Executive Licensing Panel - minutes

Centre 0015 (Sussex Downs Fertility Centre)

Interim Inspection Report

Wednesday, 25 April 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Caylin Joski-Jethi Erin Barton	Director of Strategy and Corporate Affairs Head of Intelligence Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Laura Riley Lisa Whiting	Senior Governance Manager Head of Regulatory Policy Data and Insights Analyst

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 noted that Sussex Downs Fertility Centre is located at the BMI Esperance Hospital in Eastbourne and has held a treatment and storage licence with the HFEA since 1992. The centre has a satellite treatment agreement with Goring Hall Hospital, Sussex and provides a full range of fertility services.

1.2. The panel noted that, in the 12 months to 31 December 2017, the centre provided 441 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels, this is a small sized centre.

1.3. The panel noted that HFEA held register data, for the period ending 30 September 2017, shows the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

1.4. The panel noted that, in 2017, the centre reported 25 cycles of partner insemination with three pregnancies This is in line with the national average.

1.5. The panel noted that the inspection took place on 13 February 2018.

1.6. The panel noted that at the time of the inspection, one major area of non-compliance or poor practice was identified concerning the screening of patients and donors. Four 'other' areas of non-compliance were also identified regarding the Quality Management System (QMS), equipment and materials, premises and facilities and finance. The panel noted that since the inspection, the Person Responsible (PR) has given a commitment to implementing all the recommendations made in the report, within the prescribed timescales.

1.7. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence.

2. Decision

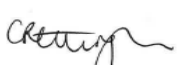
2.1. The panel particularly noted that the non-compliance, concerning the QMS, was in relation to the audit of consent to legal parenthood, acknowledging this was a historic issue which had also been identified at the centre's last renewal inspection in 2016. The panel encouraged the PR to ensure that the QMS is used to its best effect in dealing with legal parenthood and adheres to the specific practice and guidance in relation to this area.

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

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

1 May 2018

Interim Licensing Report

Centre name: Sussex Downs Fertility Centre
Centre number: 0015
Date licence issued: 1 July 2016
Licence expiry date: 30 June 2020
Additional conditions applied to this licence: None
Date of inspection: 13 February 2018
Inspectors: Karen Conyers (lead), Janet Kirkland
Date of Executive Licensing Panel: 25 April 2018

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. The foci of an interim inspection are:

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

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

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's 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.

The ELP is asked to note that this report makes recommendations for improvement in relation to one major and four 'other' areas of non-compliance or poor practice as follows:

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

Major area of non-compliance:

- The PR should ensure that a patient or donor's travel or medical history with regard to the risks of infections (such as Zika and Ebola), is fully considered prior to treatment, to determine if any additional testing may be required.

'Other' areas that requires improvement:

- The PR should ensure that all audit reports include details of the scope and methodology used.
- The PR should ensure that CE marked medical devices are used where possible.
- The PR should ensure that all medical gases are kept secure at all times.
- The PR should ensure fees payable to HFEA are made within the required timeframe.

Information about the centre

The Sussex Downs Fertility Centre is located at the BMI Esperance Hospital in Eastbourne and has held a Treatment and Storage licence with the HFEA since 1992. The centre has a satellite treatment agreement with Goring Hall Hospital, Sussex.

The centre provides a full range of fertility services.

The centre provided 441 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2017. In relation to activity levels this is a small centre.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

HFEA held register data for the year ending 30 September 2017 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages

In 2017, the centre reported 25 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.

HFEA held register data for the year ending 30 September 2017 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

Witnessing

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

Consent: To the storage of cryopreserved material

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

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[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%.

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

Staffing

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

The interim inspection was carried out at a time when the centre had reduced activity and several staff were on leave. The PR assured the inspection team that staffing levels were suitable for the activities carried out.

Quality Management System (QMS)

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

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing, consent, consent to storage and legal parenthood.

