Interim Licensing Report

Centre name: Assisted Conception Unit, King's College Hospital

Centre number: 0109

Date licence issued: 01/10/2008

Licence expiry date: 30/09/2013

Additional conditions of licence: None

Date of Inspection: 24/07/2012

Inspectors: Susan Jolliffe, Debra Bloor

Date of Executive Licensing Panel: 19/10/2012

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 centres compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an 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 2012-14 the focus of an interim inspection is:

- **Quality of service:** the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation a centre's performance.

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

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence.

The inspection team has made recommendations for improvement and these should be implemented within the time specified.

The Executive Licensing Panel is asked to note that at the time of the inspection there were recommendations for improvement in relation to one critical area of non-compliance, four major areas of non-compliance and one other areas of non-compliance. Since the inspection visit the centre has provided evidence that the following recommendations have been fully implemented:

'Major' areas of non compliance:

- the PR should ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier
- the PR should ensure that personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform

The PR has given a commitment to fully implement the following recommendations:

'Critical' areas of non compliance:

- **the PR should ensure that no gametes or embryos are kept in storage for longer than the consented period**

'Major' areas of non compliance:

- the PR must ensure that fees are paid to the Authority within the timescale specified in Directions or writing
- the PR should ensure that the centre has audited the procurement and processing procedures.

'Other' areas of practice that require improvement:

- the PR should ensure that the centre have in place robust and effective processes to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process.

Information about the centre

The Assisted Conception Unit at King's College Hospital is located in Denmark Hill London and has held their current licence with the HFEA since October 2008. In June 2012 an Executive Licensing Panel (ELP) approved a variation to the centre's licence allowing the relocation of the centre to new licensed premises. The new unit is a self-contained facility based within the grounds of the King's College Hospital.

The centre provides a full range of fertility services.

The centre provided 588 cycles of treatment (excluding partner intrauterine insemination,) in the 12 months to 30 June 2012. 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 very important indicators of centres' ability to provide high quality patient care and to meet the requirements of the law.

Outcomes[1]

HFEA held register data for the year ending January 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with the national average.

Multiple births

The single biggest risk of fertility treatment is multiple pregnancy.

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%: this represented performance that was not likely to be statistically different from the 20% live birth rate target.

For the time period April 2011 to March 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 19%: this also represents performance that is not likely to be statistically different from the 15% live birth rate target.

While the centre's efforts to meet the multiple birth rate targets are acknowledged, it is noted that the centre's strategy may need to be reviewed if the centre is to meet the 10% live birth rate target that comes into force in October 2012.

Witnessing Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification error does not occur. The following laboratory activities were observed in the course of the inspection: fertilisation checks; sperm preparation and removal of samples from storage.

[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.

Witnessing was in line with HFEA recommended practice with the following exception: during fertilisation checks only the surname was used during witnessing of dish to dish transfer (see recommendation 2).

The inspection team reviewed seven sets of patient records and concluded that whilst records of manual witnessing are maintained, the records do not always clearly describe the witnessing stages at all critical points of the clinical and laboratory process ;For example, when removing gametes from cryopreservation the cross check of information on the storage container against the information in the patient record was not recorded as being witnessed in the patient records although this cross referencing was observed in practice (see recommendation 6).

Consent : Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by five patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in all five records reviewed.

Consent: To the storage of cryopreserved material

A review of the centre's records of consent to storage of gametes and embryos showed that **not** all gametes and embryos currently in store are being stored in accordance with the consent of the gamete providers.

A review of the centre's bring forward system demonstrated that an estimated 16 sperm samples were in storage at the time of the inspection even though the consents for their storage appeared to have expired

Staffing (SLC T12)

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

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; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

However, the inspection team were informed that a member of the laboratory staff had recently resigned to take up a new post and a number of permanent laboratory staff are on maternity leave. When the current staff member leaves the unit there will be only one part time Health Professions Council (HPC) registered member of staff working in the laboratory. Discussion with the PR and senior staff did suggest that succession planning

and a review of the workload had taken place but had not been formalised (see recommendation 3)

Patient experience

During the inspection visit six patients provided feedback on their experiences and the inspection team observed interactions between centre staff and patients. A further 13 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with10 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they had 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.

Patients interviewed did suggest that it would be useful if patient information leaflets were made available in the waiting area.

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 the HFEA.

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 non-compliances:

- In the last two years, the centre has not audited how far procurement and processing procedures comply with the approved protocols, the regulatory requirements and quality indicators (see recommendation 5).
- It is not a condition of all third party agreements that the third party will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice. The centre is now fully compliant against this licence condition.
- The centre has not paid fees to the Authority within the timescale specified in Directions (see recommendation 4).

