Executive Licensing Panel - minutes

Centre 0139 (Bath Fertility Centre) Renewal Inspection Report

Friday 16 June 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Hannah Verdin (Chair) Howard Ryan Ian Peacock	Head of Regulatory Policy Report Developer Systems Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that the Bath Fertility Centre holds a Treatment and Storage licence and provides a full range of fertility services.

1.3. The panel noted that the centre has been licensed by the HFEA since 1994.

1.4. The panel noted that, in the 12 months to 28 February 2017, the centre provided 737 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium sized centre.

1.5. An inspection was carried out at the centre on 29 and 30 March 2017

1.6. The panel noted that at the time of the inspection there were two critical, eight major and three 'other' areas of practice which required improvement. The panel noted that the critical areas of non-compliance, regarding the screening of donors and consent to legal parenthood, had been fully implemented by the PR since the inspection.

1.7. The panel noted the eight critical areas requiring improvement regarding traceability, the Quality Managements System (QMS), third party agreements, satellite agreements, adverse incidents, counselling, egg sharing and record keeping. The panel noted the centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided.

1.8. The 'other' areas requiring improvement concerned safety and suitability of premises and facilities, consent to disclosure to researchers and obligations and reporting requirements.

1.9. The panel noted that the PR had given a commitment to implementing all the recommendations within the prescribed timescales

1.10. The panel noted the inspection team commends the centre on achieving a low multiple pregnancy rate and, in so doing, reduce the single biggest risk of infertility treatment. The inspection team also noted that the centre's success rates are consistent with the national average.

1.11. Th panel noted that a management review meeting was held on 6 April 2017 in accordance with the HFEA's Compliance and Enforcement policy. This meeting discussed the risk to patients, particularly relating to the screening of donors and consent to legal parenthood, and considered whether any immediate actions were necessary. It was noted that the PR and centre staff had taken immediate actions to address the failings in screening practices, had initiated audits of records to determine if any further anomalies in legal parenthood consent remained unidentified, and had responded to all the Executive's requests for information in relation to changes in these areas of practice. The PR confirmed he was seeking legal advice on the case identified during the inspection. The management review meeting was satisfied that the actions taken were appropriate and had removed any risk to patients.

1.12. The panel noted that a second management review meeting was held on 18 April 2017 to look at the centre's audits of consent to legal parenthood. It was noted that no further anomalies had been identified by the centre with regards to consent to legal parenthood, other than the one case found during the inspection. The requested assurances regarding the centre's processes for donor screening and for checking consents prior to treatments had been provided.

1.13. The panel noted that the PR had fully engaged with the inspectorate in addressing all the areas of concern identified in the report, providing regular updates on the actions planned, and taken. The centre's inspector will continue to monitor the centre's progress with the actions and implementation of the recommendations within the prescribed timescales.

1.14. The panel noted that the inspectorate recommends the renewal of the centre's Treatment and Storage licence for a period of four years without additional conditions subject to the recommendations made in the report being implemented within the prescribed timescales.

2. Decision

2.1. The panel noted the centres non-compliances, particularly the critical non-compliances relating to the screening of donors and consent to legal parenthood.

2.2. The panel noted the PR's engagement and that steps had been taken to fully implement the recommendations of the inspectorate.

2.3. The panel endorsed the inspectorate's recommendation to renew the centre's Treatment and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

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3. Chair's signature

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

Signature

Name

Hannah Verdin

Date

27 June 2017

Inspection Report

Purpose of the Inspection Report

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

Date of inspection: 29 and 30 March 2017

Purpose of inspection: Renewal of a licence to carry out treatment and storage

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

Inspectors: Karen Conyers, Susan Jolliffe, Louise Winstone, Cathy Hodgson and Danya Harris

Date of Executive Licensing Panel: 16 June 2017

Centre name	Bath Fertility Centre
Centre number	0139
Licence number	L/0139/13/a
Centre address	Bath Business Park, Roman Way, Peasedown St John, Bath, Somerset, BA2 8SG, United Kingdom
Person Responsible	Mr Nicholas Sharp
Licence Holder	Mr David Walker
Date licence issued	01 September 2013
Licence expiry date	31 August 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Bath Fertility Centre has held a treatment and storage licence with the HFEA since 1994 and provides a full range of fertility services. Other licensed activities at the centre include storage of gametes and embryos.

The centre provided 737 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2017. In relation to activity levels this is a medium sized centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 December 2015 to 30 November 2016 show the centre's success rates are in line with national averages.

