Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
5 June 2015

Minutes – item no. 5

Centre 0139 (Bath Fertility Centre) – Interim Report

Members of the Panel:	**Juliet Tizzard** Director of Strategy & Corporate Affairs (Chair) **David Moysen** Head of IT **Hannah Verdin** Head of Regulatory Policy
Members of the Executive in attendance:	**Sam Hartley** Head of Governance & Licensing

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:

- HFEA protocol for the conduct of meetings of the 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 the 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 the publication of Authority and committee papers

Consideration of Application

1. The panel noted that Bath Fertility Centre has held a licence with the HFEA since May 1994. The centre provides a full range of fertility services.

2. The panel noted that the centre's licence is due to expire on 31 August 2017.

3. The panel noted that the inspection took place on 24 March 2015.

4. The panel noted that in the 12 months to 28 February 2015, the centre provided 521 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

5. The panel noted that for IVF and ICSI, HFEA-held register data for the year ending 30 November 2014 showed the centre's success rates were in line with national averages.

6. The panel noted that in 2014, the centre performed 13 cycles of IUI with no pregnancy. This was consistent with the national average.

7. Between 1 December 2013 and 30 November 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represented performance that was likely to be statistically lower than the 10% multiple live birth rate target for this period.

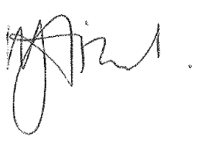
8. The panel noted that at the time of the interim inspection on 24 March 2015, three major and three other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has broadly committed to fully implementing the outstanding recommendations within the prescribed timescales.

9. The panel noted that the inspection team recommended the continuation of the centre's licence and noted that the centre's multiple pregnancy rate is below the national average and the positive comments made by patients.

Decision

10. The panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment and storage licence continued. The panel commended the centre on its low multiple pregnancy rate and the positive patient feedback received, and urged the PR to work with the Executive in addressing promptly the outstanding recommendations.

Signed: Date: 15 June 2015



Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Bath Fertility Centre
Centre number: 0139
Date licence issued: 01 September 2013
Licence expiry date: 31 August 2017
Additional conditions applied to this licence: None
Date of inspection: 24 March 2015
Inspectors: Karen Conyers (Lead), Susan Jolliffe, Lesley Brown (observer)
Date of Executive Licensing Panel: 5 June 2015

Purpose of the report

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

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

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 the focus of an interim inspection is:

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

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

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

Summary for the Executive Licensing Panel

The inspection team recommends the continuation of the centre's licence. In particular we note that the centre's multiple pregnancy rates are below national average and the positive comments made by patients.

The Executive Licensing Panel is asked to note that there are six recommendations for improvement in relation to three major and three 'other' areas of non-compliance or poor practice as follows:

'Major' areas of non-compliance:

- The PR should ensure that there is consent in place for all embryos that are in storage.
- The PR should ensure compliance with medicines management regulations.
- The PR should ensure that CE marked medical devices are used wherever possible.

'Other' areas of practice that require improvement:

- The PR should ensure that audits conducted assess the centre's compliance with regulatory requirements, approved protocols and quality indicators.
- The PR should ensure that all HFEA invoices are paid within the timescales specified by the Authority.
- The PR should ensure that all licensed treatment activity is reported to the Authority as required by General Direction 0005.

The PR has broadly provided a commitment to implement the recommendations of the report within the prescribed timescales. The Executive will continue to liaise with the PR in relation to the storage of embryos beyond the expiry of the consent provided by the gamete provider.

Information about the centre

Bath Fertility Centre was first licensed by the HFEA in May 1994. The centre's licence was renewed following an inspection in April 2013, and in May 2013 the centre's licence was varied to change the location of the licensed premises to a new purpose built facility in Peasedown St John, approximately eight miles away from Bath.

The centre provides a full range of fertility services. Treatments are provided to both NHS and self funded patients. The centre provided 521 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2015. In relation to activity levels this is a medium centre**.**

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 December 2013 and 30 November 2014 show the centre's success rates are in line with the national average.

In 2014, the centre reported a total of 13 cycles of partner insemination with no clinical pregnancies. This is in line with the national average.

Multiple births[2]

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

Between 1 December 2013 and 30 November 2014 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 6%: this means that the centre's multiple live birth rate is likely to be lower than the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos, and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: egg collection and sperm preparation. All of the procedures observed were witnessed in accordance with HFEA requirements using an electronic witnessing system.