The centre's procedures for auditing and acting on the findings of audits are broadly compliant with requirements because:

- The report of the centre's most recent audit of consent to legal parenthood does not include any description of the scope or methodology used (recommendation 2). On the day of inspection, centre staff confirmed that the audit methodology was compliant with the HFEA's Chief Executive's letter CE(14)01, and that no anomalies had been identified. The audit report was not available on the day of inspection as the quality manager was on leave. Instead, the inspection team was provided a copy of the raw data used for the audit and noted a record where it appeared that consent to legal parenthood had been completed after treatment. The inspection team requested the records of that couple, and confirmed that consent had been completed prior to treatment, and that the information in the raw data was a typographical error. This had not been picked up by the auditors or noted in the audit report which was provided after the inspection.

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

- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding: screening requirements

The centre is partially effective in ensuring compliance with guidance issued by the HFEA because it does not fully consider the patient or donor's travel or medical history with regard to the risks of infections (such as Zika and Ebola), or whether any additional testing may be required prior to treatment (recommendation 1). The inspection team noted that the centre assesses a patient or donor's travel history in relation to risks of Zika virus exposure or infection, but the list of countries referred to in the questionnaire was not up to date with current guidance. There is also a recommendation with regards to use of CE marked medical devices (see 'Equipment and materials' section below).

Medicines management

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

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

Prescription of intralipid 'off label'

Intralipid is 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.

Infection Control

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

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

Equipment and Materials

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

The CE mark status of the following medical devices was reviewed in the course of the inspection: culture media, plastic ware. We found the centre to be broadly compliant with HFEA requirements to use CE marked medical devices wherever possible because the centre is using a non-CE marked product as a medical device: a tissue grinder for dissecting testicular biopsies for use in ICSI (recommendation 3). The centre's lab manager informed the inspection team that they consider that there is no CE marked alternative to this product, or that no other process using CE marked medical devices can be used to isolate sperm for ICSI. Soon after the inspection, the inspection team requested information on how they had validated this product such that they were assured of the safety and suitability for use in isolating sperm for ICSI. Centre staff informed the inspection team that: 'The tissue grinders are toxicity tested (sperm assay) and are also autoclaved'. Where a centre is using a product as a medical device for which there is no CE marked alternative is available, it is expected that robust validation and audits of use should be in place, and that appropriate information is provided to patients regarding the use of a non-CE marked

product as a medical device, such as any possible risks associated with the use of this item.

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. The centre's most recent survey of patient feedback was reviewed on inspection. The survey was conducted between 10 March and 30 September 2017, and included questions on; cleanliness, waiting times, consultation, appointments, consent session, information, counselling, overall care, facilities and financial matters. The centre received 122 responses of which 98.6% of the responses were positive.

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;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

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

- On arrival at the centre the inspection team noted several unattended and inadequately secured large and small gas cylinders at the main entrance to the hospital (recommendation 4). In addition, it was noted that there were several small cylinders in the gas store that were not secured and were at risk of falling over. We were assured these all these issues noted had been rectified immediately.
- Fees payable to the HFEA have not always been paid within the required timeframe (recommendation 5). This was also noted at the time of the renewal inspection in 2016.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2016, recommendations for improvement were made in relation to three major and two 'other' areas of non-compliances or poor practice.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales with the exception of HFEA fee payment, noted above, that has reoccurred since the last inspection.

On-going monitoring of centre success rates

Since the last renewal inspection in January 2016 the centre has not received any performance related risk tool alerts.

Provision of information to the HFEA

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

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

Legal parenthood

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

This centre has been inspected since 2014 and 2015, when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. The centre did have some cases where anomalies in consent to legal parenthood were identified.

Following a renewal inspection in 2016 all affected patients were informed of the anomalies in writing and offered an appointment at the centre. Despite several attempts to contact them, two couples did not respond to communications from the centre. The PR assured the executive at that time that he was committed to providing necessary support to the patients concerned, and to act in accordance with HFEA guidance should any of the patients contact the centre team and wish to pursue a declaration of parenthood through the courts.

The centre's inspector and Chief Inspector visited the centre in 2017 and were satisfied that the team had taken appropriate action with regards to the patients affected by anomalies in their consent to legal parenthood, and that the processes in place for ensuring effective consent were satisfactory.