In 2016, the centre reported 22 cycles of partner insemination with three pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

Between 1 December 2015 to 30 November 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

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

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

Summary for licensing decision

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

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

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

Since the inspection visit the PR has confirmed that the following recommendations have been fully implemented:

Critical areas of non-compliance:

- **The PR should ensure that gamete donors are screened in accordance with regulatory requirements and professional body guidelines.**
- **The PR should ensure that effective consent to legal parenthood is obtained.**

Major areas of non-compliance:

- The PR should ensure written agreements are in place with all third parties who provide goods or services that influence the quality and safety of gametes and embryos.
- The PR should ensure that written agreements are in place and provided to the HFEA before the commencement of satellite services.
- The PR should ensure that the centre's internal processes for identifying and reporting adverse incidents are effective.
- The PR should ensure that egg sharing practices do not disadvantage the egg provider.

'Other' areas that require improvement:

- The PR should ensure the safe storage of medical gases.

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

Major areas of non-compliance:

- The PR should ensure that all relevant data about anything coming into contact with gametes or embryos is traceable.

- The PR should ensure that the centre's quality management system (QMS) is compliant with all relevant requirements.
- The PR should ensure that patients can access counselling services with an appropriately qualified and accredited counsellor.
- The PR should ensure that the identity of a patient is reliably confirmed and documented, and that all records are accurately completed.

'Other' areas that require improvement:

- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Recommendation to the Executive Licensing Panel

The inspection team commends the centre on achieving a low multiple pregnancy rate and, in so doing, reduce the single biggest risk of infertility treatment. The inspection team also notes that the centre's success rates are consistent with the national average. Recommendations are however made in response to two critical and eight major areas of concern.

Significant improvement is required for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided.

Because of the nature of the areas of concern identified during the inspection, a management review meeting was held on 6 April 2017 in accordance with the HFEA's Compliance and Enforcement policy. This meeting discussed the risk to patients, particularly relating to the screening of donors and consent to legal parenthood, and considered whether any immediate actions were necessary. It was noted that the PR and centre staff had taken immediate actions to address the failings in screening practices, had initiated audits of records to determine if any further anomalies in legal parenthood consent remained unidentified, and had responded to all the Executive's requests for information in relation to changes in these areas of practice. The PR confirmed he was seeking legal advice on the case identified during the inspection. The management review meeting was satisfied that the actions taken were appropriate and had removed any risk to patients.

The findings of the centre's audits of consent to legal parenthood were provided on 12 April 2017 and were reviewed by a management review meeting on 18 April 2017. The meeting noted that the centre had identified no further anomalies in consent to legal parenthood other than the one case noted on inspection, and had provided the requested assurances regarding the centre's processes for donor screening and for checking consents prior to treatments.

Since the inspection, the inspection team considers that the PR has engaged fully with the HFEA in addressing all the areas of concern identified in the report, notably the critical non-compliances concerning screening of donors and legal parenthood, and has provided regular updates on the actions planned and taken. The centre's inspector will continue to monitor the centre's progress with these actions and the implementation of this report's recommendations within the required timescales.

The inspection team have reviewed the HFEA's Guidelines for Licensing and considered the balance of evidence concerning the centre's non-compliance on inspection and subsequent actions to correct non-compliance and minimise the risk to patients. The inspection team recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

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

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos. The centre's procedures for screening donors are partially compliant with HFEA requirements.

Payments for donors (Guidance note 13; General Direction 0001)
It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused. The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non-identifying information regarding the donor from the clinic. Furthermore,

donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better

Screening of donors (Guidance note 11)
The records of three egg donors/sharers were reviewed on inspection. These donors had not been screened in accordance with UK professional body guidelines and the screening tests performed were completed using blood samples which had not been taken within the timeframes specified by the Authority (recommendation 1, SLCs T52b and T53b, CoP Guidance 11.22)

The centre's SOP for screening egg donors does not describe the requirement to screen egg donors at the time of donation or all the screening tests required (recommendation 1, SLC T33b).

The inspection team acknowledges that some screening tests had been performed prior to the donors being accepted, and were negative. However, this cannot be considered to provide assurance that the donors were negative for all required tests at the time of donation, as initial screening had been conducted between five and 13 months prior to egg collection. In addition, the donors had not been screened for gonorrhoea, did not have blood group recorded and one donor had had chlamydia screening four years previously.

Immediately following the inspection, the PR confirmed that the centre's screening practices for egg donors had been reviewed against regulatory requirements and professional body guidelines to include all screening tests required prior to, and at the time of donation, and that staff training had been undertaken. The PR also confirmed that where patients are currently attending the centre for treatment involving donor eggs or embryos created with donor eggs, he would ensure that the donors have been screened in accordance with regulatory requirements and professional guidelines. Further to this the PR has provided a copy of the centre's updated donor screening SOP and a summary of the centre's audit of compliance of their documents and processes against regulatory requirements.

