Executive Licensing Panel - minutes

Centre 0051 (Cambridge IVF) Renewal Inspection Report

Friday 16 June 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

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

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

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

1.2. The panel noted that Cambridge IVF holds a Treatment and Storage licence and provides basic fertility services.

1.3. The panel noted that the centre has been licensed by the HFEA since 1992.

1.4. The panel noted that, in the 12 months to 31 January 2017, the centre reported 196 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.5. An inspection was carried out at the centre on 11 and 12 April 2017.

1.6. The panel noted that at the time of the inspection there were two major and three 'other' areas of practice that required improvement concerning witnessing of samples placed in storage, medicine management, imports and exports, the Quality Management System (QMS), alongside equipment and materials. The panel noted that all the recommendations had been fully implemented, and where necessary, the PR will provide an update or summary of audits conducted to ensure that the corrective actions taken have been effective.

1.7. The panel noted that, since the last inspection, the centre's multiple live birth rate has been consistently below the national target, for which the centre is to be congratulated.

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

2. Decision

2.1. The panel endorsed the inspectorate's recommendation to renew the centre's Treatment and Storage licence for a period of four years without additional conditions subject to the PR providing an update or summary of audits conducted, within the prescribed timescales, to ensure that corrective actions have been effective.

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3. Chair's signature

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

Signature

Name

Hannah Verdin

Date

27 June 2017

Inspection Report

Purpose of the Inspection Report

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

Date of inspection: 11 and 12 April 2017.

Purpose of inspection: Renewal of a licence to carry out Treatment and Storage.

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

Inspectors: Polly Todd (lead), Susan Jolliffe and Lesley Brown.

Date of Executive Licensing Panel:16 June 2017.

Centre name	Cambridge IVF
Centre number	0051
Licence number	L/0051/15/b
Centre address	Kefford House, 2 Maris Lane, Trumpington, Cambridge, CB2 9LG, United Kingdom
Person Responsible	Mr Stephen Harbottle
Licence Holder	Ms Amanda Cahn
Date licence issued	1 October 2013
Licence expiry date	30 September 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Cambridge IVF, formerly known as The Rosie Hospital, has held a Treatment and Storage licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 196 cycles of treatment (excluding partner intrauterine insemination)in the 12 months to 31 January 2017. In relation to activity levels this is a small centre.

Other licensed activities of the centre included storage of gametes and embryos.

This current licence has been varied to reflect a change of Person Responsible (PR) in November 2014.

Pregnancy outcomes[1]

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

In 2016, the centre reported 22 cycles of partner insemination with two pregnancies, which is in line with the national average.

Multiple births[2]

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

Between November 2015 to October 2016the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4%: this represents performance that is not likely to be statisticallydifferent from the 10% multiple live birth rate target.

The centre is to be congratulated on its multiple birth rate which has been consistently below the national target of 10% since the interim inspection 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%.

Summary for licensing decision

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

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

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

Since the inspection visit, all the recommendations have been fully implemented. Where required, and by the dates specified, the PR will provide an update or summary of audits conducted to ensure that the corrective actions taken have been effective:

Major areas of non-compliance:

- The PR should review the current processes for witnessing and assess the risks of any current or future witnessing practices.
- The PR should ensure compliance with medicines management regulations and best practice guidance.

'Other' areas that requires improvement:

- The PR should ensure that all imports of gametes fully complies with General Directions 0006.
- The PR should ensure that the QMS complies with Standard Licence Conditions (SLCs) and code of practice guidance.
- The PR should establish a documented procedure to guide the actions to be taken in the event of equipment malfunction or failure.

Recommendation to the Executive Licensing Panel

The inspection team notes that success rates are consistent with national average and the centre's multiple live birth rates have been consistently below the national target since the last inspection for which the centre is to be congratulated.

