Executive Licensing Panel - minutes

Centre 0051 (Cambridge IVF)

Interim Inspection Report

Tuesday, 9 July 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Anna Coundley Dan Howard	Director of Strategy and Corporate Affairs Policy Manager Chief Information Officer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

- 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 Cambridge IVF, formerly known as The Rosie Hospital, is part of the Cambridge University Hospitals NHS Foundation Trust. The centre has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services to both NHS and self-funded patients. Other licensed activities at the centre included storage of gametes and embryos. The centre is registered with the Care Quality Commission (CQC.)

1.2. The panel noted that, in the 12 months to 28 February 2019, the centre had provided 348 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a small sized centre.

1.3. The panel noted that IVF and ICSI HFEA register data, for the year ending 28 February 2019, show the centre's success rates are in line with the national averages, with the following exception;

- clinical pregnancy rates following IVF in patients aged less than 38 years are lower than average at a statistically significant level.

1.4. The panel noted that, for the year ending 31 December 2018, the centre reported 15 cycles of partner insemination, with four pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that, HFEA register data, for the year ending 28 February 2018, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%. This represents performance that is likely to be statistically lower to the 10% multiple live birth rate target for this period. The multiple pregnancy rate, since 2015, indicates that the centre is to be congratulated, as this is likely to have been consistently below the national target of 10% since the interim inspection of the centre in 2015.

1.6. The panel noted that the inspection took place on 17 April 2019.

1.7. The panel noted that at the time of inspection there were four major areas of non-compliance concerning the storage of gametes and embryo's, the Quality Management System (QMS), medicines management and legal parenthood. There were also two 'other' areas of non-compliance regarding pregnancy success rates and infection control. Since the inspection, the Person Responsible (PR) has confirmed that the recommendations concerning the storage of gametes and embryo's, the QMS and medicines management have been implemented.

1.8. The panel noted that the PR had provided a commitment to fully implement the recommendations connected to legal parenthood, pregnancy success rates and infection control, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

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

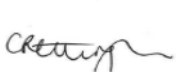
2. Decision

2.1. 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

16 July 2019

Interim Licensing Report

Centre name: Cambridge IVF
Centre number: 0051
Date licence issued: 1 October 2017
Licence expiry date: 30 September 2021
Date of inspection: 17 April 2019
Inspectors: Nicola Lawrence and Andrew Leonard
Date of Executive Licensing Panel: 9 July 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 (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 current foci for 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

Summary for licensing decision

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 four major and two 'other' areas of non-compliance or poor practice.

Since the inspection the Person Responsible (PR) has confirmed that the following recommendations have been implemented:

Major areas of non compliance:

- The PR should ensure that there is effective consent to storage in place for all stored embryos.
- The PR should ensure that the quality management system is robust and fit for purpose.
- The PR should ensure medicines management practice is compliant with regulatory requirements and best practice guidance.

The PR has given a commitment to fully implement the following 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 procedures for legal parenthood consents are robust and compliant with statutory requirements and CoP guidance.

'Other' areas of practice that require improvement:

- The PR should seek to improve the pregnancy success rates for IVF treatments involving fresh embryos in women under 38 years old.
- The PR should ensure that infection control measures and practices are compliant with regulatory requirements and best practice guidelines.

Information about the centre

Cambridge IVF, formerly known as The Rosie Hospital, is part of the Cambridge University Hospitals NHS Foundation Trust. The centre has held a Treatment and Storage licence with the HFEA since 1992.

The centre provides a full range of fertility services to both NHS and self-funded patients and is registered with the Care Quality Commission (CQC)

The centre provided 348 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2019. In relation to activity levels this is a small centre. Other licensed activities at the centre included storage of gametes and embryos.

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]

For IVF and ICSI, HFEA held register data for the year ending 28 February 2019 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages, with the following exception:

- clinical pregnancy rates following IVF in patients aged less than 38 years are lower than average at a statistically significant level (Recommendation 5).

For the year ending 31 December 2018 the centre reported 15 cycles of partner insemination with four clinical pregnancies. This represents a clinical pregnancy rate 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 28 February 2019 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 5%. This represents performance that is likely to be significantly lower than the 10% multiple live birth rate target for this period. Indeed, the centre's multiple pregnancy rate since 2015 indicates that the centre is to be congratulated, because its multiple birth rate is likely to have been consistently below the national target of 10% since the interim inspection of the centre in 2015.

