurse manager stated that she will discuss the counsellor's plans for the future and keep the Executive informed regarding future plans to recruit to this role.	
SAQ – Guidance Note 7: Multiple births. Is your centre likely to meet the current multiple birth rate target (SLC T123).	Refer to page 8 of the report.	**No further action is required.**
SAQ – Guidance Note 17: Storage of gametes and embryos Has your centre audited how far storage procedures comply with the approved protocols, the regulatory requirements and QIs in the last two years (SLC T36).	Storage audits are performed biennially. The report of the last audit performed in October 2011 was reviewed on inspection. Some administrative errors were identified and the corrective action implemented was documented (SLC T36). The laboratory manager explained that they had responded negatively to this SAQ question in error.	**No further action is required.**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
SAQ – Guidance Note 19: Traceability Are the containers (dishes, vials, ampoules, tubes etc) at all stages of procurement, processing, use and storage of gametes and embryos labelled with the patient's/donor's full name and a further unique identifier or a uniquely identifying donor code (including labelling in the form of electronic tags) (SLC T101).	Refer to page 20 of the report.	**No further action is required.**
SAQ – Guidance Note 24: Third party agreements Is it a condition of all agreements that the third party will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA CoP (SLC T116).	Three TPAs reviewed on inspection demonstrated compliance with SLC T116.	**No further action is required.**
SAQ – Guidance Note 25: Premises and facilities Are all licensed premises in the same building (HF&E Act 1990 (as amended), Schedule 2, 4(2)(d)).	A tour of the centre demonstrated that all licensed premises are in the same building. Egg collections are very occasionally performed in the main hospital theatres in a separate building. This activity is covered by a TPA.	**No further action is required.**

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
SAQ – Guidance Note 25: Premises and facilities Does your centre keep records of regular cleaning and disinfection of the premises (SLC T26).	The laboratory manager explained that the hospital's cleaning department maintains the records of the cleaning of the premises.	**No further action is required.**
SAQ – Guidance Note 26: Equipment and materials Can your centre provide documented evidence of the revalidation of equipment after repair (SLC T25).	Refer to page 10 and page 21 of the report.	**No further action is required.**

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 require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None noted at the time of inspection.			

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Consent to disclosure to researchers In one of the 18 registration forms reviewed on inspection, a discrepancy was noted where a patient had consented for research, but this consent decision was incorrectly entered on the HFEA register. This discrepancy was corrected at the time of inspection. In two of the 18 registration forms audited, a discrepancy was again noted where a patient had consented for	The PR should conduct an audit of a representative number of consent to disclosure forms (completed since October 2009) in the patient records against the consent decisions that have been submitted to the HFEA. The findings of the audit and any relevant corrective actions should be documented and a copy provided to the Executive by 21 June 2012. If the audit findings indicate a systemic problem, a full audit of all consent to disclosure	An audit is scheduled for week commencing 30 April 2012. A copy of the audit's findings will be sent to Sara Parlett before 21 June 2012.	The Executive is satisfied with the PR's response and will continue to monitor progress. One of the two discrepancies noted where the consent decision submitted to the HFEA was inconsistent with that recorded on the HFEA register has been corrected by the centre. The other discrepancy is currently being investigated by the HFEA IT department. The findings of this investigation will be discussed with the PR once completed.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
research, but this consent decision was not correctly recorded on the HFEA register. However, evidence was provided on inspection that the information submitted to the HFEA via the centre's database was consistent with that consented by the patient. This discrepancy is being further investigated by the Executive. General Direction 0005.	forms completed since October 2009 may be required. The PR should ensure that in future, all data submitted regarding consent to disclosure of identifying information from the HFEA register is entered accurately and is supported by the patient record. Further action may be required of the PR, depending on the outcome of the investigation into the two other discrepancies noted on inspection.		
Sperm storage At the time of inspection the sperm samples of one patient were in storage without valid consent. HF&E Act 1990 (as amended) Schedule 3, Paragraph 8 (1).	At the end of the inspection, the laboratory manager confirmed that the samples had been thawed and allowed to perish. Post inspection, the laboratory manager provided details of a comprehensive notification system that has been implemented to remind centre staff when consent to storage	N/A	N/A

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	for sperm samples is about to expire, to ensure that samples destined to be allowed to perish do not remain in storage past the consented period. A system is already in place for embryos in storage. **No further action is required.**		
Process validation The validation of the process for assisted hatching has not been performed. SLC T72.	Post inspection, the laboratory manager submitted evidence demonstrating that this process has now been validated. **No further action is required.**	N/A	N/A