The inspection team recommends the renewal of the centre's Treatment and Storage licence for a period of four years without additional conditions.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

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

What the centre could do better
If samples need to be placed into storage at the weekend, there is no second person available to witness that the samples have been placed into the correct location in the storage tanks and that this procedure has been documented correctly (see recommendation 1). SLC T71, CoP 18.27, 18.28.

Donor selection criteria and laboratory tests

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

What the centre does well

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

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

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non-identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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

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

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

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

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

The premises of the centre's satellite/transport facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

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

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

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

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

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

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

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures arecompliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

Procurement of gametes and embryos (Guidance note15)
The centre's procedures are compliant with HFEA requirements to:

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

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

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

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

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

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

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

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

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

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

Equipment and materials (Guidance note 26)

The centre uses equipment and materials that are compliant with HFEA requirements.All equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.
The centre is compliant with HFEA requirements to validate critical equipment.

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better
Medicines management (Guidance Note 25)
On inspection, the following issues were noted during a review of five patient records:

- in four patients' records the amount of controlled drug administered did not match that recorded in the controlled drug register;
- in all five records, the time of administration of the controlled drug had not been recorded in the patient records, the prescription chart or the anaesthetic chart;
- in three cases, the amount of drug administered to the patient and/or disposed of, was not recorded in the controlled drug register, only the amount that had been supplied.
- in one case, the unique patient identifier was illegible in the controlled drug register.

SLC T2; DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'; Misuse of Drugs Regulations (2001), see recommendation 2.

Imports and exports (Guidance note 16; General Direction 0006)
When reviewing two imports of gametes, from both within and outside of the EEA, it was not possible to confirm if, before giving consent, the gamete providers had been given a written notice stating that the law governing the use of gametes and the parentage of any resulting child may not be the same in the United Kingdom as in the country from which the gametes were imported. General Direction 0006, see recommendation 3.

Quality management system (QMS) (Guidance note 23)
On inspection, the following issues were noted:

- there was no standard operating procedure (SOP) for legal parenthood detailing when legal parenthood applies and the consent forms required;
- the quality indicators for consent, welfare of the child and the provision of information were not sufficient, for example, they did not take into account whether forms had been completed correctly.
- there were no quality indicators for record keeping and a record keeping audit had not been performed;
- two versions of the welfare of the child SOP were accessed for the review of the inspection team, one of which had been superseded by the other.

SLC T34; T35; T36, see recommendation 4.

Equipment and materials (Guidance note 26)
The centre does not have documented procedures to guide actions to be taken in the event of malfunction or failure of each piece of critical equipment. SLC T27, see recommendation 5.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of biological sciencesand has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

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

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

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

Welfare of the child and safeguarding

What the centre does well

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

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

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

Embryo testing Preimplantation genetic screening Embryo testing and sex selection
What the centre does well **Preimplantation genetic screening (Guidance note 9);** **Embryo testing and sex selection (Guidance note 10)** The centre's does not undertake embryo testing therefore these guidance notes are not applicable to this inspection.
What the centre could do better Not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to fourcouples who provided feedback on their experiences. Feedback was positive, with all of the individuals commenting that they have compliments about the care that they received.

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

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

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

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

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

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)

The centre does not undertake egg or sperm sharing arrangements, therefore this guidance note is not applicable to this inspection.

Surrogacy (Guidance note 14)

The centre does not offer treatments involving surrogacy, therefore this guidance note is not applicable to this inspection.

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

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

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and / or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

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

What the centre does well

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

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about its effectiveness and, in some cases, it may be necessary for a patient 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 further assurance of the effectiveness of the centre's procedures, the inspection team reviewed two sets of records where consent to legal parenthood was required. Effective consent to legal parenthood with a prior offer of counselling was seen to be in place before treatment in both cases.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre to be compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research(General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing assisted reproductive technologies and those born following treatment.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

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

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

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

Screening of patients
Storage of gametes and embryos

What the centre does well

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

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

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

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

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

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

Section 3: Monitoring of the centre's performance

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

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

On-going monitoring of centre success rates

The centre has not received any alerts relating to its success rates.

