Executive Licensing Panel - minutes

Centre 0109 (Assisted Conception Unit, King's College Hospital) – Interim Inspection report

Friday, 4 September 2015

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Paula Robinson (Chair) David Moysen Nick Jones	Head of Business Planning Head of IT Director of Compliance & Information
Members of the Executive	Trent Fisher Sam Hartley	Secretary Head of Governance & Licensing
External adviser	None	
Observers	Howard Ryan	Technical Report Developer

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 The panel had before it:

1. Consideration of application

1.1. The panel noted that the Assisted Conception Unit at King's College Hospital, centre 0109, has held a licence with the HFEA since 1992 and provides a full range of fertility services. The Trust has recently merged to form a partnership with the Hewitt Fertility Centre, Liverpool.

1.2. The centre has two transport centres, Epsom and St Helier NHS Trust, centre 0259 and Kingston Hospital Assisted Conception Unit, centre 0270.

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

1.4. The panel noted that the inspection took place on 15 July 2015.

1.5. The panel noted that in the 12 months to 31 May 2015, the centre provided 685 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.6. The panel noted that for IVF and ICSI, HFEA-held register data for the period March 2014 to February 2015 showed the centre's success rates were in line with national averages.

1.7. The panel noted that in 2014 the centre reported 180 cycles of partner insemination with 15 pregnancies. This represented a clinical pregnancy rate of 8% which is in line with the national average.

1.8. Between March 2014 and February 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 17%. This means that the centre's live birth rate is likely to be consistent with the 10% maximum multiple live birth rate target.

1.9. The panel noted that at the time of the interim inspection on 15 July 2015, three major and three other areas of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has committed to fully implementing all of the recommendations within the prescribed timescales.

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

2. Decision

2.1. The panel had regard to its decision tree and was satisfied that 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

Paula Robinson

Date

14 September 2015

Interim Licensing Report

Centre name: Assisted Conception Unit, King's College Hospital
Centre number: 0109
Date licence issued: 01/10/2013
Licence expiry date: 30/09/2017
Additional conditions applied to this licence: none
Date of inspection: 15/07/2015
Inspectors: Louise Winstone and Shanaz Pasha
Date of Executive Licensing Panel: 04/09/2015

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.

The ELP is asked to note that there are recommendations for improvement in relation to three major and three '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 establish and implement an action plan for resolving the cases where gametes and embryos are in store beyond the consented storage period.
- The PR should ensure compliance with medicines management regulations and Trust policy.
- The PR should review procedures for submitting licensed treatment data to the HFEA to ensure that it is provided accurately and within the timeframes specified in Directions.

'Other' areas of practice that require improvement:

- The PR should take appropriate action to ensure that the centre's website is compliant with requirements.
- The PR should ensure that all HFEA invoices are paid within the timescales specified by the Authority.
- The PR should ensure that daily checks of the resuscitation trolley and oxygen and suction in the recovery area are carried out and documented.

Information about the centre

The Assisted Conception Unit at King's College Hospital has held a licence with the HFEA since July 1992.

The centre provides a full range of fertility services and has two transport centres, Epsom and St Helier NHS Trust, centre 0259 and Kingston Hospital Assisted Conception Unit, centre 0270.

The Trust has recently merged to form a partnership with the Hewitt Fertility Centre, Liverpool. The centre is still called the King's Assisted Conception Unit but have plans to rename it the King's – Hewitt unit.

The Centre provided 685 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2015. In relation to activity levels this is a medium sized 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]

For IVF and ICSI, HFEA held register data for the period March 2014 to February 2015 show the centre's success rates are in line with national averages.

In 2014 the centre reported 180 cycles of partner insemination with 15 pregnancies. This represents a clinical pregnancy rate of 8% which is in line with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy. Between March 2014 and February 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%. This means that the centre's live birth rate is likely to be consistent with 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 following laboratory activities were observed in the course of the inspection: egg collection, thawing of embryos, sperm preparation. All of the procedures observed were witnessed using a manual witnessing system in accordance with HFEA requirements.

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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. 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, the reports of the audits of all stored samples were reviewed and the 'bring-forward' system was discussed with staff. This revealed that the centre does not have written effective consent for the storage of all stored samples. This includes twenty three sperm samples and embryos of four patients. The centre has recently reviewed its 'bring-forward' system and has made changes. At the time of the last inspection, it was noted that the centre did not have effective consent for the storage of one sperm sample. The PR provided assurance that this would be addressed and it was resolved within the required timeframe. As this referred to only one sample, the non compliance found on this inspection has not been upgraded to a critical non compliance (see 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.

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 necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing, consent to storage and medicine management. The inspection team considered that the centre's audit practices are broadly compliant with requirements, with the following exception: the centre has not conducted an audit of their controlled drugs (see medicines' management section below).