[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%.

Consent to the storage of cryopreserved material

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 that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

During the inspection we evaluated the centre's processes for storing gametes and embryos and these were compliant with HFEA requirements with the following exception; embryos from one patient were in storage beyond the expiry date of the consent to store (see recommendation 1). This was discussed in detail with staff at the centre who explained that the patient is eligible to extend storage but is unable to make this decision. The case is under constant review and the centre felt that this was a particularly difficult situation where a decision to dispose of the embryos could be subject to legal challenge. Staff are therefore reluctant to discard the embryos until a decision can be made by the patient regarding the storage period. The embryos remain in storage without effective consent whilst a resolution can be sought.

The storage issue outlined above was not considered indicative of a systemic failure of the bring forward system which was considered robust. All patients with stored gametes and/or embryos are contacted annually. A list of patients whose samples are approaching the end of the storage period is generated from an electronic database and checked by laboratory staff prior to contacting the patients.

Staffing

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

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Quality Management System (QMS)

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

The effectiveness of the centre's QMS was assessed by evaluating a sample of the centre's audits. We also considered whether the clinic's processes for implementing learning are effective.

The centre's audits of documentation of witnessing, consent to storage and medicines management were reviewed during the inspection. The inspection team considered that the

centre's audit practices are broadly compliant with requirements with the following exceptions.

- The centre's audit of witnessing did not include any evaluation of the reasons for mismatches identified from the electronic witnessing system report (see recommendation 4). The consultant embryologist was confident that the centre's processes for witnessing are robust, that mismatches recorded were false alarms and that staff would not proceed if any real mismatches of gametes or embryos had taken place. Having observed witnessing practices and from discussions with the laboratory staff, the inspection team were assured that witnessing practices are compliant with requirements.
- In relation to the centre's audit of consent, standard practice is to give patients the option to consent to the maximum 10 year statutory storage period and the consent decision is recorded on a database. However the centre's audit did not include a comparison of the consent expiry dates recorded in the database against the period recorded in the patient's consent forms to assess the accuracy of the electronic records. The inspection team consider that there is a risk that any inaccuracy in the electronic records could lead to gametes or embryos being stored outside the terms of the gamete provider's consent (see recommendation 4).
- The centre's audit of medicines management had identified two non-compliances which and not been acted upon (see recommendation 4). These were that the Controlled Drugs Accountable Officer (CDAO) should not participate in the supply and administration of controlled drugs and that they should establish links with the Local Intelligence Network (also see medicines management section below),

The centre is broadly effective in implementing learning from their audits and from guidance from the HFEA. However, they had not acted on non-compliances identified in their medicines management audit (see recommendation 2) and had not fully implemented guidance issued in 2013 in relation to the use of CE marked medical device (see equipment and materials section below, recommendation 3).

Medicines Management

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

During the inspection the centre's processes for medicines management and the safe storage disposal and administration of medicines were reviewed and found to be compliant with guidance with the following exceptions:

- the controlled drug cupboard contained a mixture of Schedule 2, 3, and 4 drugs, with the Schedule 2 drug on the bottom shelf. Controlled drugs are subject to safe custody requirements (under the Misuse of Drugs Safe Custody Regulations 1973). They must be stored in a locked receptacle, such as an appropriate controlled drugs cabinet or approved safe which can only be opened by a person authorised to possess a controlled drug, or a person authorised by them, to ensure a safe system of working (see recommendation 2);
- the centre's CDAO participates in both the supply and administration of controlled drugs in the course of her clinical activities at the centre. This is contrary to the regulatory requirements for Accountable Officers, set out in the

Controlled Drugs (Supervision and Management of Use) Regulations 2006; www.opsi.gov.uk (see recommendation 2);

- controlled drugs wastage is not documented in the controlled drug book which is contrary to the requirements of the Controlled Drugs (Supervision of Management and Use) Regulations 2006 (see recommendation 2).

Infection Control

Having suitable arrangements in place to ensure that patients experience care in a clean environment is important, as well as ensuring that both patients and staff are protected from acquiring infections.

During the inspection, we assessed compliance with infection control guidance by observation, and found that the centre's procedures were compliant with guidance.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for use in treatment to ensure the safety of gametes and embryos and patients. Approval of such products is denoted by the issue of a 'CE mark'.