Suitable premises and suitable practices
Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports

Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
It is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose. The centre's premises are broadly suitable.

The centre has procedures in place that are compliant with requirements to ensure that risks are considered so that patients and staff are in safe surroundings that prevent harm.

The centre has one satellite service, the premises of which are considered suitable for the activities performed there.

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

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

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

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
It is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively. The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway.

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements

for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

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

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

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

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

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

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

Traceability (Guidance note 19)
The centre's procedures are partially compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability:

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

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

Third party agreements (Guidance note 24)
The centre's third party agreements are partially compliant with HFEA requirements.

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

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

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

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

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

The centre's procedures for reporting adverse incidents are partially compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA with the exception noted below. The centre investigates all adverse incidents that have occurred.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
The centre has full gas cylinders stored in a room on the ground floor which are not securely chained to the wall (recommendation 11, SLC T2, Health Technical Memorandum 02-01: Medical gas pipeline systems, Part B: Operational management). The cylinders are large and pose a safety threat if they are accidentally knocked over.

Traceability (Guidance note 19)
Traceability records for eight items currently in use in the laboratory were reviewed during the inspection. Of these, one item was not recorded as 'in use' in the records (recommendation 3, SLC T99).

Quality management system (QMS) (Guidance note 23)
The following non-compliances were noted in the QMS (recommendation 4):

- the centre has not audited consent to disclosure to researchers and records of manual witnessing in the last two years (SLC T36);
- the scope and methodology of the centre's audit of 'consent' was not clear (SLC T36); and
- there is no SOP to direct non-clinical emergency procedures (SLC T33b);
- the centre did not receive the last two Clinic Focus documents (February and March 2017) and failed to identify this problem, suggesting that the system for implementing new regulatory requirements or guidance within the QMS is not robust (SLC T34). These documents contained Chair's Letter CH(17)01 which described several changes to the Code of Practice and new consent forms. Previous regulatory guidance has been acted on, therefore processes are in place to do this, but they are not robust enough to ensure all guidance is monitored and acted on.

Third party agreements (Guidance note 24)
The centre has not established a written agreement with the Royal United Hospital Bath NHS Foundation Trust's laboratory which undertakes the centre's diagnostic screening tests (recommendation 5, SLC T111).

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has recently commenced a satellite arrangement but has not finalised the agreement or informed the HFEA about it (recommendation 6, General Direction 0010). It was noted that appropriate processes are in place for this satellite arrangement which is with a clinician who has previously been the PR of a HFEA-licensed centre. This provides assurance that the satellite arrangement has been managed in accordance with the regulatory requirements pertaining to HFEA-licensed activities.

Adverse incidents (Guidance note 27)
The inspection team noted a breach of confidentiality in a set of records but this had not been reported as an incident internally or to the HFEA (recommendation 7, SLC T120). The incident identified was immediately reported to the HFEA. The inspection team reviewed the centre's incident logs and were assured that all internally reported incidents were appropriately managed and reported to the HFEA.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

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

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.
What the centre could do better Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not carry out embryo testing and therefore this area of practice is not relevant to this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well
During the inspection, the inspectors spoke to one lady who provided feedback on her experiences at the centre. The centre's most recent patient survey responses were also reviewed. Feedback from patients was positive about the care that they received.

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

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

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

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

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

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

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

Egg sharing arrangements (Guidance note 12; General Direction 0001)
For centres providing egg sharing arrangements it is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

The centre's procedures for egg sharing arrangements are partially compliant with HFEA requirements.

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

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

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

What the centre could do better

Counselling (Guidance note 3)
The centre's counsellor is not accredited by the British Infertility Counselling Association (BICA) and does not have sufficient evidence to demonstrate equivalence to BICA accreditation (recommendation 8, SLC T14, CoP 2.12b). It is noted that the current counsellor has commenced working towards British Association for Counselling and Psychotherapy (BACP) accreditation and has completed the BICA introductory course.

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The inspection team were concerned that the centre's processes for distributing eggs in an egg sharing arrangement, disadvantage the egg share provider if less than eight and/or an odd number of eggs are collected (recommendation 9, SLC T2). The centre's agreement for egg sharing states that the egg share provider is asked to commit to donating a minimum of four eggs. The centre's SOP states that if between five and eight eggs are collected, four are donated, and if an odd number of eggs are collected, the extra egg is donated.

From information in the HFEA register for all egg sharing treatments since the renewal inspection in 2013, one egg share provider has donated four of seven eggs collected, keeping three for her own use. Since the inspection the centre have confirmed that this is the only case where eight or less eggs have been collected from an egg share provider since 2010 and that both the provider and recipient had live births from this treatment. Thus, this potentially unfair egg distribution appears to have not had significant effect on egg share providers since 2010. The centre has now provided their updated egg sharing SOP, patient information and consent forms, confirming a revised egg distribution arrangement is now in place, which the inspection team considers is fair to the egg sharer provider and recipient.

