Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

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

Minutes – item no. 3

Centre 0051 (Cambridge IVF) – Interim Report

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

Declarations of interest: members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to Licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

Consideration of Application

1. The panel noted that Cambridge IVF has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

2. The panel noted that the centre's licence is due to expire on 30 September 2017.

3. The panel noted that the inspection took place on 14 April 2015.

4. The panel noted that in the 12 months to 28 February 2015, the centre provided 139 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

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

6. The panel noted that in 2014, the centre performed 12 cycles of IUI with one pregnancy. This was consistent with the national average.

7. Between 1 December 2013 and 30 November 2014, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%. This represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

8. The panel noted that at the time of the interim inspection on 14 April 2015, two major and five other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) had made progress and committed to fully implementing the outstanding recommendations within the prescribed timescales.

9. The panel noted that the inspection team recommended the continuation of the centre's licence and noted the positive comments made by patients.

Decision

10. The panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment and storage licence continued. In particular, the panel commended the centre on its low multiple pregnancy rate.

Signed: Date: 15 June 2015

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Cambridge IVF
Centre number: 0051
Date licence issued: 1 October 2013
Licence expiry date: 30 September 2017
Additional conditions applied to this licence: None
Date of inspection: 14 April 2015
Inspectors: Karen Conyers (Lead), Susan Jolliffe, Grace Lyndon (HFEA observer), Helen Crutcher (HFEA observer)
Date of Executive Licensing Panel: 5 June 2015

Purpose of the report

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

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

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

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

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

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

Summary for the Executive Licensing Panel

The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients.

The ELP is asked to note that there are seven recommendations for improvement in relation to two major and five 'other' areas of non-compliance or poor practice.

Since the inspection the PR has given a commitment to fully implementing all the following recommendations within the prescribed timescales.

'Major' areas of non-compliance:

- The PR should ensure compliance with medicines management regulations.
- The PR should ensure that CE marked medical devices are used wherever possible.

'Other' areas of practice that require improvement:

- The PR should review the efficacy of the centre's QMS with regard to the process of ensuring implementation of corrective actions following audits.
- The PR should take appropriate action to ensure that the centre's website is compliant with requirements.
- The PR should review whether there are barriers to the implementation of learning from guidance provided by the HFEA and/or other sources.
- The PR should ensure the safe storage of medical gases.
- The PR should ensure that all HFEA invoices are paid within the timescales specified by the Authority.

Information about the centre

Cambridge IVF was formerly known as The Rosie Hospital and has been licensed by the HFEA since 1992. An application to vary the centre's licence to a Treatment with Storage licence was approved in September 2011. An application to approve the appointment of Stephen Harbottle as PR was approved by the ELP in November 2014.

Cambridge IVF is part of the Cambridge University Hospitals NHS Foundation Trust and is registered with the Care Quality Commission (CQC). The centre provides a full range of fertility services to both NHS and self funded patients. The centre provided 139 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2015. In relation to activity levels this is a small centre.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

HFEA held register data for the year ending 30 November 2014 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

For the year 2014 the centre reported 12 cycles of partner insemination with one pregnancy. This represents a performance which is in line with national average.

Multiple births[2]

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

Between 1 December 2013 and 30 November 2014, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%: this means that the centre's multiple live birth rate is likely be meet the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos, and that identification errors do not occur. The inspection team were not able to observe any laboratory activities but centre staff were able to describe the witnessing procedures that would be undertaken during an egg collection, thawing of gametes/embryos and sperm preparation. From these discussions the inspection team was able to evaluate that the centre's procedures are witnessed in accordance with HFEA requirements using an electronic witnessing system.

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[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2] The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

During the inspection we evaluated the centre's processes for storing gametes and embryos and these were compliant with HFEA requirements. The centre has a bring-forward system to ensure that all samples are stored in line with the gamete provider's consent. All patients with stored gametes and/or embryos are contacted annually.

Staffing

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

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times.

Quality Management System (QMS)

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

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

The centre's audits of documentation of witnessing, consent to storage and medicines management were reviewed during the inspection. The inspection team considered that the centre's audit practices are partially compliant with requirements. It was noted that the centre had not conducted an audit of controlled drugs (see medicines management section below) and they had not fully implemented the corrective action identified in their audit of stored gametes (see recommendation 3). The centre's audit of gametes in storage identified a missing signature on one page of a storage consent form although it is noted the form was signed at the end. The inspection team were concerned that the corrective action identified in the audit, which was to obtain an updated consent to storage form, had not been implemented.

The centre is broadly effective in implementing learning from their audits and from guidance from the HFEA (see recommendation 5). However, they had not fully implemented guidance issued in 2013 in relation to the use of CE marked medical devices (see equipment and materials section below), had not completed the corrective action identified as necessary in their storage audit (see recommendation 3) and had not ensured compliance of the centre's website with guidance issued in 2011 (see recommendation 4).