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

- The centre's audits of witnessing and consent to storage.
- The use of CE marked medical devices.
- The content of the centre's website.

- The use of the most recently issued HFEA consent form versions.
- The centre's audit of legal parenthood.
- The HFEA reports of adverse incidents from 2010-2012 and 2013.
- HFEA Clinic Focus articles.

The centre is broadly effective in implementing learning from guidance from the HFEA, with one exception. The centre's website is not compliant with the requirements of the Chair's letter CH (11)02 in the following areas;

- Data relating to live birth rates is not less than three years old (see recommendation 4).

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. The centre's processes were reviewed for medicines management and the safe storage, disposal and administration of medicines and were considered partially compliant with guidance.

A number of practices were observed that required improvement relating to the management of medicines (see recommendation 2):

- There were four instances in the controlled drugs record book where alterations had not been recorded according to the requirements of the Misuse of Drugs Regulation 2001.
- Controlled drugs wastage is not routinely documented in the controlled drug book which is contrary to the requirements of the Misuse of Drugs Regulation 2001, schedule 27.
- In four out of four sets of notes reviewed, the theatre care record included a list of drugs, which were all encircled by a bracket followed by a single signature in the "prescribed by" column. The same was repeated in the administered by column. It was not clear if all three drugs had been prescribed and administered or just one. This is contrary to professional guidelines and good practices.
- The centre has not conducted an audit of their controlled drugs within the last year, which is contrary to their trust policy (SLC T2).

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 observed infection control practices and found them to be compliant with guidance.

Equipment and Materials

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

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 compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

During the inspection we spoke to one patient about their experiences at the centre and observed interactions between centre staff and patients. A further fifteen patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, with ten of the individuals providing written feedback giving compliments about the care 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;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

The negative comments received from five patients relating to their experiences of members of the centre's administration staff were discussed with the PR during the inspection. He advised the inspectors that actions have already been taken to address this matter including recruitment to the administration team. The inspection team urge the centre to continue to monitor patient feedback to ensure the actions taken are effective.

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 and from observations during the visit to the centre, the inspection team identified the following areas requiring improvement:

- The centre has two sperm production rooms for patients. Both have locks but there were no signs on the outside of the rooms to indicate when the rooms are in use. Centre staff use a laminated sheet to indicate when the rooms are in use, however, on inspection it was noted that this sign frequently flips over and was therefore not an effective system of maintaining patient privacy. This was discussed with staff during the inspection and the inspection team urge the centre to consider what method would be the most appropriate to show when the rooms are in use.
- The centre has a policy which requires the daily checking of the defibrillator equipment on the resuscitation trolley and the piped oxygen and suction in the recovery area. Observations during the inspection and a review of the documentation indicated that these checks were not being carried out daily (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 four major and ten 'other' areas of non compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales with the exception of that relating to the late payment of invoices which is described below.

On-going monitoring of centre success rates

Since the last renewal inspection in April 2013 the centre has received three risk tool alerts in relation to the late payment of HFEA invoices, which is indicative of non compliance with the requirements of Chair's letter CH(10)02 (see recommendation 5). This was highlighted as an issue following the last renewal inspection which led to a management review meeting at the HFEA in October 2013.

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 partially compliant with requirements to submit information to the HFEA because:

- The centre has a large number of late and missing data submission errors that have not been addressed (see recommendation 3).

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 sent the report of the audit to the HFEA within the required timeframe.

On inspection, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA and that actions had been taken in response to the audit findings.

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	Inspection team's response to the PR's statement
None identified.			

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. Consent The centre does not have written effective consent for the storage of all cryopreserved sperm and embryos (Schedule 3, 8(1) and (2) HF&E Act 1990 (as amended)).	The PR should establish an action plan for resolving the cases where sperm and embryos are in store beyond the consented storage period. A copy of the plan should be provided to the HFEA by the time this report is considered by a Licensing Committee. The plan should aim to resolve all the current issues by 15 October 2015. The PR should provide monthly updates to the HFEA on progress in implementing the proposed actions.	An action plan has been made and is being acted upon. A copy has been submitted with this report along with an update on implementation. All patients with samples in storage and whose storage consents have expired have been written to/ telephoned as per their last recorded contact details and samples are being disposed of/ consents extended as per patient wishes/ as is approriate. Ongoing updates will be provided by the PR as requested.	The Executive acknowledges the PR's response and his commitment to fully implementing the recommendation. The inspector will continue to monitor this issue until resolution. Further action required.
2. Medicines Management There were four instances	The PR should ensure compliance with medicines management regulations and	The guidelines and documentation are being reviewed and will be amended	The Executive acknowledges the PR's response and his commitment to fully