Compliance with recommendations made at the time of the last inspection

Following the interim inspection in June 2010 recommendations for improvement were made in relation to five major non-compliances. The PR provided information and evidence that all but one of the recommendations have been fully implemented: the one outstanding recommendation regarding CPA accreditation was discussed at this inspection

The unit performs diagnostic semen analysis but the laboratory is not CPA accredited. In the course of the inspection it was noted that the centre has a quality management system; has validated procedures and equipment for semen analysis; HPC registered staff suitably qualified to perform and interpret the tests and; participates in the national external quality assessment scheme (NEQAS) for semen analysis. In consideration of this, the centre is considered to have a status equivalent to that of CPA and no further action is required by the centre in relation to CPA accreditation.

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 has a good record of data submission and compliance with related regulatory requirements. Nevertheless, there are currently a number of outstanding early outcome forms that still need to be submitted by the centre. Late submission and/or failure to submit early outcome forms can have an adverse impact on the mechanism by which the HFEA monitors centre performance (e.g. clinical pregnancy rates monitoring via the risk based assessment tool - RBAT).

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 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 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 PRs statement
1. **Consent: To the storage of cryopreserved material (SLC T82 (a))** On 24 July 2012, the centre had 16 sperm samples in storage where the consents for their storage appeared to have expired, contrary to HF&E Act 1990 (as amended)	The PR must ensure that gamete and embryo samples are stored within the terms of the gamete provider's consent and within the statutory storage periods. The PR should provide a summary report to the HFEA documenting the number of samples in store where there is no valid consent to storage or where the statutory storage period has been exceeded. The report should be submitted to the HFEA by 24 September 2012. The report should	Following the inspection we have found that there are 4 samples that are being stored beyond their consent expiry dates. Of the16 sperm samples that initially appeared to have been stored beyond the expiry of consent, it was found that 12 of these samples were either no longer in storage or the consents had	The inspection team is satisfied with this response. A detailed summary report has been received and a full report is expected by 24 October 2012.

Schedule 3, 8 (1) and 8 (2).	document the actions to be taken by the centre and the expected timescales for obtaining consent or confirming that samples can be allowed to perish. The PR is reminded that the centre should follow their documented procedures to ensure that all reasonable efforts have been made to contact the gamete providers prior to any disposal without consent. If there is possibility of legal challenge to the disposal of gametes then the PR should report this to the HFEA: See guidance in Chair's letter CH(03)03. http://www.hfea.gov.uk/2687.html The centre should review their bring forward procedures, a summary report of the review including corrective actions and timescales for their implementation should be submitted to the HFEA by 24 October 2012.	been updated, and although this had been documented in the respective notes, it had not been entered into the database. This has now been rectified. The summary report will be submitted to the HFEA by the 24th of September as requested. We have sought legal advice regarding disposal without express written consent to dispose due to the gamete provider being non-contactable and a full report will be submitted to the HFEA by the 24th of October as requested The gamete storage database has been audited and a summary report and corrective actions decided. The database management SOP has been updated in light of the audit findings. As above details of this will be submitted by the 24th of October.	

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
- 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 PRs statement
2. **Witnessing (SLC T101)** During witnessing at the time of fertility checks only the surname was witnessed during dish to dish transfer.	The PR should ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, processing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and that witnessing checks cross are made against the patient's full name **and** a further identifier. This should be implemented immediately It is recommended that the centre's witnessing SOP is reviewed to ensure that it is compliant with HFEA requirements for witnessing; that where there are changes required to practice, staff are provided with immediate training in the proper conduct of witnessing. This should	These changes have already been implemented as recommended following the inspection. The witnessing SOPs have been updated accordingly along with the witnessing paperwork that is filed in the notes. Staff have been provided with appropriate training. A summary report will be provided by the 24th of October as requested A re-audit of witnessing documentation and audits of witnessing practice are scheduled to take place later this month. Reports to be submitted by the 24th of January.	The inspection team are satisfied with this response. A summary report is due 24 October followed by a re-audit of the witnessing practices. These will be monitored by the lead inspector.

	be completed by 24 October 2012 and a summary report of any changes and corrective actions should be supplied to the lead inspector. The centre should also carry out audits of witnessing practice (including both an audit of practice against compliance with regulatory requirements, the approved protocols and quality indicators and an audit of centre staff practice). A summary report of the findings of these audits and any required corrective actions and a timescale for their implementation should be submitted to the lead inspector by 24 January 2013.		
3. **Staffing (SLC T12)** A senior member of the laboratory staff had resigned to take up a new post and a number of permanent laboratory staff were on maternity leave, which would leave only one part time HPC qualified member of staff available to carry out and supervise the activity of two trainee members of staff in the laboratory.	The PR should ensure that personnel in the centre are available in sufficient number and are qualified and competent for the tasks they perform. The PR should assess how many treatment cycles can be safely accommodated taking into account the number of staff available; their skills mix and experience; the equipment and premises. The PR	A staffing assessment has been completed and the number of cycles performed per week is currently being limited to 15 which the team considered appropriate for our current staffing levels and skill mix. As a result of the assessment the number of GP semen analyses performed is also currently being capped. These limits will remain in place until we are satisfied that staffing levels and skill mix are	The inspection team is satisfied with the response. This will be reviewed at the next inspection.