Medicines Management

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

During the inspection the centre's processes for medicines management and the safe storage disposal and administration of medicines were reviewed and found to be partially compliant with guidance. The following non-compliances were noted:

- controlled drugs wastage is not documented in the controlled drug book which is contrary to the requirements of the Misuse of Drugs Regulation 2001, schedule 27 (see recommendation 1);
- the centre has not conducted an audit of controlled drugs, which is contrary to the Controlled Drugs (Supervision of Management and Use) Regulations 2013 (see recommendation 1).

Infection Control

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

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

Equipment and Materials

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

In the course of the inspection the CE mark status of a sample of the medical devices used by the clinic was reviewed. The centre is partially compliant with the HFEA requirement to use CE marked medical devices wherever possible (see recommendation 2). The following medical devices used by the centre are not CE marked: tubes used for follicular aspirates during egg collection and serological pipettes used to prepare sperm samples.

Patient experience

During the inspection visit we spoke to three patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further five patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with three of the individuals also providing written feedback to the HFEA commenting that they had 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 prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire, pre-inspection assessments and from observations during the visit to the centre, the inspection team identified the following non-compliances:

- The centre's website is not compliant with requirements of Chair's letter CH(11)02: 'Responsible use of websites: duty of centres' as it did not provide a live birth rate per treatment cycle started, or raw numbers rather than percentages for data where there were fewer than 50 cycles per year (see recommendation 4).
- The centre had a number of full and empty gas cylinders that were in a designated area outside the building, some full cylinders were secured in a wire mesh cage and some were not. Medical gas cylinders should be kept in a purpose built cylinder store that should allow the cylinders to be kept dry, well ventilated and in a clean condition. When designing the cylinder store a risk assessment should be carried out to ensure that the chosen location is as safe as is practicable. Health Technical Memorandum.02-01: Medical gas pipeline systems. Part B: Operational management https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/153576/HTM_02-01_Part_B.pdf (see recommendation 6)

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2013 recommendations for improvement were made in relation to two major and eight 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the timescales with the exception of one 'other' area of non-compliance which was to review of content of third party agreement, which was completed soon after the required timescale.

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

Since the last inspection in April 2013 the centre has not received any performance related risk tool alerts. However, during the last 12 months, the centre has been issued with several risk tool alerts related to the late payments of HFEA invoices, which is non-compliant with the requirements of the Authority as issued in Chair's letter CH(10)02 (see recommendation 7).

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. The centre is compliant with data submission requirements.

The partners of women treated with donated gametes or embryos, where the couple are not married or in a civil partnership, must give written consent in order to become the legal parent of any child born. If this consent is not documented properly or if proper information

is not provided or counselling offered prior to both parties giving consent there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood. In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre had completed a compliant legal parenthood audit in October 2013 in response to recommendations from their renewal inspection, and no actions had been necessary as a result of the findings. Therefore it was not considered necessary to repeat this audit in 2014.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non-compliance

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

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

‘Major’ area of non-compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
1. Controlled drugs wastage is not documented in the controlled drug book which is contrary to the requirements of the Misuse of Drugs Regulation 2001, schedule 27. The centre has not conducted an audit of controlled drugs, contrary to the Controlled Drugs (Supervision of Management and Use) Regulations 2013. SLCT2.	The PR should ensure compliance with medicines management regulations. The PR should undertake a review to identify the factors that have led to these non-compliances with medicines management regulations. A summary report of the review including corrective actions and the timescale for the implementation of corrective actions should be provided to the centre’s inspector by 14 July 2015. The PR should also update the medicines management standard operating procedure (SOP) to ensure compliance with medicines management regulations and	We have consulted with the anaesthetics team and are in the process of implementing a new procedure to ensure that the disposal of drugs is appropriately documented. A reminder has been sent to all anaethetics staff from the CUH Anaesthetics lead to ensure all staff working at Cambridge IVF are fully aware of this requirement. The CUH requiremtn for routine contrrolled drug audit is 6 monthly for theatre areas and Cambridge IVF will add this to our audit schedule to ensure that future audits are perfomed in a timely manner. We will provide details to our	The Executive acknowledges the PR’s responses and his commitment to fully implementing the recommendation. Further action is required.

	provide a copy to the centre's inspector by 14 July 2015. Within three months of implementing changes, the centre should carry out an audit of medicines management procedures to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the audit should be supplied to the centre's inspector by 14 October 2015.	inspector prior to the 14th July 2015 and will provide evidence of a further audit being performed prior to the 14th October 2015.	
2. The following medical devices used by the centre are not CE marked: tubes used for follicular aspirates during egg collection and serological pipettes used for sperm preparation. SLC T30. Clinic Focus April 2013	The PR should conduct a review of all medical devices currently in use to identify where products are not CE marked and take action to source alternatives. The PR should provide the centre's inspector with a list of all medical devices including disposable plastic ware, equipment, and culture medium indicating the CE mark status of these products. Where devices are not CE marked then the PR should indicate the proposed timescale for sourcing alternatives by 14 July 2015. We do not recommend the	Cambridge IVF are investigating alternative products which are supplied by Vitrolife in the UK and CE marked. Samples of these have been requested for assessment and toxicity testing. Should these products pass our in house testing and be demonstrated to confer no detriment to our culture environment we will implement them in preference to the non CE marked alternative where a viable CE marked alternative is available prior to the 14th October 2015. A list of all consumables will be	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.

	implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this it is expected that all medical devices should be CE marked by 14 October 2015.	provided to our inspector prior to 14th July 2015.	