The centre's practice for screening egg donors also applies to egg sharers and is not compliant with regulatory requirements and professional body guidance, as discussed in the 'Screening of Donors' section above.

Information

What the centre does well

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

The centre's procedures for providing information to patients and/or donors are compliant with HFEA requirements. It is noted that the centre's success rates on the website at the time of inspection included clinical pregnancy rates, but not live birth rates or the national success rates, after a change to the website in the last two years. Patients are however all provided written success rate information that is compliant with requirements and this data was immediately uploaded to the website after the inspection.

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

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

What the centre does well

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

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

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided the findings of their audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies. On a previous inspection in March 2015 we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are

effective methods for assessing the on-going competence of staff to take this consent, and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the HFEA.

To provide assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood with a prior offer of counselling was seen to be in place before treatment in all cases, but one anomaly was noted, as discussed in the 'What the centre could do better' section below.

In summary, the inspection team considers that the centre's current processes for obtaining effective consent to legal parenthood appear to be compliant with HFEA requirements. However, a comprehensive audit of consent to legal parenthood is needed to confirm this, as the last audit was performed in 2014.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The HFEA Register is a rich source of information about treatment using assisted reproductive technologies (ART). It can be used by researchers and linked to other health registers to improve knowledge about the health of patients who have undergone ART and those born as a result of it. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA, so that the HFEA holds an accurate record of patients' consent and only releases patient identifying information, to researchers, with a patient's consent.

The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

What the centre could do better

Legal parenthood (Guidance note 6)
During this inspection, the centre informed the inspection team that they had not undertaken an audit of consent to legal parenthood since the audit requested by the HFEA in 2014 (see recommendation 2, SLC T36). This undermines the PR's reassurance in October 2015 that 'effective audit procedures are in place to ensure on-going compliance with consent taking requirements.' It also leaves the centre exposed to a risk that consenting processes may not have been robust at times and further cases of anomalous consent to legal parenthood may be present without being detected.

The inspection team reviewed five sets of records of patients who had had treatment with donor sperm in circumstances where consent to legal parenthood was required. In one case the patient had put their year of birth instead of the year of signing the consent form in the page declaration section on page 2 of the PP form (see recommendation 2, Sections 37(1) and 44(1) of Part 2 of the HFE Act 2008 and SLC T47). The PR provided immediate assurance that he would seek legal advice on this finding.

Immediately following the inspection, the PR agreed to a request from the Executive to audit legal parenthood consents in treatments since those included in the 2014 audit and

to review the records audited in 2014 to determine if there are any consenting anomalies not noted at the time of the 2014 audit. The centre has now provided the findings of both audits and no further anomalies that could have the potential to impact on legal parenthood have been identified. The centre's quality manager confirmed that an audit of consent to legal parenthood has been added to the audit schedule and will now be undertaken annually.

The centre's SOP states that the partners of women receiving treatment who are not married or in a civil partnership will only be recognised as the legal parent if WP and PP forms have been completed before gamete or embryo transfer takes place. Some staff at the centre informed the inspectors that they would ask patients to complete a consent to legal parenthood if they were unsure whether the couple were married or in a civil partnership. The inspection team were concerned that this approach may indicate that all staff do not fully understand the requirements in relation to consent to legal parenthood (recommendation 2, SLC T15).

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Six discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register (recommendation 12, CH(10)05 and General Direction 0005). Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure. This failing leads to a risk that the HFEA may release patient identifying information, to researchers, without consent.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

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

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

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed. It is important to ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, it is important that the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The centre's procedures for storing gametes and embryos are compliant with HFEA requirements.

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

Use of embryos for training staff (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority. The centre's procedures for using embryos for training staff are compliant with HFEA requirements.
What the centre could do better Nothing identified at this inspection

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
Good medical records are essential for the continuity of the patient's care. The centre's procedures for keeping records are partially compliant with HFEA requirements to ensure that accurate medical records are maintained.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. To do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information about licensed activities to the Authority are broadly compliant with HFEA requirements.

What the centre could do better

Record keeping and document control (Guidance note 31)
An audit of records identified the following issues (recommendation 10, SLC T46):

- In one set of records there was no documentation of by whom the patient/donor had been reliably identified.
- An email for one patient was filed in another patient's records.
- The marital status of a couple undergoing treatment is not routinely documented in the records. This leads to a risk that some couples may be asked to complete consent to legal parenthood when not required.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
Twenty eight percent (32/116) of IVF and 28% (17/60) of DI treatments reviewed at inspection had been reported to the HFEA outside the period required (recommendation 13, General Direction 0005). The centre has also been informed of some minor data quality issues which the centre need to correct.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, recommendations for improvement were made in relation to three areas of major non-compliance and three 'other' areas of non-compliance.