In the course of the inspection the CE mark status of a sample of the medical devices used by the clinic was reviewed. The centre is partially compliant with HFEA requirement to use CE marked medical devices wherever possible (see recommendation 3). The following medical devices used by the centre are not CE marked: protein supplement for culture media, tubes and dishes used for follicular aspirates during egg collection.

The addition of a non-CE marked supplement to a CE marked culture media product invalidates the CE mark status of the culture medium. In a Clinic Focus article issued in April 2013 clinics were advised that in the absence of any prospect that non-CE marked products would meet the requirements of licence conditions, they should implement a plan of action to ensure compliance within the following year. The centre did not act on this guidance suggesting that the centre's procedures for taking action in response to guidance issued by the HFEA may not be robust.

Patient experience

During the inspection visit we spoke to three patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further 37 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with 27 of the individuals also providing written feedback commenting that they had compliments about the care that they received, and that staff were supportive and professional.

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 prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team identified the following non-compliance: embryos from one patient were in storage beyond the date of the consent to store as discussed above (see recommendation 1)

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2013 recommendations for improvement were made in relation to one major and five 'other' areas of non-compliance. The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

On-going monitoring of centre success rates and risk tool alerts

Since the last inspection in April 2013 the centre has been asked to review procedures for the provision of ICSI treatment for women aged <38 years. The PR responded to the request and there have been no further alerts relating to success rates in this patient group.

During the last 12 months, the centre has been issued with several risk tool alerts related to the late payments of HFEA invoices, which is non-compliant with the requirements of the Authority as issued in Chair's letter CH(10)02 (see recommendation 5).

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. During the last 12 months, the PR has received a number of risk tool alerts in relation to submission of data to the HFEA which have not been addressed (see recommendation 6).

The partners of women treated with donated gametes or embryos, where the couple are not married or in a civil partnership, must give written consent in order to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood. 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 sent the report of the audit to the HFEA within the required timeframe. On inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and that no actions had been necessary as a result of the findings.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical 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			

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. The centre did not have consent for the storage of cryopreserved embryos for one patient. It is noted that the HFEA’s assessment framework recommends classification of storage without consent as a critical non-compliance but in consideration that the gametes of only one patient are being stored without consent and that there are specific issues that have made the centre reluctant to dispose of the embryos then this has been classified as major. Schedule 3, 8(1) HF&E Act.	The PR should ensure that there is consent in place for all embryos that are in storage. The PR should seek legal advice and/or guidance from a multidisciplinary team with respect to this case and provide an update on the proposed next steps by the time this report is considered by a Licensing Committee. The PR is reminded of guidance issued by the HFEA in CH (03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.	This single case was discussed during the inspection and comments made. It was felt that the Inspectors had understood the reason for this particular circumstance. The report indicated we should seek legal advice or guidance. We had drawn to the attention of the inspectors the guidance we had sought previously from the HFEA which is documented in the patient’s notes. We	The Executive acknowledges the PR’s responses. It is noted that the centre received the following advice from the HFEA in October 2013 - a month before the expiry of consent to the storage of the embryos: “*I would advise that your proceed with caution here and suggest that you do not discard this lady’s embryos at this time as her capacity to make an informed decision may be impaired due to a current mental health issues but this does not*

		had received clear guidance that it was appropriate to continue to store these embryos due to the mental ill health of the patient who remained unable to make a decision about her storage. We still feel it is appropriate not to discard these embryos while this patient remains ill. We have remained in contact with the patient's psychiatric carer. We have obtained confirmation from the sperm bank that the sperm provider consented to storage of embryos for 10 years. In conclusion this is a difficult case but the retention of material beyond the consented storage period is for good medical reasons.	*necessarily mean that going forward, she will continue to lack mental capacity, which would require a medical statement and an advocate to be appointed for this lady.* The advice also recommended that the centre should document their decision and suggested that the centre's rationale for retaining the embryos in storage until such time as the patient has capacity or that lack of mental capacity, if formally stated, would be accepted. It is acknowledged that the centre is acting in accordance with this advice but given the lapsed time, the recommendation that the PR should seek further legal advice and/or guidance from a