	should ensure that activity levels are maintained within the identified limits and a copy of the assessment should be provided to the lead inspector by 24 October 2012. .	adequate for activity to increase to normal levels. A HPC registered Embryologist has been appointed to join the lab on a years contract to cover maternity leave and another permanent Senior Embryologist post is currently being advertised in order to fill the soon to be vacant Consultant Embryologist post. A locum appointment has been made to fill this vacancy until the permanent appointment is filled. We will therefore have a full complement of laboratory staff in October. Following the new staff appointments, completion of appropriate induction and training a further work force assessment will be completed. Cycle numbers will remain at the current reduced levels until staffing levels are assessed as adequate to support an increase back to normal throughput (20 cycles per week.)	

4. **Payment of HFEA fees (SLC T09(d))** In June 2012, the average number of days which invoices had been outstanding for the previous year was 85 days.	The PR must ensure that monthly fees are paid to the Authority within 28 days. An action plan to address this should be sent to the lead inspector by 24 October 2012.	We recognise that this has been an ongoing problem and are working with the trust finance department to resolve this issue. The action plan will be sent as requested.	The inspection team are satisfied with this response. An action plan is expected by 24 October 2012.
5 Audit (SLC T36) In the last two years, the centre has not audited how far procurement and processing procedures comply with the approved protocols, the regulatory requirements and quality indicators.	The PR should ensure that an audit of procurement and processing procedures is completed A copy of the audit plan should be forwarded to the lead inspector by 24 October 2012, followed by quarterly updates.	There are approximately 27 procurement and processing procedure SOPs. Following discussion with the lead inspector a timetable for the completion of these audits (over a six month period) will be submitted by the 24th of October along with the target date for completion of the audit timetable. As requested regular updates (at least at three month intervals) will be provided to the lead inspector along with the audit summaries, corrective actions and target dates for completion.)	A robust audit programme has been developed. Quarterly updates of the audit plan will be monitored by the lead inspector.

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	Inspection team's response to the PRs statement
6. Witnessing (SLC T71) The documentation recording the witnessing checks does not always accurately reflect practice.	The PR should review the documentation of witnessing checks, and ensure an audit of patient records is completed. A summary report should be submitted to the lead inspector by 24 January 2013.	The documentation of witnessing checks is currently being reviewed and some changes have already been made. A summary report will be submitted as requested.	The inspection team are satisfied with the response. The summary report will be reviewed through on going monitoring by the lead inspector.

Additional information from the Person Responsible
Re: compliance with HFEA standard licence conditions. It is a condition of our standard TPA that all third parties providing a service that requires the implementation of a TPA meet the standard HFEA licence conditions and guidance as set out in the HFEA COP.

HFEA Executive Licensing Panel Meeting

19 October 2012

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

Minutes – Item 3

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

Members of the Panel:	Committee Secretary:
Juliet Tizzard – Head of Policy & Communications (Chair)	Joanne McAlpine
Hannah Darby – Senior Policy Manager	Observing:
David Moysen – Head of IT	Neil McComb – Register Information Officer

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of 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 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 Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has held its current licence with the HFEA since October 2008.

2. The Panel noted that in June 2012 the Executive Licensing Panel approved a variation to the centre's licence allowing the relocation of the centre to new licensed premises.

3. The Panel noted that this is a medium-sized centre which provides a full range of services and carried out 588 cycles of treatment (excluding partner intrauterine insemination,) in the 12 months to 30 June 2012.

4. The Panel noted that the data held on the HFEA register for the year ending January 2012 show the centre's clinical pregnancy rates are in line with national averages.

5. The Panel noted that for the time period April 2011 to March 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles was 19%. This represents performance that is not likely to be statically different from the 15% live birth rate target.

6. The Panel noted that, at the time of the inspection, there were one critical and four major areas of non-compliance identified by the Inspectorate.

7. The Panel noted that, since the inspection, the Person Responsible (PR) has provided evidence that two major areas of non-compliance have been addressed and has given a commitment to fully address the remaining non-compliances.

8. The Panel noted that, since the inspection, the PR had significantly reduced – from 16 to 4 - the number of sperm samples stored beyond the time period consented to.

9. The Panel noted that that the Inspector had identified two non-compliances relating to witnessing, and noted that a summary report is due to be submitted to the Inspectorate on 24 October 2012. The Panel endorsed the Inspectorate's plan to monitor the centre to ensure that this has been addressed within the prescribed timeframe.

10. The Panel noted that the Inspectorate recommends the continuation of the centre's licence with no additional conditions.

Decision

11. The Panel endorsed the Inspectorate's recommendations made in the report and encouraged the centre to address them within the

timescales specified. The Panel agreed to the continuation of the centre's licence with no additional conditions.

Signed:  Date: 30 October 2012

Juliet Tizzard (Chair)