‘Other’ areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
3. The centre’s audit of gametes in storage included a review of patient consent forms. The audit identified a missing signature on one page of the storage consent form; although it is noted the form was signed at the end. The inspection team were concerned that the corrective action identified in the audit, which was to obtain an updated consent to storage form, had not been implemented. SLC T36.	The PR should review the efficacy of the centre’s QMS with regard to the process of ensuring implementation of corrective actions following audits. The centre’s inspector should be advised of the findings of this review and any changes in practice identified by 14 July 2015. Within three months of implementing changes, the centre should carry out an audit of the processes for implementing corrective actions to identify whether the changes have been effective. A summary report of the audit should be supplied to the centre’s inspector by 14 October 2015. The PR should also review the findings of audits performed since the last inspection to ensure that any corrective actions identified	The patient who had not completed the form correctly has been contacted and will be attending to sign the form as soon as possible. The Cambridge IVF Clinical Governance Team will meet to review how the action point did not get actioned when it was clearly evident at audit that this anomaly was outstanding. The findings will be reported to our inspector by the 14th July 2015. The outcome of the audit and review of findings will be sent to our HFEA inspector along with details of any other outstanding corrective actions identified by the 14th October 2015 as requested.	The Executive acknowledges the PR’s responses and his commitment to fully implementing the recommendation. Further action is required.

	have been fully implemented. A summary of the findings of this review including any corrective actions identified and timescales for implementation should be provided to the centre's inspector by 14 October 2015.		
4. The centre's website is not compliant with requirements of Chair's letter CH(11)02 'Responsible use of websites: duty of centres' as it did not provide a live birth rate per treatment cycle started or raw numbers rather than percentages for data where there were fewer than 50 cycles per year. CH(11)02.	The PR should take appropriate action to ensure that the centre's website is compliant with requirements and advise the centre's inspector of the updates by 14 July 2015.	The centre are looking at a review of the way outcome data is presented on the website to make sure it is meaninful even in groups where the activity levels are limited. A revised proposal for how this will be represented will be sent to our Inspector prior to the 14th July 2015.	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.
5. The centre had not fully implemented guidance issued in 2013 in relation to the use of CE marked medical devices, had not completed the corrective action identified as necessary in their storage audit and had not ensured compliance of the centre's website with guidance issued in	The PR should review whether there are barriers to the implementation of learning from guidance provided by the HFEA and/or other sources. The PR should provide feedback on this review to the centre's inspector by 14 July 2015.	There was The Centre will perform a complete review and will report back to the inspector with any corrective actions implemented before the 14th July 2015.	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.

2011. SLCT32.			
6. The centre had a number of full and empty gas cylinders that were in a designated area outside the building, some full cylinders were secured in a wire mesh cage and some were not. Medical gas cylinders should be kept in a purpose built cylinder store that should allow the cylinders to be kept dry, well ventilated and in a clean condition. When designing the cylinder store a risk assessment should be carried out to ensure that the chosen location is as safe as is practicable. SLC T17	The PR should ensure the safe storage of medical gases. The PR should complete a risk assessment for the storage of medical gases, to include a review of stock levels. The completed risk assessment and findings, with a corrective action plan and implementation dates should be provided to the centre's inspector by 14 July 2015.	This incident was caused by an isolated incident in which stock of medical grade Air was over ordered. As a result of this our caged storage capacity was exceeded temporarily. A risk assessment of the safe storage of medical and laboratory gases will be performed and this and any corrective actions reported back to our inspector prior to the 14th July 2015.	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is required.
7. During the last 12 months, the centre has been issued with several risk tool alerts related to the late payments of HFEA invoices. SLC T9d and CH(10)02.	The PR should take appropriate action to ensure that all HFEA invoices are paid within the timescales specified by the Authority. The centre's inspector should be advised of the actions taken by 14 July 2015.	Corrective action has already been implemented to ensure that payment of HFEA invoices is made within the timeframe stated by the authority moving forwards. A report of how this has been	The Executive acknowledges the PR's responses and his commitment to fully implementing the recommendation. Further action is

		achieved and assessment of its compliance will be send to the inspector prior to the 14th July 2015.	required.

Additional information from the Person Responsible
Cambridge IVF would like to thank the HFEA inspection team for the professionalism they exhibited during this unannounced inspection.