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

On-going monitoring of centre success rates

Since the last inspection in March 2015 the centre has not received any HFEA risk tool alerts related to their success rates.

Areas of practice requiring action

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

Critical area of non-compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Screening of donors The records of three egg donors/egg sharers were reviewed on inspection and these donors had not been screened in accordance with the timeframes specified by the Authority, and had not had all screening tests undertaken in accordance with professional guidelines. The centre's SOP for screening egg donors does not describe the requirement to screen egg	The PR should ensure that gamete donors are screened in accordance with regulatory requirements and professional body guidelines. Immediately after the inspection the PR confirmed that revised screening practices and relevant staff training had been implemented the day after the inspection. Further to this the PR has also provided a copy of the centre's updated donor screening SOP and a	The PR has obtained advice from an expert microbiologist and an expert virologist. The risk assessment has been provided to our inspector. It was concluded there is no provable risk. An audit of egg donor treatments has been undertaken and a copy provided to our inspector. Screening requirements were found to be compliant with our donation SOP and regulatory requirements.	The executive acknowledges the PR's response and his commitment to fully implement this recommendation. The PR has sought the advice of several experts in relation to the risk to patients who have received treatment with eggs or embryos created with donated eggs, from donors where the screening has not been compliant with

donors at the time of donation, or the screening tests required. SLC T52, SLC T53b and SLC T33b.	summary of the centre's audit of compliance of their documents and processes against regulatory requirements. The PR should seek the advice of an expert virologist/microbiologist to assess the risk to patients who have received treatment with eggs or embryos created with donated eggs, from donors where the screening has not been compliant with regulatory requirements. The PR should inform the centre's inspector of the timeline for obtaining this expert advice when responding to this report. As revised screening practices were implemented the day after the inspection the centre should carry out an audit of egg donor treatments conducted since these changes to ensure that screening is compliant with the centre's updated SOP and regulatory requirements. A summary of the findings of the audit should be provided to the	A root cause analysis has been undertaken and findings reported to our inspector.	regulatory requirements. A summary of the expert opinions has been provided and concludes there is 'no provable risk' in relation to the issues identified during the inspection. The PR has provided the requested audit of egg donor treatments conducted since the changes to screening practices confirming that compliant practices are now in place. The PR has also provided the root cause analysis due by 30 June which includes corrective actions identified and timescales for implementation. The executive notes that all but two actions have been completed, with these due to be implemented by 30 June. No further action is required.

	centre's inspector when responding to this report. The PR should conduct a root cause analysis to identify why the centre's processes for screening egg donors and egg sharer providers were not compliant with regulatory requirements and professional guidance. The PR should provide the centre's inspector with a copy of this analysis, including any corrective actions identified and timescales for implementation, by 30 June 2017.		
2. Consent to legal parenthood The inspection team reviewed five sets of records of patients who had had treatment with donor sperm in circumstances where consent to legal parenthood was required. In one case the patient had put their year of birth instead of the year of signing of the consent form in the page declaration	The PR should ensure that effective consent to legal parenthood is obtained. The centre should seek legal advice regarding the legal parenthood consent anomaly identified by the inspection team. When responding to this report, the PR should provide the centre's inspector with a summary of the legal advice and the actions planned in response to it, including how	Bath Fertility Centre understands the implications of failing to take proper consent to legal parenthood and takes this issue seriously. Legal advice has been sought from our solicitor who has provided a very considered opinion, concluding that the intention of the signed form is evident. It is clear that the form was signed prior to treatment which is the important issue here. We will however be	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a copy of the legal advice and has confirmed that he will be contacting the couple concerned.