Other areas of practice that require improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Completion of consent forms In one set of notes, the patient's details on page one of the consent to disclosure consent form had not been documented. The nurse manager took corrective action at the time of inspection by completing the required information. General Direction 0007.	The PR should ensure that systems are in place to confirm that consent forms are completed appropriately prior to treatment. The nurse manager explained on inspection that the centre uses checklists to ensure that consent is in place prior to treatment and that staff would be reminded to review the content of the consent forms for completeness prior to completing the checklist. 21 June 2012.	This has been discussed by the nursing team at their monthly meeting.	The Executive is satisfied with the PR's response and will review this area of practice at the next inspection. **No further action is required.**
Witnessing In three sets of patient notes audited on inspection, the record of the practitioner performing one of the required witnessing steps was absent.	The PR is reminded that all witness checks must be recorded at the time of the procedure. The laboratory manager has submitted the report of a	Although the actual signature of the practitioner was missing in these cases, the identity of the practitioner had been recorded by the witness using the practitioner's staff code	The Executive is satisfied with the PR's response and will continue to monitor progress.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
In two of these cases, the final 'witnessing check' box had been checked. SLC T71. **This was an issue at the last inspection.** The centre's documented QI monitoring SOP states that the frequency for auditing of the witnessing QI is quarterly, however the last audit was performed in February 2011. SLC T35.	witnessing audit carried out post inspection, detailing the findings and corrective action to take. A re-audit is planned for three months time. The Executive is satisfied with this response and recommends that accurate completion of witnessing records continues to be frequently monitored as part of the centre's audit programme. The PR should ensure that there is consistency between the documented frequency for auditing of the centre's witnessing QI and the actual frequency of audit. The PR should submit: • The report of the witnessing audit due to be carried out in three months time. And • The QI monitoring SOP, if revisions to the auditing frequency are required.	(the practitioner signs the sheet once they have completed the procedure). The relevant sections have now been signed. The witnessing sheet is now being double-checked at the end of a patient's treatment by the laboratory assistant. The next witnessing audit is scheduled for 3 July 2012, 3 months after the latest audit. The frequency of witnessing audits will remain as quarterly for the foreseeable future.	

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	21 June 2012.		
Hepatitis B screening One set of patient notes reviewed, where the patient had recently had treatment, had not been screened for anti-HBc. SLC T50.	The PR should ensure that, prospectively, all patients are screened for anti-HBc. The PR should inform the Executive of the actions to be taken to ensure that this is performed. 21 June 2012.	All Hep B screening requests will have "fertility treatment" entered in the information box. This alerts the HPA lab in Bristol to test for anti-HBc as well as HBsAg. Patient information packs list both Hep B tests that are required if the patient asks their GP to do screening tests prior to their appointment.	The PR is asked to also ensure that patients who had screening prior to October 2011 and return for treatment in the future are screened for anti-HBc. The Executive will continue to monitor progress.
Submission of data Submission of outcome forms for treatments that involved donor gametes, where the donors are not registered with the HFEA. It is likely that the donors are registered with the HFEA, but that discrepancies with the donor code naming convention caused the errors. Post inspection, the HFEA registry team has confirmed	The PR should review the centre's processes to ensure that donors are registered correctly with the HFEA. The PR should ensure that where errors in the data submitted to the HFEA are identified, these are cleared within two calendar months. Immediately.	All of the donors had been registered with the HFEA; the errors were due to donor code naming conventions. Numerous corrections to forms were attempted. In future, lab staff will contact HFEA Registry more quickly if errors cannot be resolved by correction forms.	The HFEA registry team has confirmed that the recent errors have been resolved but the seven historic errors remain. The PR is asked to liaise directly with the HFEA registry team to resolve these discrepancies by 21 June 2012. The Executive will continue to monitor progress.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
that all but one of the recent errors has been resolved and that the centre is actively working to resolve the historic errors. General Direction 0005.			
Staff complement The laboratory manager stated that the laboratory team was not at full staff complement. As such, the laboratory manager explained that she does not currently have sufficient time to carry out the quality management role. SLC T12 and CoP Guidance 23.3 (d).	The PR should regularly review staff resource levels to ensure that there is sufficient time available for the laboratory manager to allocate to the quality management role. Particular consideration should be given to the significant increase in quality management activities that will be required with respect to the planned new premises. 21 June 2012.	We are appointing a new Laboratory Assistant, with part of the role dedicated to assisting the implementation of the Quality Management System.	The Executive is satisfied with the PR's response and will continue to monitor progress.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

1 June 2012

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

Minutes – Item 4

Centre 0139 – (Bath Fertility Centre) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Mark Bennett, Director of Finance & Facilities Paula Robinson, Head of Business Planning	Joanne McAlpine

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has been licensed since 1994 and offers IVF/ICSI and donation treatment to NHS and privately funded patients.

2. The Panel noted the centre carried out approximately 500 IVF/ICSI cycles last year.

3. The Panel noted that the centre plans to relocate at the end of 2012 to new premises currently being built in Peasedown St John, approximately eight miles away. The Panel noted that an application to vary the centre's licence is expected to be submitted to the Executive Licensing Panel in due course.

4. The Panel noted that the centre last had an interim inspection in February 2010 and the HFEA core and current themes were the focus of that inspection. However, the Panel noted that it was agreed by the Head of Inspection that this interim visit on 21 March 2012 would focus only on those themes that were not covered at the previous inspection, unless there was a specific reason to do otherwise.

5. The Panel noted that the data held on the HFEA register for the period December 2010 to November 2011 show that the centre's success rates for IVF and ICSI are in line with the national average.

6. The Panel noted that, for the year 2011, the centre also reported 40 cycles of partner IUI with 2 pregnancies.

7. The Panel noted that, at the time of the inspection, there were a number of areas of practice that required improvement: three major and five other areas of non-compliance or poor practice.

8. The Panel noted that since the inspection visit the Person Responsible (PR) has been proactive in addressing several of the areas of non-compliance or poor practice and has given a commitment to fully implement the outstanding recommendations in the report within the prescribed timescales.

9. The Panel noted that the Inspectorate recommended the continuation of the centre's licence without additional conditions, subject to compliance with the recommendations made in the report being implemented within the prescribed timescales.

10. The Panel noted the progress that has been made at the centre since the last inspection, and encouraged the PR to continue to work with the Inspectorate to resolve the outstanding non-compliances as soon as possible.

Decision

11. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence, with no additional conditions.

Signed: Date: 19 June 2012
Juliet Tizzard (Chair)