		Unless we are directed by the HFEA we will continue to store this material until the patient is in a position to make a decision when she has clear mental capacity to do so.	multidisciplinary team is considered proportionate. The Executive will seek further information on the proposed next steps and actions taken in relation to the recommendation to seek guidance from suitably qualified specialists responsible for the patient's care. The PR should provide monthly updates to the centre's inspector regarding this case. Further action is required.
2. Medicines Management: The controlled drug cupboard contained a mixture of Schedule 2, 3, and 4 drugs, with the Schedule 2 drug on the bottom shelf. Controlled drugs are subject to safe custody requirements (under the Misuse of Drugs Safe Custody Regulations 1973). They must be stored in a	The PR should ensure compliance with medicines management regulations. The PR should undertake a review to identify the factors that have led to these non-compliances with medicines management regulations. A summary report of the review including corrective actions and the timescale for the implementation of corrective actions should be provided to the centre's	Our drug storage system is identical to that which we have used for 20 years when we were based in our former premises. Several HFEA inspections have occurred during that time with no concerns. The current drug	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. The PR is reminded that prior to October 2014 the HFEA did not inspect this area. Clinics were made aware of this through a

locked receptacle, such as an appropriate controlled drugs cabinet or approved safe which can only be opened by a person authorised to possess a controlled drug, or a person authorised by them, to ensure a safe system of working. The CDAO participates in both the supply and administration of controlled drugs in the course of her clinical activities at the centre This is contrary to the regulatory requirements for Accountable Officers, set out in the Controlled Drugs (Supervision and Management of Use) Regulations 2006; www.opsi.gov.uk. Controlled drugs wastage is not documented in the controlled drug book which is contrary to the requirements of the Controlled Drugs (Supervision of Management and Use) Regulations 2006. SLCT2 and SLCT17.	inspector by 24 June 2015. Within three months of implementing changes, the centre should carry out an audit of medicines management procedures to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the audit should be supplied to the centre's inspector by 24 September 2015.	cupboard is kept locked when we are not accessing the controlled drugs for patient sedation purposes. It is in a secure area only accessed with swipe cards and therefore the area can only be accessed by qualified staff. The Home Office inspection during our application for our controlled drugs licence made no specific requirements about our storage facility. However, we are going to obtain a separate small drug cupboard to secure the controlled drugs as per the report requirement. Because we are a small team the CDAO has been a member of the nursing team. Now that our Business	Chair's letter CH(14)01. The PRs comments are accepted in lieu of a review. Further action is required in relation to the audit due by 24 September 2015.

		Manager has returned form maternity leave we will appoint her as CDAO. Controlled drug wastage is now documented in our controlled drugs stock book as requested.	
3. The following medical devices used by the centre are not CE marked: protein supplement for culture media, tubes and dishes used for follicular aspirates during egg collection. The addition of a non-CE marked supplement to a CE marked culture media product invalidates the CE mark status of the culture medium. In a Clinic Focus article provided in April 2013 clinics were advised that in the absence of any prospect that non-CE marked products would meet the requirements of licence conditions, they should implement a plan of action to ensure compliance within the following year. The centre did	The PR should conduct a review of all medical devices currently in use to identify where products are not CE marked and take action to source alternatives. The PR should provide the centre's inspector with a list of all medical devices including disposable plastic ware, equipment, and culture medium indicating the CE mark status of these products. Where devices are not CE marked then the PR should indicate the proposed timescale for sourcing alternatives by 24 June 2015. We do not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this it is expected that all medical devices should be CE marked by 24 September 2015.	We enclose a list of the consumables and their CE status in the laboratory setting. It will be noted that where no CE marked alternative is available we have undertaken Risk Assessments and validation. This report references a Clinic Focus from 30th April 2013 and states "they should implement a plan of action to ensure compliance within the following year". The Clinic Focus does not contain this direction; it states "you should	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. The PR confirms that non-CE marked protein supplement for media is no longer in use and that CE marked alternatives for the other items will be used as soon as possible. The PR should inform the centre's inspector when all medical devices in use are CE marked by 24 September 2015. Further action is required

not act on this guidance. SLC T30. Clinic Focus April 2013	The PR should review whether there are barriers to the implementation of learning from guidance provided by the HFEA and/or other sources. The PR should provide feedback on this review to the centre's inspector by 24 June 2015.	consider implementing a plan of action to ensure compliance within the next year." We hope the committee will note the difference in emphasis here. This, together with the wording of T30 and guidance 26.5 in the CoP, led us to believe that we were compliant. We can report that we have now changed our culture medium to one that is available with a CE mark. This medium has only became available recently. The report contained a comment regarding implementation of learning from guidance provided by the HFEA and/or other sources. I can confirm that we have monthly Head of Department meetings	in relation to the review due by 24 June 2015.

		at Bath Fertility Centre with standard agenda items which includes the HFEA and CQC, as well as many others. We will however review our process at the next meeting and report back by 24th June. I personally do not believe we have any specific barriers to HFEA guidance being observed, although on occasion the guidance itself could be clearer.	