Areas of practice requiring action

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

Critical area of non-compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
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 to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several 'other' areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. **Witnessing:** If samples need to be placed into storage at the weekend, there is no second person available to witness that the samples have been placed into the correct location in the storage tanks and that this procedure has been documented correctly SLC T71, CoP 18.27, 18.28.	The PR should review the current processes for witnessing and assess the risks of any current or future witnessing practices. The inspectors acknowledge discussions with the PR that a second person could be trained to witness at the weekends. The PR should provide an update on actions taken when responding to this report.	We have always had availability of witnessing on Saturdays, however due to staffing limitations we were unable to support a witness on Sundays, this was explained to the HFEA at our previous inspections, witnessing was performed retrospectively on Mondays. The only procedures we have on Sundays are day 6 blastocyst vitrifications which are infrequent. We have considered this recommendation from the HFEA and, effective 4th June 2017 we will deploy a new on-call rota to provide witnessing cover to the unit. A copy of	The Executive acknowledges the PR's response and prompt action in implementing this recommendation, and confirms receipt of revised practice proposals. No further action required.

		our proposal for this change in practice is attached for your futher information.	
2. Medicines management: During a review of five patients' records the following issues were noted: • in four patients' records the amount of controlled drug administered did not match that recorded in the controlled drug register; • in all five records, the time of administration of the controlled drug had not been recorded in the patient records, the prescription chart or the anaesthetic chart; • in one case, the unique patient identifier was illegible in the controlled drug register; • in three cases, the amount of drug administered to the patient and/or disposed of, was not recorded in the controlled drug	The PR should ensure compliance with medicines management regulations and best practice guidance. The PR should review medicines management practices, including a review of staff training and relevant SOPs. A summary report of actions taken, should be forwarded to the centre's inspector by 11 July 2017. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted to the centre's inspector by 11 October 2017. The PR should also investigate why one of the issues noted, reoccurred following the last inspection and comment on what action	Reply from David De Monterverde-Robb-Lead Pharmacist for Theatre at CUH: The Theatres Controlled Drug register has been adopted in order to allow not simply supplies to be recorded - as with the standard Ward CD register - but also if there is a destruction to record such recording is also facilitated adjacent to the recording of supply. The anaesthetic record is the record of administration and the CD register is the record of supply. By Trust policy, there is an expectation that the administered and destroyed sections are completed only if there is a part dose remaining which requires a record of waste to be documented. All part doses wasted must be recorded in the CD register. The Kefford House(Cambridge IVF) will undertake	The Executive acknowledges the PR's response and prompt action in implementing this recommendation. No further action beyond submission of a controlled drugs audit, due 11 October 2017.

register, only the amount that had been supplied. This last point was identified as a non compliance at the centres last inspection in 2015. SLC T2;DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)';Misuse of Drugs Regulations (2001).	have been taken to address this when responding to this report.	a quarterly audit comparing anaesthetic chart administration records against controlled drug register entries to monitor compliance. We have adapted CUH's 3 Monthly Controlled Drug audit to include a notes audit. This will compare 5 sets of notes against the documentation in the Controlled Drug book and the anaesthetic chart in the patent's notes. This will be carried out by the fertility nurses team at Cambridge IVF. Enclosed is a copy of audit for for this purpose, the first audit will be performed in June 2017 and every 3 months thereafter. Also attached is the CUH Trust wide policy pertaining to Control and Security of Controlled Drugs. We also enclose a copy of an email from Hemantha Alawattegama- Lead Anaesthetist for Theatres at CUH who has sent an email to all his colleagues reminding	

		them to complete the amounts used and wastage of Controlled drugs accurately in the CD book. Ongoing compliance with this requirement will be monitored as part of the prospective 3 monthly audit schedule.	

