Executive Licensing Panel - minutes

Centre 0044 (The Centre for Reproductive and Genetic Health)

Interim Inspection Report

Tuesday, 15 January 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Niamh Marren Helen Crutcher	Director of Strategy and Corporate Affairs Regulatory Policy Manager Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Hannah Carpenter Richard Sydee	Senior Governance Manager Policy Officer Director of Finance and Resources

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:

- 9th 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 The Centre for Reproductive and Genetic Health is located in central London and has held a licence with the HFEA since 1992. The centre provides a full range of fertility treatment services, including embryo testing. Other licensed activities at the centre include storage of gametes and embryos.

1.2. The panel noted that, in the 12 months to 30 September 2018, the centre had provided 1,343 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre.

1.3. The panel noted that, at the time of the inspection, the centre had not submitted IUI data for 2017; this was submitted three days after the inspection. In 2017 the centre reported 134 cycles of partner insemination with 17 clinical pregnancies of which one was a twin pregnancy. This represents a clinical pregnancy rate of 13%, which is comparable to the national average

1.4. The panel noted that HFEA register data, for the year ending 30 June 2018, show the centre's success rates, in terms of clinical pregnancy rates, are in line with the national averages, with the following exceptions:

- the clinical pregnancy rate following IVF in patients aged less than 38 years is above the national average at a statistically significant level;
- the clinical pregnancy rate following IVF in patients aged 38 years and over is above the national average at a statistically significant level;
- the clinical pregnancy rate following ICSI in patients aged less than 38 years is above the national average at a statistically significant level;
- the clinical pregnancy rate following ICSI in patients aged 38 years and over is above the national average at a statistically significant level;
- the clinical pregnancy rate following frozen embryo transfer (FET) in patients aged less than 40 years is above the national average at a statistically significant level.

1.5. The panel noted that HFEA register data, for the year ending 30 June 2018, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

1.6. The panel noted that the inspection took place on 13 November 2018.

1.7. The panel noted that at the time of inspection there was one area of major of non-compliance identified concerning medicines management. Four 'other' areas of non-compliance were also identified regarding provision of information to the HFEA, the website, adverse incidents and satellite agreements. Since the inspection, the Person Responsible (PR) has fully implemented the recommendations regarding the website, adverse incidents and satellite agreements, giving a commitment to fully completing all the outstanding non-compliances, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment (including embryo testing) and storage licence, particularly noting that the centre has reduced its multiple birth rate since 2016, from 20% to 14%, whilst maintaining success rates which are higher than the national average at a statistically significant level. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period. The inspection team considered this achievement to be one which provides evidence of the PR's

commitment to continually improve all aspects of the service and has been achieved through a high level of engagement with both the HFEA and centre staff.

2. Decision

2.1. The panel noted, with concern, evidence of a reoccurring non-compliance, regarding medicines management, which was also identified at the renewal inspection in 2016.

2.2. The panel acknowledged the centre's positive engagement with patient feedback, submitted through the 'Choose a Fertility Clinic' mechanism, available on the HFEA website, to improve the quality of service provided.

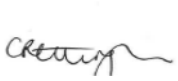
2.3. The panel noted the reduction of the centre's multiple birth rate since 2016, from 20% to 14%, whilst maintaining success rates which are higher than the national average at a statistically significant level.

2.4. The panel was satisfied the centre was fit to have its treatment (including embryo testing) 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

18 January 2019

Interim Licensing Report

Centre name: The Centre for Reproductive and Genetic Health
Centre number: 0044
Date licence issued: 01 April 2017
Licence expiry date: 31 March 2021
Additional conditions applied to this licence: None
Date of inspection: 13 November 2018
Inspectors: Karen Conyers (lead), Polly Todd and Debbie Jefferies (observer)
Date of Executive Licensing Panel: 15 January 2019

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 (SLCs).