[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%.

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: egg collections. All of the procedures observed were witnessed using a manual and electronic 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 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 and of the accuracy of 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 not effective because: five sets of embryos remain in storage even though the gamete providers had consented to the removal from storage and discard of one of the sets and to the removal from storage and use in training of the other four sets, up to 11 months previously (Recommendation 1).

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.

During the inspection the PR reported that the centre is in a phase of increasing activity, and there are plans to further increase activity levels to approximately 600 cycles per year. The centre will recruit additional staff members in anticipation of this increase, including a quality manager. The inspection team expects the PR to ensure that appropriate staffing resources are in place prior to the centre's activity levels being increased, to ensure safe and compliant activity. Staffing will be reviewed at the next inspection.

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: medicines management; infection control; legal parenthood; witnessing; consent to storage; traceability.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements because: the centre's audit process failed to identify concerns noted by the inspection team relating to the following areas:

- Controlled drugs
- Legal parenthood

In addition, the audit of traceability focussed on the materials used in processing but did not audit the traceability of equipment. Thus it did not identify that the centrifuge used in processing sperm is not documented in laboratory records and therefore is not traceable (Recommendation 2).

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:

- leadership
- patient support
- imports of gametes and embryos from outside the EU/EEA
- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions
- HFEA Clinic Focus articles regarding screening requirements
- HFEA Clinic Focus articles regarding the mix up of laboratory gases and equipment failures.

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

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 because:

- In eight cases, the amount of controlled drug supplied, administered and discarded, was not witnessed in the controlled drug register. This was identified as a non compliance at the centre's last inspection in 2017.
- The carry-over of stock from one page to the next is not witnessed.

(Recommendation 3).

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 broadly compliant with guidance because:

- Some of the furniture in clinical areas did not meet infection control requirements to have wipe clean non-porous surfaces.
- Clinical waste was not stored in locked containers. The PR was aware of this prior to inspection and has made a request for suitable waste bins to be provided. The bins were in a locked compound.

(Recommendation 6).

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: plasticware, sperm pots and culture media in the laboratory. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only 3 patients have provided feedback in the last 12 months, giving an average 2 star rating to the clinic. This suggests that the clinic does not actively encourage patient feedback to the HFEA website. For the system to work well, it's important that every patient knows about the rating system. The PR has already considered ways to promote the use of this facility and has ordered computer tablets to provide a convenient way for patients to leave feedback. This will be followed up at the next inspection. Because of the lack of feedback, the centre's own most recent patient survey responses were reviewed. Twenty one patients had provided feedback, all of which was positive.

During the inspection the inspectors spoke to two patients and their partners who provided positive feedback on their experiences. The patients also complimented the centre on their introduction of "Pure IVF" following the withdrawal of CCG funding for IVF treatment, this enables patients to access low-cost treatment. The centre has also been nominated for a Trust "Values Award" for introducing this treatment option.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;

- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

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 fully compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to two major and three 'other' areas of non-compliances or poor practice. The PR provided information and evidence that the recommendations had been fully implemented before the report was considered by a licensing committee.

On-going monitoring of centre success rates

Since the last renewal inspection in April 2017 the centre has received one risk tool alert related to performance, to which the PR has responded appropriately. However, the centre's success rates for IVF treatments involving fresh embryos in women under 38 years old remain lower than the national average at a statistically significant level. The PR commenced an investigation into this issue prior to inspection. The PR has provided a commitment to keep success rates in this group of patients under regular review and to provide regular updates to the centre's inspector. (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. This information is held in the HFEA Register. The clinic is compliant with requirements to submit information to the HFEA.

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.

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. The audit showed that whilst two couples were identified as potentially being affected by legal parenthood consent anomalies, further investigation found they were either married or in a civil partnership at the time of treatment.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

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 five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required and also the results of the most recent legal parenthood consenting audit.