section on page 2 of the PP form. The centre has not conducted an audit of consent to legal parenthood since 2014. Some staff at the centre informed the inspectors that they would ask patients to complete a consent to legal parenthood if they were unsure whether the couple were married or in a civil partnership. Sections 37(1) and 44(1) of Part 2 of the HFE Act 2008, SLC T36 and SLC T15. This has been graded as a critical non-compliance and cited separately to other requirements for audit, because it undermines the PR's reassurance, provided in October 2015, that 'effective audit procedures are in place to ensure on-going	the centre intends to communicate with and support the couple affected. Immediately after the inspection the PR was asked to conduct an audit of consent to legal parenthood for all patients who have had treatment with donor sperm, or with embryos created with donor sperm (fresh or frozen) from the date of the treatments included in the 2014 audit to date, and to re-audit those treatments included in the 2014 audit. Copies of the findings of both these audits have been provided to the centre's inspector and no further anomalies in consent to legal parenthood other than the one case noted on inspection were identified. The PR should review the centre's processes for obtaining consent to legal parenthood including, but not limited to, staff training in the requirements for obtaining consent to legal parenthood, awareness of previous HFEA	contacting the couple regarding this anomaly as he suggested and he will aid us in drafting a letter to them. A copy of his extremely helpful advice has been provided to our inspector. Our centre's processes for obtaining consent to legal parenthood have been reviewed: • A "marital status" box has been added to the form which patients complete themselves when they register here • Relevant staff have been reminded to record marital status on our database when entering patient details • The importance of checking carefully each page of consent forms has been discussed with staff at departmental meetings and at our recent AGM on 10 May 2017 • The donation SOP has been updated to emphasise further the importance of correct completion of legal parenthood forms. The changes to the SOP have been discussed with the nursing team and with all staff at our recent AGM	The PR has also provided a summary of the findings of the review of practices in this area including actions taken in response to this finding. No further action is required.

compliance with consent taking requirements.'	communications in this area and the introduction of a new legal parenthood consent form and guidance from April 2017. A summary of the findings of the review including staff training undertaken since the inspection should be provided to the centre's inspector when responding to this report.	• The SOP for taking consent has been checked against guidance from the HFEA (April 2017) and promulgated to all staff via email. We have received confirmation from each staff member that they have read it • The consent SOP emphasises the importance of checking whether a patient's circumstances have changed if they are returning for subsequent treatment cycles • Consent forms are checked prior to each treatment cycle and this is recorded on relevant checklists which include WP, PP, PBR, SWP and SPP forms and the circumstances in which they should be completed • PDFs of the latest versions of HFEA consent forms have been saved to our shared drive and an Excel file created with hyperlinks to each form. For each type of treatment the Excel file also lists under which circumstances parenthood forms must be completed	

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
3. Traceability Traceability records for eight items currently in use in the laboratory were reviewed during the inspection. Of these, one item was not recorded as 'in use' in the centre's traceability records. SLC T99.	The PR should ensure that all relevant data about anything coming into contact with gametes or embryos is traceable. The PR should review the centre's processes for recording all items for traceability purposes. A summary of the findings of the review, including corrective actions with timescales for implementation, should be provided to the centre's inspector by 30 June 2017. Within three months of the implementation of changes to the traceability procedures, the centre should conduct an audit of practice and a summary report of	This review is in hand and the findings will be provided to our inspector by 30 June 2017.	The executive acknowledges the PR's response and his commitment to fully implement this recommendation. The review due by 30 June 2017 and audit due by 30 September 2017 are awaited. **Further action is required**.

	the findings of the audit should be submitted to the centre's inspector by 30 September 2017.		
4. QMS The following non-compliances were noted in the QMS: • the centre has not audited consent to disclosure to researchers and records of manual witnessing steps in the last two years; • the scope and methodology of the centre's audit of 'consent' was not clear; • there is no SOP to direct the following procedure: non-clinical emergency; and • the process by which new regulatory requirements or guidance are implemented within the QMS is not sufficiently robust. SLC T32, T33b and T36.	The PR should ensure that the centre's QMS is compliant with all relevant requirements. The PR should review the centre's QMS to ensure it includes audits of all critical activities with clear scope and methodologies, and effective processes for monitoring and acting upon regulatory change and guidance. A copy of the findings of these reviews including proposed corrective actions should be provided to the centre's inspector by 30 June 2017. The audit of manual witnessing steps has been provided. Copies of the audits of consent to disclosure to researchers and 'consent' (including scope and methodology), and the SOP noted should be provided to the centre's inspector by 30 June 2017.	This review is in hand and the findings will be provided to our inspector by 30 June 2017	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided the review of all HFEA updates and guidance issued since the last inspection in March 2015 and has confirmed that the centre has acted on all recent regulatory requirements, where applicable. The remaining review, audits and SOP due by 30 June 2017 are awaited. **Further action is required.**