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. In particular we note that the centre has reduced its multiple birth rate since 2016, from 20% to 14%, whilst maintaining success rates which are higher than the national average at a statistically significant level. The inspection team consider this achievement to be one which provides evidence of the PR's commitment to continually improve all aspects of the service and has been achieved through a high level of engagement with both the HFEA and centre staff.

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.

Since the inspection visit, the PR has given a commitment to fully implement all the recommendations, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

Major areas of non-compliance:

- The PR should ensure that medicines management practice is in line with statutory requirements.

'Other' areas of practice that require improvement:

- 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 take appropriate action to ensure that the centre's website is compliant with requirements.
- The PR should ensure that all adverse incidents and near misses are reported to the HFEA.
- The PR should ensure that written agreements are in place and provided to the HFEA before commencement of satellite services.

Information about the centre

The Centre for Reproductive and Genetic Health is located in central London and has held a licence with the HFEA since 1992. The centre provides a full range of fertility treatment services, including embryo testing. Other licensed activities at the centre include storage of gametes and embryos.

The centre provided 1,343 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2018. In relation to activity levels this is a large centre**.**

The centre's licence was varied in June 2018 to reflect a change of Licence Holder.

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 June 2018 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exceptions:

- the clinical pregnancy rate following IVF in patients aged less than 38 years is above the national average at a statistically significant level;
- the clinical pregnancy rate following IVF in patients aged 38 years and over is above the national average at a statistically significant level;
- the clinical pregnancy rate following ICSI in patients aged less than 38 years is above the national average at a statistically significant level;
- the clinical pregnancy rate following ICSI in patients aged 38 years and over is above the national average at a statistically significant level and
- the clinical pregnancy rate following frozen embryo transfer (FET) in patients aged less than 40 years is above the national average at a statistically significant level.

At the time of the inspection the centre had not submitted IUI data for 2017 (see recommendation 2), however this was submitted three days after the inspection. In 2017 the centre reported 134 cycles of partner insemination with 17 clinical pregnancies of which one was a twin pregnancy. This represents a clinical pregnancy rate of 13%, which is comparable to 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 June 2018 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

The PR and centre staff are to be commended on their success in reducing the multiple pregnancy rate from 20% at the time of the last inspection in 2016, thereby reducing the single biggest risk of fertility treatment whilst still achieving success rates above the national average at a statistically significant level as set out above.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activity was observed in the course of the inspection: embryo thawing. The procedure observed was witnessed using a manual witnessing system in accordance 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

[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%.

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.

On inspection, reports of audits of all stored gametes and embryos, the 'bring-forward' system and the accuracy of the storage records were reviewed and discussed. 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 inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations 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 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, legal parenthood, infection control and management of medicines.

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

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 has been effective in ensuring compliance with guidance issued by the HFEA, with the exception of the centre's website. The website is not compliant with guidance as it does not provide a like-for-like comparison to national outcomes because the time period used for the centre's live birth rates is not the same as for the HFEA published data (see recommendation 3).

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 partially compliant with guidance for the following reasons (see recommendation 1):

- There was a correction in the controlled drugs register that had been made by over-writing the original entry. This is not in line with statutory regulations.
- The carry-over of stock had not been witnessed in some cases.
- The time of administration of controlled drugs was not recorded or witnessed in some cases. Not recording the time of administration of a controlled drug was a non-compliance at the renewal inspection in 2016.

Prescription of intralipid 'off label'

Intralipid is a sterile liquid soybean and egg yolk-based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

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, plasticware and consumables. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection, patients were not available to speak with the inspectors about their experiences at the centre.

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. The centre has a rating of 4.5 out of 5 on the HFEA website and this is based on 99 responses. Of these, 47 patients provided additional free text comments and feedback was generally very positive with patients complimenting staff at the clinic. However, three individuals reported a number of concerns in aspects of their experience at the centre. Themes and trends noted in this feedback was discussed in detail with the PR and centre staff.

Similar themes in feedback received directly to the HFEA was also noted in the centre's own complaints log and patient survey. These related primarily to unexpected costs (for example additional medicines and procedures), clarity of information, and level of service which patients noted as sometimes being inconsistent.