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. Imports and exports When reviewing two imports of gametes there was no confirmation that the gamete providers had been given a written notice stating that the law governing the use of gametes and the parentage of any resulting child may not be the same in the United Kingdom as in the country from which the gametes were imported. General Direction 0006.	The PR should ensure that all import of gametes fully complies with General Directions 0006. The PR should review the centre's procedures for importing gametes. A summary report of the review including corrective actions taken, should be provided to the centre's inspector by 11 July 2017.	Our recent audit of our transport of samples in and out of the unit did not reveal any issues we believed were not compliant with GD006. However, following very positive discussions with our laboratroy inspector we accept that the process can be improved and clafified. We have developed a checklist which, effective 1st June 2017 will be sent to every supplying centre of	The Executive acknowledges the PR's response and confirms receipt of the documented noted. No further action beyond submission of an audit due 11 October 2017

	Within three months of implementing corrective actions, the PR should audit the gamete importing processes to determine whether corrective actions taken have been effective in achieving compliance. A summary report of this review should be provided to the centre's inspector by 11 October 2017.	donor gametes and embryos on every occasion that gametes or embryos are imported or exported. Cambridge IVF will only accept imports into the centre and will only export to other centres who satisfy the requirements of GD006 and are prepared to sign the checklist to that end. A copy of the checklist is attached for your further information.	
4. Quality management system (QMS) On inspection, the following issues were noted: • there was no SOP for legal parenthood detailing when legal parenthood applies and the consent forms required; • the quality indicators for consent, welfare of the child and the provision of information were not sufficient, for example, they did not take into	The PR should ensure that the QMS complies with SLC and code of practice guidance. The PR should ensure the observations noted in this report are addressed, and forward copies of any amended documents by 11 July 2017. The PR should ensure that uncontrolled versions of documents are not used and provide a comment on	Our existing information pertaining to Legal Parenthood has been amalgamated into one SOP which will be reviewed at our next clinical governance meeting, A copy of the document is attached for your futher information. Quality Indicatiors for WoC, provision of information and obtaining consent have been reviewed and more robust quality indicators are being implemented. We have	The Executive acknowledges the PR's response and prompt action in implementing this recommendation. No further action required.

account whether forms had been completed correctly • there were no quality indicators for record keeping and a record keeping audit had not been performed; • two versions of the welfare of the child SOP were accessed for the review of the inspection team, one of which had been superseded by the other. SLC T34; T35; T36.	proposed actions when responding to this report.	updated our audit schedule to reflect this and increased the frequency of the relevant audits to a 3 monthly cycle. A copy of the modified audit form is attached and our QI's have been updated. Our audit practices have been updated to ensure that effective audit of record keeping is implemented and maintained in house rather than by our parent organisation. A new set of QI's have been defined, a copy of which is attached and the first audit is scheduled for June 2017. The audit will ensure compliance against the HFEA CoP section 31 and Directive 0012. A copy of the audit will be forwarded after it has been completed. Cambridge IVF are currently exploring the feasibility of installing Q-Pulse software as an alternative to our in-house document control system to improve robustness and improve version control. We	

		will report back to the HFEA the outcome of our feasibility study.	
5. Equipment and materials The centre does not have documented procedures to guide actions to be taken in the event of malfunction or failure of each piece of critical equipment. SLC T27.	The PR should establish a documented procedure to guide the actions to be taken in the event of equipment malfunction or failure. The PR should provide the centre's inspector with a copy of this procedure by 11 October 2017.	The Cambridge IVF Business Continuity Plan was reviewed and amemded to ensure that it is compliant with the requirements of SLC T27. A copy of the plan will be printed out to ensure that should electronic systems all fail for any reason we still have physical access to this important source of information A copy of the revised and updated document is attached for your consideration.	The Executive acknowledges the PR's response and prompt action in implementing this recommendation and confirms receipt of the revised 'Business continuity plan'. No further action required.

Reponses from the Person Responsible to this inspection report