	The centre should review all HFEA updates and guidance issued since the last inspection in March 2015 to ensure they are aware of all recent regulatory requirements. A summary report of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 30 June 2017.		
5. Third party agreements The centre has not established a written agreement with the Royal United Hospital Bath NHS Foundation Trust's laboratory which undertakes the centre's diagnostic screening tests. SLC T111.	The PR should ensure written agreements are in place with all third parties who provide goods or services that influence the quality and safety of gametes and embryos. The PR should establish the written third party agreement with the service provider identified and confirm this has been completed by 30 June 2017.	The TPA with the RUH Clinical Biochemistry service has been signed and a copy provided to our inspector. All our other TPAs are currently under review; updated TPAs have been sent to the relevant providers/suppliers. Several have already been completed by third parties and we are still awaiting responses from 7 of our third parties.	The executive acknowledges the PR's response and that he has provided a copy of the signed third party agreement as recommended. No further action is required.
6. Satellite agreements The centre has recently commenced a satellite arrangement but has not	The PR should ensure that written agreements are in place and provided to the HFEA before	We hold a Service Level Agreement with the Winterbourne Hospital which	The executive acknowledges the PR's response and

finalised the agreement or informed the HFEA about it. General Direction 0010.	commencement of satellite services. The finalised written agreement for the satellite service should be provided to the centre's inspector when responding to this report.	was finalised and signed in June 2015, before any satellite treatments were undertaken. The agreement is compliant with HFEA General Direction 0010. We have provided a copy of the agreement to our inspector.	the satellite agreement provided. No further action is required.
7. Adverse incidents The inspection team noted a breach of confidentiality in a set of records but this had not been reported as an incident internally or to the HFEA. The incident identified was immediately reported to the HFEA. SLC T120.	The PR should ensure that the centre's internal processes for identifying and reporting adverse incidents are effective. The PR should review the centre's processes for reporting adverse incidents to determine why the incident had not been identified and reported internally. The review should also consider whether there may be other unreported incidents and how the centre will ensure that in future all adverse incidents will be identified and reported. A summary of the findings of the review including corrective actions and the timescales for implementation should be	It is unclear why this IG breach had not been reported to BFC management, who would have ensured reporting to the HFEA. Our Information Governance SOP specifies that any confidentiality breach must be reported. All staff were emailed at the time of inspection to remind them that any breaches of patient confidentiality must be reported to the HFEA as an incident. Incident reporting was discussed at our AGM on 10 May 2017, where any incidents reported during the previous 12 months were	The executive acknowledges the PR's response and his commitment to fully implement this recommendation. The PR has provided the requested review of processes including actions taken to address this finding. No further action is required.

	provided to the centre's inspector by 30 June 2017.	summarised and learning points discussed (including 3 IG breaches). The importance of reporting any adverse incident was stressed and it was emphasised that we operate a "no blame" culture: if an incident occurs the processes and procedures are analysed and where relevant, corrective actions implemented. All staff were asked to consider if on reflection there may have been other incidents which should have been reported and to notify any member of the Leadership team in confidence – no other episodes were recalled by any member of staff.	
8. Counselling The centre's counsellor is not accredited by BICA and does not have sufficient evidence to demonstrate equivalence to BICA accreditation. SLC T14, CoP 2.12b.	The PR should ensure that patients can access counselling services with an appropriately qualified and accredited counsellor. The PR should ensure compliance with this requirement by 30 September 2017.	Our counsellor is a skilled, experienced therapist and I am confident that she is able to offer our patients appropriate counselling. She is supervised by Jennifer Hunt and has monthly supervision sessions with her either face to face or via	The executive acknowledges the PR's response and his commitment to fully implement this recommendation. The PR has outlined the proposed route by which the centre's counsellor will

		skype. Jennifer is a former HFEA board member and is the Senior Infertility Counsellor at IVF Hammersmith. She is a founder member of BICA and was their first Chair; currently she is a member of the Accreditation Board for Infertility Counselling, Co-chair of the BICA Training Group and a member of the BICA Advisory Group. As such, Jennifer is perfectly placed to guide and support our counsellor's application for accreditation, and to supervise her work at Bath Fertility Centre. Our counsellor completed her PG Dip Psychosexual Therapy in December 2016. This qualifies her to apply for BACP accreditation via route 4.2, and she will be forwarding her completed application to BACP by the end of June 2017. BACP quote four months for marking this pack (although if queries are referred the process can take longer).	achieve BICA accreditation or equivalence. The executive notes the timescales provided and accepts the suggested date of 30 December 2017 to achieve compliance with this requirement. **Further action is required.**

		BICA accreditation sits on the back of the more significant BACP work, and she will prepare her BICA case work and essays in advance so that they can be dispatched as soon as possible to BICA once she has attained BACP accreditation. Given the period required by the professional bodies to assess applications, a realistic timescale for her to achieve BICA accreditation would be 30 December 2017.	
9. Egg sharing The inspection team were concerned that centre's processes for distribution of eggs in an egg sharing arrangement disadvantage the egg share provider if less than eight, and/or an odd number of eggs are collected. SLC T2.	The PR should ensure that egg sharing practices do not disadvantage the egg share provider. Since the inspection, copies of the changes to practices, including updated SOP, patient information and the egg share agreement have been provided confirming a revised egg distribution arrangement is now in place, which the inspection team considers is fair to the egg sharer provider and recipient.		No further action was required.