Actions taken by the centre in response to their complaints and patient feedback was discussed at length with the centre's Chief Operating Officer. He advised the inspectors of the actions that have already been taken to address any potential areas of weakness. These included reviewing the way in which patients are advised of costs, and the development of a 'patient service standard' to drive improvements in the patient experience. Patients who had submitted complaints had been invited to be part of this service development and this engagement was proving to be a positive step.

The inspection team also reviewed the centre's analysis of feedback provided by patients between January and August 2018. In response to this feedback the centre is implementing a 'named nurse' system whereby patients are assigned a nurse to support them throughout their treatment journey and have also appointed an individual to work across all staff groups to improve customer service and the patient experience.

The General Manager noted that responses to the paper questionnaires had declined sharply recently and many patients prefer to provide feedback on online platforms. Samples of the online feedback received was also reviewed during the inspection.

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 and

- 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:

- The centre had not reported two adverse incidents relating to a breach of confidentiality to the HFEA (see recommendation 4). The inspection team reviewed the investigations and actions taken in response to these incidents and are assured that the centre's processes for internal incident reporting and investigation are thorough. The inspection team requested that the centre report these incidents to the HFEA.
- The centre has recently commenced a satellite arrangement with a Consultant in Margate, but the agreement is not compliant with requirements of General Direction 0010 and does not fully reflect current or proposed satellite activities (see recommendation 5). The inspection team noted that this satellite activity, which started in October 2018, has only involved the provision of initial information and that so far patients have attended the centre for further detailed consultations.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2016 recommendations for improvements were made in relation to four major and five '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. However, the inspection team noted the recurrence of a similar non-compliance relating to the controlled drugs register as discussed above in the section 'Medicines management'.

In May 2017, the Daily Mail newspaper published several reports about the practices of some fertility clinics and centre 0044 was featured in one article, specifically about the egg freezing programme at the centre. In response, the HFEA undertook an investigation and inspection at the centre and three recommendations for actions to be taken were made. The PR provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Since the last renewal inspection in October 2016 the centre has received several risk tool alerts related to multiple pregnancy rates, to which the PR has responded appropriately, providing evidence and information that the issue was being addressed. In August 2018, the centre's multiple pregnancy rates were noted to have reduced as is now not likely to be significantly different to the 10% multiple live birth rate target.

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 broadly compliant with requirements to submit information to the HFEA. There are a considerable number of data submission issues related to late or missing data (see recommendation 2). The centre's Head of Embryology informed the inspection team that four out of five staff members responsible for data submission had left the centre in a short space of time contributing to these issues. However, these positions have been filled and it is expected that current issues with data submissions will be resolved.

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. At the centre's last inspection in October 2016, legal parenthood consenting processes were found to be robust.

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. Five sets of records where treatment with donor sperm had recently been provided were audited by the inspection team. Of these two sets were in circumstances was where consent to legal parenthood was required and no issues were identified.

These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

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 review
None identified			

‘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
Medicines management 1. On inspection the following issues were noted: • There was a correction in the controlled drugs register that had been made by over-writing the original entry. This is not in line with statutory regulations. • The carry-over of stock had not been witnessed in some cases. • The time of administration of controlled drugs was not recorded or witnessed in some cases.	The PR should ensure that medicines management practice is in line with statutory requirements. The PR should review medicines management practices, with reference to, but not exclusively, the issues identified in this report. A summary report of this review including corrective actions and timescales for implementation, should be provided to the centre’s inspector by 13 February 2019.	Communication has been sent out to all clinicians, anaesthetists and prescribing staff to ensure that they are aware of the non-complicance. Corrective measures have been introduced to include a review of the controlled drugs SOP and a further controlled drugs audit which shows 100% compliance has taken place. The controlled drugs SOP and most recent audit findings are attached as part of this report.	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has provided a summary of the review into this area of practice and actions taken to address the findings on inspection. The audit of medicines management practice, to ensure that any corrective actions taken have been effective in achieving and