On this interim inspection centre staff confirmed that to date, none of the couples previously contacted have sought a declaration of parenthood through the courts.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Of five sets of records reviewed on inspection, one set was identified where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required and no issues were noted. These activities enabled the inspection team to conclude that while the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements, the audit reports of these processes require improvement, as discussed above.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non-compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive reivew
None identified on this inspection			

‘Major’ area of non-compliance

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

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
Screening of patients and donors 1. The centre does not fully consider the patient or donor’s travel or medical history with regard to the risks of infections (such as Zika and Ebola), or whether any additional testing may be required prior to treatment. The inspection team noted that the centre assesses patient or donor’s travel history in relation to risks of Zika virus exposure or infection, but the list of	The PR should ensure that a patient or donor’s travel or medical history with regard to the risks of infections (such as Zika and Ebola), is fully considered prior to treatment, to determine if any additional testing may be required. The PR should also ensure that patients and donors are made aware of the most recent guidance related to the risk from infection by Zika virus. The PR should review the	The centres process for considering patients and donors travel history will be reviewed and the revised policy and associated documentation will be sent to the HFEA by 13.05.18. Attached is the revised patient information leaflet for ZIKA virus and associated patient questionnaire The policy will be amended to reflect a broader process and specific patient information relating to ZIKA and EBOLA	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has provided a new general travel questionnaire, an updated Zika patient information leaflet and a summary of the initial review of the centre’s processes in relation to this area of practice. The PR has confirmed that the new travel questionnaire is in

countries referred to in the questionnaire was not up to date with current guidance. SLCs T50d and T52h. Clinic Focus articles: February 2016, March 2016, August 2016, February 2017 and September 2017.	centre's processes for considering and assessing a patient or donor's travel or medical history. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector with the PR's response to this report. The PR should consider, with expert advice if necessary, if there is any risk to patients or donors resulting from the failure to perform an assessment of past or present Zika or Ebola virus exposure or infection in all patients and donors to date. If risk is present, appropriate risk control measures should be implemented. A summary of the finding of this review should be provided to the centre's inspector with the PR's response to this report. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A	viruses will be created/amended. This will include links to te appropriate websites for patients to have the most up to date information. A review of changes concerning ZIKA virus implemented in Feb 2017 has been conducted. A patient questionnaire was created and issued, for all treatment cycles, to all patients, to ascertian if they had visited any countries where there was a risk of ZIKA transmission. If they had visited any of these countries appropriate measures were taken to eliminate the risk of ZIKA transmission. A full audit of the effectiveness of these changes will be conducted and a report submitted to the HFEA by 30.04.18. as agreed with the centres inspector. There have been no cases of babies born suffering from ZIKA virus from the centre. The centre has not had any cases of Ebola. During the time Ebola was more	use with immediate effect. The executive welcomes the PR's proposal to audit records in order to evaluate if there has been any risk to patients or donors resulting from past or present Zika or Ebola virus exposure, or infection. The findings of the audit of previous patients and donors and the further information regarding the changes to the centre's processes due by 30 April 2018 and 13 May 2018, respectively, are awaited. An audit to evaluate the effectiveness of changes introduced in this area of practice due by 13 June 2018 is also awaited. **Further action is required**.

	summary report of the findings of the audit should be provided to the centre's inspector by 13 June 2018.	prevalent, there were notices in all patient areas advising of the potential risks. A repeat audit will be carried to check the effectiveness of the new policy changes, including EBOLA, and a summary report of the findings will be submitted to the HFEA by 13.06.18.	

‘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.