These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent are partially compliant with HFEA requirements because:

- In one patient record, a married couple having IVF treatment using donated sperm had signed PP (your consent to being the legal parent) and WP (your consent to your partner being the legal parent) consent forms, when only a PBR form should have been considered for completion (your consent to being registered as the legal parent in the event of your death).
- In another record, an unmarried couple having IVF treatment using donated sperm had signed WP and PP forms. However, when they returned for a subsequent treatment the record indicated they were now in a civil partnership, but the consents had not been reviewed. They should have considered completing a PBR form and withdrawn the legal parenthood consents recorded in the PP and WP forms.
- In another patient record, the partner by marriage of a woman having IVF treatment using donated sperm had not completed a PBR form. The patient is pregnant.
- In two patient records, the offer of counselling was not documented.
- The centre's checks of legal parenthood consents before treatment had failed to detect and address the concerns above, which primarily involve the staff failing to account correctly for the marital/civil partner status of couples when legal parenthood consent is considered.
- The centre's audit of legal parenthood had been performed according to the method specified by the HFEA, however it was not robust since it had not identified the anomalies identified by the inspection team noted above.

The centre had not identified these anomalies at the time of treatment or through legal parenthood audits.

(Recommendation 4).

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	Inspection team's response to the PR's statement
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.

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	Inspection team’s response to the PR’s statement
1. Storage of gametes and embryos Five sets of embryos remain in storage even though the gamete providers had consented to the removal from storage and discard of one of the sets and to the removal from storage and use in training of four sets, up to 11 months previously. HF&E Act 1990 (as amended), Schedule 3 (8)(1) and SLC T79.	The PR should ensure that there is effective consent to storage in place for all stored embryos. The PR should ensure that embryos are allowed to perish or are used in training activities when gamete providers withdraw their consent to storage and consent to embryo discard or use in training. The PR is reminded of guidance issued in Chairs letter (03)03 in relation to the timely	We had held embryos for research and training purposes whilst we identified a suitable project for them. This work is on-going. We accept that we need to set a limit on how long this period should be and will apply a maximum duration of 6 months in such cases prospectively. We will also ensure that requests for discard of gametes or embryos are performed prospectively within 28 days of notification.	The Executive acknowledge the PR’s response, review of processes and actions taken in implementing this recommendation. No further action required other than submission of the report summary by 17 July 2019.

	disposal of cryopreserved material where there is consent to do so and actions to take should there be a possibility of legal challenge to the disposal of cryopreserved material. The PR should establish an action plan for resolving the cases where embryos are in store beyond the consented storage period. A copy of the plan should be provided to the HFEA when responding to this report. The PR should conduct a review to identify reasons why material has continued to be stored without written effective consent. A copy of this review along with identified corrective actions to prevent future occurrences should be submitted the centre's inspector by 17 July 2019.	We will ensure that our patient paperwork is updated to reflect these changes. We will perform a scheduled monthly discard of embryos which cannot be used for training or discard or which breach our 6 month limit prospectively. All gametes or embryos stored with no identified training or research purpose were disposed of prior to the 10th June 2019 when this report was returned to the HFEA. We continue to work to identify appropriate research projects which would benefit from a supply of embryos which have been consented for such purposes. A summary report will be provided in advance of the 17th July 2019 date proposed.	
2. QMS	The PR should ensure that the	We are undertaking a	The Executive acknowledges

The centre's own audit process failed to identify concerns noted by the inspection team relating to the following areas described in detail elsewhere in the report: • Controlled drugs • Legal parenthood consents In addition, the audit of traceability focussed on the materials used in processing but did not review the traceability of equipment. The centre does not have a dedicated quality manager. There has been a vacancy for one year. The PR is covering this role. SLC T36.	QMS is robust and fit for purpose. The PR should review the centre's auditing methodology to ensure that all audits evaluate compliance with the regulatory requirements, the centre's approved protocols and quality indicators and that any corrective actions identified are fully implemented. A summary report of the review including corrective actions and the timescale for implementation of corrective actions should be provided to the centre's inspector by 17 July 2019.	complete review of our Audit and KPI schedule. This process was commenced prior to this interim inspection. Our objective is to ensure that the data we are collecting is not only easily interpretable but also representative of the primary functions of the centre. We aim to ensure that our revised KPI and audit data will allow for close comparison between Cambridge IVF clinic data and that presented by the HFEA via CaFC for our clinic and for national comparative data. A summary report will be provided in advance of the 17th July 2019 date proposed. A review of traceability indicated the need to record the identity of the centrifuge used for sperm preparation for treatment. Both centrifuges used for this purpose are subject to regular calibration and validation as a result of	the PR's response and review of processes and actions taken in implementing this recommendation. No further action required other than submission of the report summary by 17 July 2019.