noted in the controlled drugs record book where alterations had not been recorded according to the requirements of the Misuse of Drugs Regulation 2001. Controlled drugs wastage was not documented in the controlled drugs book which is contrary to the requirements of the Misuse of Drugs Regulation 2001, schedule 27. In four out of four sets of notes reviewed on inspection, the theatre care record included a list of drugs, which were all encircled by a bracket followed by a single signature in the prescribed by column. The same was repeated in the administered by column. It was not clear if all three drugs had been prescribed and administered or just one. This is contrary to professional guidelines and good practices. The centre has not conducted an audit of their controlled drugs within the last year, which is contrary to the trust's	best practice guidance. The PR should advise the HFEA of the actions taken with respect to this recommendation in responding to this report. Within three months, the centre should conduct an audit of their medicines management practices including *inter alia* management of controlled drugs and record keeping. A summary report of the audit detailing the findings and any further corrective actions and the timescale for their implementation should be supplied to the centre's inspector by 15 October 2015.	once changes have been agreed with pharmacy. Our current Controlled Drug management practice is in keeping with the trust Medicines Administration policy but as this does not appear to meet with the Misuse of Drugs regulations we are currently working with the Trust Pharmacy department to resolve these issues. The trust pharmacy department audits controlled drug management and record keeping for all departments within Kings College Hospital including the Assisted Conception Unit. We are disappointed that this has not taken place . Pharmacy have been requested to schedule an audit of medicine management practices as a matter of urgency and the relevant information will be supplied as requested .	implementing the recommendation. Further action required.

policy to audit controlled drugs every three months. SLC T2.			
3. Data submission The centre does not submit licensed treatment data to the HFEA within the timeframes specified in Directions. The centre also has a large number of historic data errors that have not been corrected. General Direction 0005.	The PR should review the centre's data submission processes and should take corrective actions to prevent late or absent data reporting. A summary of the review including corrective actions required and the timescale for their implementation should be provided to the HFEA by 15 October 2015. The PR should also review information on the clinic portal related to the centre's HFEA Register data errors and should ensure that historic data submission errors are corrected by 15 October 2015. 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 by 15 January 2016.	Data submission processes are currently under review. We are pleased to be able to say that we have recently employed a number of additional laboratory support staff, including two laboratory administrators and anticipate that this, along with a review of the data submission processes with resolve the issues that we have had with timely data submission and resolution of errors.	The Executive acknowledges the PR's response and his commitment to fully implementing the recommendation. Further action required.

	It is also recommended that the PR reviews error reports on a weekly basis to prevent a build up of unresolved data issues which may affect the quality of the data held by the HFEA.		

‘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	Inspection team’s response to the PR’s statement
4. Website The centre’s website is not compliant with the requirements of Chair’s letter CH (11)02 ‘Responsible use of websites: duty of centres’ as the data is not less than three years old. CH (11)02.	The PR should inform the HFEA of actions that have been taken to ensure that the centre’s website is compliant with requirements when responding to this report.	New success rates data has been collated and submitted to the Website administration team for inclusion on the ACU website as per HFEA requirements.	The Executive acknowledges the PR’s response. The PR is asked to inform the centre’s inspector when the changes to the website have been made. Further action required.
5. Finance During the last 12 months, the centre has been issued with three risk tool alerts related to the late payments of HFEA invoices. This was an issue identified during the last inspection which led to a management review meeting. 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 should undertake a review to identify the barriers to the prompt payment of invoices. A summary report of the findings of the review and any corrective actions identified as necessary should be provided to the centre’s	We recognise that there has been an issue with delayed payment of HFEA invoices. We have discused this with our finance department and requested a review of the process to identify barriers to payment as requested. The outcome of this review and subsequent audit will be submitted as requested.	The Executive acknowledges the PR’s response and his commitment to fully implementing the recommendation. Further action required.

	inspector by 15 October 2015. Within 3 months of implementation of corrective action, the centre should audit the payment of invoices to determine if the corrective actions have been effective in ensuring payment of HFEA invoices within prescribed terms. A copy of the audit should be provided to the HFEA by the 15 January 2016.		
6. The centre has a policy which requires the daily checking of the defibrillator equipment on the resuscitation trolley and the piped oxygen and suction in the recovery area. Observations during the inspection and a review of the documentation indicated that these checks were not being carried out daily. SLC T2.	The PR should ensure that daily checks of the resuscitation trolley and oxygen and suction in the recovery area are carried out and documented. Within 3 months of the implementation of the corrective action, the centre should audit these checks and their documentation to ensure effectiveness. A summary of the audit should be sent to the HFEA by 15 October 2015	The clinical team have been reminded regarding the need for daily checks of essential resus equipment. This will be audited and the outcome submitted as requested.	The Executive acknowledges the PR's response and his commitment to fully implementing the recommendation. Further action required.

Additional information from the Person Responsible
We would like to thanks the inspectors for their feedback. We accept the comments within this report and will seek to address the issues raised as soon as possible.