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
QMS 2. The report of the centre’s most recent audit of consent to legal parenthood does not include any description of the scope or methodology used Centre staff confirmed that the audit methodology was compliant with CE(14)01, and no non-compliances were noted. SLC T36.	The PR should ensure that all audit reports include details of the scope and methodology used. The PR should ensure that the scope and methodology of the centre’s audit of consent to legal parenthood is included in the audit report. A copy of the updated audit report should be provided to the centre’s inspector by 13 May 2018. The PR should review the centre’s processes for documenting the scope, methodology and findings of audits, including corrective actions and timescales for implementation. A summary of	A repeat audit will be carried out and the audit report will contain details of the scope and methodology of this audit. This will be sent to the HFEA by 13.05.18. This report will contain all the findings of the audit and include any corrective actions and timescales for completion.	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR will provide a report of a repeat audit of consent to legal parenthood by 13 May 2018. The PR should also provide the findings of a review of the centre’s processes for documenting the scope, methodology and findings of audits, including corrective actions and timescales for implementation by 13 May 2018. **Further action is required**.

	the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 13 May 2018.		
Equipment and materials 3. The centre is using a non-CE marked product as a medical device: a tissue grinder for dissecting testicular tissue samples for use in ICSI. Where a centre is using a product as a medical device for which there is no CE marked alternative is available, it is expected that robust validation and audits of use should be in place, and that appropriate information is provided to patients regarding the use of a non-CE marked product as a medical device, such as any possible risks associated with the use of this item. SLC T30, T24, T28 and T72.	The PR should ensure that CE marked medical devices are used where possible. We would not recommend precipitous changes that might impact on the quality of treatment, however, the PR should ensure that a plan is developed and implemented so that appropriately CE marked medical devices are used. In consideration of this it is expected that all medical devices in use at the centre should be CE marked by 13 August 2018. If the PR considers that there is no CE marked medical device available, or no other process using CE marked medical devices can be used to isolate sperm for ICSI, then he should ensure that robust	All medical devices used at the centre are CE wherever possible. The tissue grinder is not CE marked and patient information has been updated to this effect, including outcome of robust validaiton processes implemented to eable the continued use of the tissue grinder. A copy of the validation processes and audits will be sent to the HFEA by 13.05.18.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The validation, audits and updated patient information due by 13 May 2018 are awaited. **Further action is required**.

	validation and audits of use should be in place for this product, and that patients are informed that a non-CE marked medical device is being used. A copy of the validation, audits involving the use of this product in treatment, and patient information should be provided to the centre's inspector by 13 May 2018.		
Premises and facilities 4. On arrival at the centre the inspection team noted several unattended and inadequately secured large and small gas cylinders at the main entrance to the hospital. In addition, it was noted that there were several small cylinders in the gas store that were not secured, and were at risk of falling over. We were assured that all of these issues had been rectified immediately.	The PR should ensure that systems are in place for the safe storage of gases at all times. We were assured this had been actioned on the day of inspection. However, the PR should consult with the hospital's gas safety officer with regards to the issues noticed on inspection, to ensure that this does not happen again. The PR should advise the centre's inspector that this action has been implemented by 13 May 2018.	All cylinders are chained up during delivery of new cylinders and the collection of empty cylinders. This process is now audited once each month and a copy for March, April and May audits will be sent to the HFEA by 13.05.18.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed the actions that have been taken to prevent recurrence of this non-compliance. The audits due by 13 May 2018 are awaited. **Further action is required**.

SLC T17 and Health Technical Memorandum 02-01: Medical gas pipeline systems Part B: Operational management.			
Finance 5. Fees payable to the HFEA have not always been paid within the required timeframe. SLC T9d and CH (10)02. This was also noted at the time of the renewal inspection in 2016.	The PR should ensure fees payable to HFEA are made within the required timeframe. The PR should take appropriate action to ensure that all HFEA invoices are paid within the timescales specified by the Authority, and advise the centre's inspector of these actions by 13 May 2018.	Business Services Team Leader for BMI Healthcare has confirmed 'we are reducing the payment terms on the system from 28 days to 21 days, which mean the invoices should reach the HFEA account before thay fall overdue'. PR will ensure this is the case and follow-up any invoices not processed within the required timeframe.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided information on the actions taken to address this issue. Payment of fees within the timescale specified by the Authority will continue to be monitored. **Further action is required**.

Additional information from the Person Responsible
Attached patient ZIKA virus questionnaire and information leaflet (SDFC 317) and (SDFC 348)