		which we had not considered that this discrimination was necessary. Having discussed this point with the inspector at the time of the visit, this additional data has been added to our laboratory form for sperm preparation and is being collected prospectively. A Quality Manager was interviewed and appointed to the Cambridge IVF on the 4th June 2019 to start in post approximately 2 months thereafter.	
3. Medicines Management The following issues were noted on inspection: • In eight cases, the amount of controlled drug supplied, administered to the patient and disposed of, was not fully witnessed in the controlled drug register. This was identified as a non compliance at the centre's last inspection in 2017. • The carry-over of stock from one page to the next	The PR should ensure medicines management practice is compliant with regulatory and best practice guidance. The PR should review medicines management practice and address the issues identified in this report. A summary report of this review including corrective actions taken, should be provided to the centre's inspector by 17	Discussions are taking place with the CUH Anaesthetics team. Our dedicated ODP commences in post in July. We believe that having that consistency in the ODP role on site rather than rotation of ODPs and anaesthetists from CUH. Will provide us with greater control over the governance requirements of medicines management. The document provided to us by our inspector following the	The Executive acknowledges the PR's response and review of processes and actions taken in implementing this recommendation. No further action required other than submission of the report summary by 17 July 2019.

is not witnessed. SLC T2; The Association of Anaesthetists of Great Britain & Ireland (AAGBI) (2018) Controlled Drugs in Peri-operative Care; Department of Health (2007) Safer Management of Controlled Drugs; A guide to good practice in secondary care (England).	July 2019	interim inspection has been forwarded on to the anaesthetic lead for Cambridge University Hospitals NHS Foundation Trust, our parent organisation. Daily check, revision to audit form and our own ODP to provide consistency to the processes of practice and audit will ensure compliance against this requirement A CAPA process has been commenced regarding this issue. A summary report will be provided in advance of the 17th July 2019 date proposed.	
4. Legal Parenthood The following issues were noted on inspection: • In one patient record, a married couple having IVF treatment using donated sperm had signed PP (your consent to being the legal parent) and WP (your consent to your partner being the legal parent)	The PR should ensure that procedures for legal parenthood consents are robust and compliant with statutory requirements and regulatory guidance. The PR should undertake a full review of legal parenthood consenting processes, including staff training	A full review of our legal consenting process is scheduled for June 2019. We will ensure that our pathway is clarified not only for obtaining appropriate consent but also for ensuring that where consent should be modified or withdrawn this is performed in a timely manner	The Executive acknowledges the PR's response and review of processes and actions taken in implementing this recommendation. A copy of the summary of the root cause analysis is to be provided to the centre's inspector by 17 July 2019.

consent forms, when only a PBR form should have been considered for completion (your consent to being registered as the legal parent in the event of your death). • In another record, an unmarried couple having IVF treatment using donated sperm had signed WP and PP forms. However, when they returned for a subsequent treatment the record indicated they were now in a civil partnership, but the consents had not been reviewed. They should have considered completing a PBR form and withdrawn the legal parenthood consents recorded in the PP and WP forms. • In another patient record, the partner by marriage of a woman having IVF treatment using donated sperm had not completed a	requirements, actions taken and timeframes for implementation of corrective actions. A summary report of this report should be provided to the centre's inspector by 17 July 2019. When responding to this report, the PR should provide a summary of the actions taken to address the concerns raised in each of the cases highlighted, confirming if correctly completed consent forms have been provided by the patients. Should this not be the case, the PR should provide details on the legal advice obtained and actions planned in response, including how the centre intends to communicate with and support the couple affected. The PR should conduct a root cause analysis (RCA) into the circumstances which led to the failings in the parenthood consenting process in these	and in accordance with the requirements of the HFEA Code of Practice. We will audit our practice to determine compliance with legal parenthood is assured for all relevant patients. We will ensure wider compliance with the use of the PBR form as appropriate and discourage the practice of blanket consenting by completing forms which are irrelevant or not necessary in a particular patient or couples circumstances. Internal training will be provided to all relevant clinic staff in June 2019. Our medical team have been reminded of the importance of deploying the PBD form in all relevant circumstances. Our clinic pre-treatment checklist has been updated to	Further action is required.