	No further action is considered necessary.		
10. Record keeping An audit of records identified the following issues: • In one set of records there was no documentation of by whom the patient/donor has been reliably identified. • An email for one patient was filed in another patient's records. • The marital status of couples is not routinely documented. SLC T46.	The PR should ensure that the identity of a patient is reliably confirmed and documented, and that all records are accurately completed. The PR should undertake a review of the centre's processes for establishing the identity and marital status of patients and for accurate record keeping. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 30 June 2017. Within three months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 30 September 2017.	We have always checked patient ID by asking patients to bring a suitable document such as passport/driving licence etc. The document number is recorded on the patient registration form which patients complete. The person registering the patient (admin team) checks the document number against the original document and signs the registration form at the bottom to confirm that his has been done and by whom. The registration form has been updated to include a field for marital status. The importance of documenting ID check and of recording marital status was discussed at our recent AGM. An email was also sent to all staff reminding them to ensure marital status is recorded and to sign the form	The executive acknowledges the PR's response and his commitment to fully implement this recommendation. The PR has provided the requested review of practices in this area and actions taken to address this non-compliance. The audit due by 30 September 2017 is awaited. **Further action is required.**

		confirming that ID had been checked and by whom. A further email reminds staff to check patient details on each page before filing any information in patient notes to minimise the risk of misfiling occurring. We will undertake an audit of records to ensure these actions have been effective in achieving compliance and will submit the findings to our inspector by 30 September 2017.	

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
11. **Safety and suitability of premises and facilities** The centre has full gas cylinders stored in a room on the ground floor, not securely chained to the wall. Health Technical Memorandum 02-01: Medical gas pipeline systems, Part B: Operational management SLC T17.	The PR should ensure safe storage of medical gases. The PR should complete a risk assessment for the suitability of the medical gas store. The completed risk assessment and findings, including corrective actions and the timescales for implementation should be provided to the centre's inspector by 30 June 2017.	The storage of medical gas cylinders had been considered a low risk hazard as the plant room is only accessed for maintenance or for changing cylinders which is performed by staff who have received training in gas safety and manual handling of cylinders. Following inspection we instructed our maintenance contractors to install chains for securing cylinders and this has now been completed.	The executive acknowledges the PR's response and that he has confirmed that gas cylinders are now securely stored. No further action is required.
12. **Consent to disclosure to researchers** Six discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register.	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.	The submissions that were identified as being incorrect have been corrected. This issue regarding accurate reporting of patients' consent to disclosure was discussed with the relevant staff at	The executive acknowledges the PR's response and his commitment to fully implement this recommendation. The PR has confirmed that the incorrect submissions have been corrected and has

CH(10)05 and General Direction 0005 *NB. The Centre's designated HFEA Form Returnee has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected.*	The PR should also correct the submissions that have been identified as being incorrect and confirm this has been completed when responding to this report. The PR should review the centre's procedures to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on patient's consent forms. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 30 June 2017. Within six months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 30 December 2017.	meetings on 31 March and 3 April, and at our AGM on 10 May 2017. The relevant SOP for HFEA form submissions is under review and will be updated to emphasise the importance of this matter. We will undertake an audit of records to ensure these actions have been effective in achieving compliance and will submit the findings to our inspector by 30 December 2017.	provided the requested review of processes including actions taken. The audit due by 30 December 2017 is awaited. **Further action is required.**

13. Obligations and reporting requirements Twenty eight percent (32/116) of the IVF and 28% (17/60) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required. General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should review the centre's procedures used to submit licensed treatment data to identify and address the reasons for poor quality submissions. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector when responding to this report. Within six months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 30 September 2017.	I consider our processes for reporting treatments to the HFEA to be robust. IVF and DI treatments are both reported via EDI by the embryology team as soon as the laboratory episode is completed, well within the statutory 10 working days. The issue with 28% of treatments not being reported in 2016 is I believe due to problems with the EDI system which is administered by the HFEA and is beyond our control. We reported a problem with our EDI submissions to Mellowood Medical (who support our IDEAS database) on 8 January 2016. Mellowood contacted EDI Support at the HFEA requesting the necessary intervention from the EDI team. On 26 January Mellowood asked our clinic to also contact HFEA EDI Support and to stress the urgent nature of the problem as they had not had a	The executive acknowledges the PR's response and his commitment to fully implement this recommendation. The PR has provided the requested review and the executive notes the centre's difficulties in data submission last year. The audit due by 30 September 2017 is awaited. **Further action is required.**

		response to their request. Our inspector and our register information officer were copied in to this email. The problem was not resolved until late March 2016 by which time a large number of forms were outside the statutory reporting period.	

Reponses from the Person Responsible to this inspection report