Controlled Drugs in Peri-operative care 2006 NICE guideline [NG46] April 2016 ‘Controlled Drugs: Safe use and management’ Misuse of Drugs Regulations 2001 (Regulation 20c) DH 2007 ‘Safer Management of Controlled Drugs; a guide to good practice in secondary care (England)’ section 4.7.1.3	Within three months after the review, the PR should audit medicines management practice, to ensure that any corrective actions taken have been effective in achieving and maintaining compliance. A summary report of the audit should be provided to the centre’s inspector by 13 May 2019.		maintaining compliance due by 13 February 2019 is awaited. **Further action is required**.

‘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
2. Provision of information to the HFEA At the time of the inspection, the centre had not submitted data relating to partner insemination for 2017. This has now been submitted. There are a considerable number of data submission issues related to late or missing data. 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 centre has been provided with a report of data submission issues and the PR should ensure that these are addressed. A summary of the progress made in addressing these issues, and the timescales for completion should be provided to the centre’s inspector with the PR’s response to this report. The PR should review the systems and processes used	The outstanding data has now been submitted and any submission errors have been reviewed and rectified. Data entry submission reports will be audited monthly and any errors will be escalated to the senior management team members for review and correction. A further audit will be provided by the time frame specified.	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has provided a summary of the review into this area of practice and actions taken to address the findings on inspection. The audit due by 13 May 2019 is awaited. **Further action is required**.

	for licensed treatment data submission to identify the reasons for this non-compliance. 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 13 February 2019. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 13 May 2019.		
3. Website The centre's website is not compliant with guidance as it does not provide a like-for-like comparison to national outcomes because the time period used for the centre's live birth rates is not the same as for the HFEA published data. CoP 4.12(e)	The PR should take appropriate action to ensure that the centre's website is compliant with requirements. The PR should ensure that the centre's website is compliant with requirements when responding to this report.	This is now complete and the website is compliant.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The centre's website has been updated. **No further action is required**.

4. Adverse incidents The centre had not reported two adverse incidents relating to a breach of confidentiality to the HFEA. SLC T118. This non-compliance has been graded as 'other' because the inspection team accepts that incident reporting and investigation at the centre is thorough and generally compliant. In these two cases staff considered the incident did not need to be reported; the inspection team considered otherwise.	The PR should ensure that all adverse incidents and near misses are reported to the HFEA. The PR should review all adverse incidents in the centre's incident register since the time of the last inspection in 2016 and report retrospectively to the HFEA any which fulfil the criteria of adverse incidents or near misses. This recommendation should be implemented by 13 February 2019.	All adverse incidents will continue to be discussed at the quality review meeting. These two breaches of confidentiality have now been reported retrospectively. All other incidents recorded in the internal incidents log have been reviewed by the PR and senior management team and do not meet the criteria of adverse incidents or near misses.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has confirmed that there are no unreported incidents that fulfil the criteria of adverse incidents or near misses since the time of the last inspection, and the two incidents noted in the report have been reported to the HFEA. **No further action is required**.
5. Satellite agreements The centre has recently commenced a satellite arrangement, but the agreement is not compliant with requirements of General Direction 0010 and does not fully reflect current or proposed satellite activities. General Direction 0010.	The PR should ensure that written agreements are in place and provided to the HFEA before commencement of satellite services. The finalised written agreement for the satellite service identified during the inspection should be provided to the centre's inspector when responding to this report.	This agreement has now been updated and is attached. Any further satellite services will also meet the general direction 0010 with a comprehensive agreement in place before the service commences.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The updated satellite agreement has been provided and is compliant with General Direction 0010. **No further action is required.**

This non-compliance has been graded as 'other' because the inspection team accepts that this satellite activity, which started in October 2018, has only involved the provision of initial information and to date these patients have attended the centre for further detailed consultations.			

Additional information from the Person Responsible