PBR form. The patient is pregnant. • In two patient records, the offer of counselling was not clear. • The centre's checks of legal parenthood consents before treatment had failed to detect and address the concerns above, which primarily involve the staff failing to account correctly for the marital/civil partner status of couples when legal parenthood consent is considered. • The centre's audit of legal parenthood had been performed according to the method specified by the HFEA, however it was not robust since it had not identified the anomalies identified by the inspection team noted above. The centre had not identified these anomalies at the time of treatment or through legal	cases, and why consent form checks failed to identify the anomalies. A copy of the RCA should be provided to the centre's inspector by 17 July 2019.	include a check of the presence of a PBR form where appropriate. PBR forms will be completed for any relevant patients who currently have embryos in store and prospectively for all relevant patients. Our legal parenthood audit will be enhanced to ensure the appropriate deployment of the PBR form is captured during the audit process. A summary report will be provided in advance of the 17th July 2019 date proposed.	

parenthood audits. Schedule 3 HF&E Act 1990 (as amended) SLC T57, T61			

‘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	Inspection team’s response to the PR’s statement
5. Pregnancy success rates The centre’s success rates for IVF treatments involving fresh embryos in women under 38 years old are lower than the national average at a statistically significant level. The PR commenced an investigation into this prior to inspection. The PR has provided a commitment to keep success rates in this group of patients under regular review and to provide regular updates to the centre’s inspector. SLC T2	The PR should seek to improve the pregnancy success rates for IVF treatments involving fresh embryos in women under 38 years old. The PR should provide the centre’s inspector with a report of his investigation into the centre’s success rate in this group of patients when responding to the report. Following this, the PR should provide the centre’s inspector with quarterly updates on the actions taken to improve the success rate, with a goal of improving the success rates by 17 October 2019.	A quality review of our outcome data for all patient groups is on-going. An audit of Bemfola use was performed on 121 patients and revealed no negative impact on treatment outcome. We have identified inter-operator variations in treatment outcomes and observational audits of practice are scheduled. Our commitment to Elective Freeze All Replace later has resulted in a decline in our headline pregnancy rate for women under the age of 38 because the patients with the	The Executive acknowledges the PR’s response and commitment to fully implement the recommendation. The PR has provided a review of the centre’s success rates for IVF treatments involving fresh embryos in women under 38 years old. The PR is to continue to provide quarterly updates on the actions taken to address the success rates. Further action is required.

		best prognosis are electively freezing all embryos. This is mitigated by statistically significantly higher outcomes from subsequent frozen cycles performed for this patient group thereafter. We are validating our data submission to the HFEA to ensure that the information we are reporting pertaining to the Treatment form is an accurate reflection of the output of the treatment cycle to ensure that cycles are not being misreported where the objective of the cycle was elective freeze all. Regular updates to our inspector will be provided in advance of the 17th October 2019.	
6. Infection control The following issues were noted on inspection: • Some of the furniture in clinical areas did not meet infection control	The PR should ensure that infection control measures and practices are compliant with regulatory requirements and best practice.	New furniture is being procured to ensure that all chairs in clinical areas have wipe-free surfaces moving forwards.	The Executive acknowledges the PR's response and commitment to fully implement the recommendation. A summary of the risk

requirements to have wipe clean non-porous surfaces. • Clinical waste was not stored in locked containers. The PR was aware of this prior to inspection and has made a request for suitable waste bins to be provided. The bins were in a locked compound. SLC T2. Department of Health (2013) Health Building Note 00-09: Infection control in the built environment section 3.105.	The PR should, in consultation with the infection control lead and relevant infection control advisors, perform a risk assessment of the issues identified in the report and provide the centre's inspector with a summary of how these concerns will be addressed by 17 July 2019.	We are in dialogue with CUH, our parent organisation about what assurances they can provide that all large clinical waste skip bins provided to Cambridge IVF will have functional locks. We believe this is best practice despite the fact that the bins themselves are stored in a secure compound. We have commissioned a site security review to be conducted in June 2019. We will ensure that these issues are addressed and provide responses to our inspector before the 17th July 2019.	assessment and report is to be provided to the centre's inspector by 17 July 2019. Further action is required.

Additional information from the Person Responsible

I would like to thank the inspection team on behalf of Cambridge IVF for their professionalism during the inspection process and accommodating the fact that the attended on a day where we were very busy with patient activity. We were very happy to hear the positive feedback the HFEA inspection team received regarding the quality of service they had received at Cambridge IVF on the day of the inspection visit. We are in the process of deploying tablet devices within Cambridge IVF so that patients can share their feedback at the time of treatment via CaFC.

We valued the feedback of the inspection team which was fair and constructive.