‘Other’ areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. The centre’s audits of : • consent to storage did not include a review of the patient’s consent forms against the data held in the centre’s bring forward system database, • witnessing did not include a review of the mismatches identified in the electronic witnessing report, • medicines management found two areas of non-compliance which had not been implemented. SLCT36.	The PR should ensure that audits conducted assess the centre’s compliance with regulatory requirements, approved protocols and quality indicators. The PR should conduct a review to identify the factors that led to the failure to ensure that audits evaluate compliance with the regulatory requirements, the centre’s approved protocols and quality indicators and that corrective actions are fully implemented. A summary report of the review including corrective action and the timescale for the implementation of corrective actions should be provided to the centre’s inspector by 24 June 2015.	We have now undertaken storage consent and witnessing review audits which have been provided to the lead inspector. We can also report that any mismatches on the electronic witnessing system are now tabled as a standard agenda item for discussion at each monthly embryology team meeting. With regard to medicines management – see comments above. We will be conducting a review to identify factors which led to failure to evaluate the audits and will report back by the 24th June 2015.	The Executive acknowledges the PR’s responses and his commitment to fully implementing the recommendation. Further action is required in relation to the review due by 24 June 2015.
5. During the last 12 months, the centre has been issued with	The PR should take appropriate action to ensure that all HFEA	We would ask that our inspector forwards these alerts	The Executive acknowledges the PR’s

several risk tool alerts related to the late payments of HFEA invoices. SLCT9d and CH(10)02.	invoices are paid within the timescales specified by the Authority, and advise the centre's inspector of these by 24 June 2015.	to a member of our finance team. Dr Gadd will provide their email addressess to our inspector.	responses. Risk tool alert emails are sent to the PR as it is his duty to ensure that HFEA payment terms are met. Further information is required with regard to actions the PR will take to ensure compliance with these requirements by 24 June 2015.
6. During the last 12 months, the PR has received a number of risk tool alerts in relation to submission of data to the HFEA which have not been addressed. SLC T9e, SLC T41 and General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the Authority as required by General Direction 0005. The PR should confirm that all the issues identified in the risk tool alerts have been addressed when responding to this report. The systems and processes used for licensed treatment data submission should be reviewed to identify the factors that have led to this non-compliance. The PR should provide the centre's inspector with a summary report of the findings of the review including any corrective actions	These are consistently related to typographical errors on sperm donor codes at the time of treatment form submission. They are simply due to human error, e.g. using a hyphen instead of underscore. We would request that these alerts be forwarded to our Quality Manager, Dr Stephanie Gadd. We note that an audit will be required of these changes to be reported to the inspector by September. We will undertake to achieve this as requested.	The Executive acknowledges the PR's responses. Risk tool alert emails are sent to the PR as it is his duty to ensure the accuracy of data submitted to the HFEA. Further action is required in relation to the review due by 24 June and audit due by 24 September 2015.

	identified and the timescale for their implementation by 24 June 2015. The PR should conduct an audit three months after implementing any changes to confirm that any changes made to systems and processes have been effective In ensuring compliance with submission requirements. A summary report of the findings of the audit should be provided to the centre's inspector by 24 September 2015.		

Additional information from the Person Responsible
The team were generally disappointed at the tone of the Interim Licensing Report. It seems as if the focus of the inspection has reverted to an inspection of process with little attention to outcome. We believe we are a low risk unit with a good track record and have much to be proud of. For example on Page 3 the report states – "the centre's multiple pregnancy rate for all IVF/ICSI and FET cycles for all age groups is 6%: this represents performance that is likely to be lower than the 10% multiple birth rate target for this period". Since the 10% multiple birth rate is a target and not a statistical comparison then 6% is definitely lower than 10%. We believe this is a real achievement and a positive comment would have been entirely appropriate at that point. During the inspection it was mentioned that the HFEA had received a good deal of positive patient feedback in respect of our service. This has been provided to us following a direct request from myself. We understand that the patient comments cannot be included on our website although since there are a large number of comments which are mostly positive this would give a fair, unbiased assessment by the general population of our service. I would therefore like to suggest patients may be asked to give their permission to use their comments anonymously to help patients when they are trying to choose where to have treatment.