Interim Inspection Report

Date of Inspection: 10 June 2010
Length of inspection: 5 hours
Inspectors: Ellie Suthers and Sarah Brain

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 13 October 2010 and 25 August 2010.

Date of Licence Committee: 30 September 2010

Purpose of the Inspection report
The purpose of the inspection is to assess centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. The report summarises the findings of the interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Licence Committee which make the decision about the continuation of the centre's licence.

Centre details

Centre Name	Assisted Conception Unit, King's College Hospital
Centre Number	0109
Licence Number	L0109/12/c
Centre Address	1st Floor, Mapother House, King's College Hospital, Denmark Hill, London. SE5 9RS
Telephone Number	02032995390
Person Responsible	Mr. Mike Savvas
Licence Holder	Ms Sarah Dawson
Date Licence issued	01/03/2010
Licence expiry date	30/09/2013
Additional conditions applied to this licence	None

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Report to Licence Committee

Recommendation to the Licence Committee

The inspector considers that, overall there is sufficient information available to recommend the continuation of the unit's licence without additional conditions.

The inspector also recommends that the Licence Committee requires that the Person Responsible complies with following recommendations within the prescribed timeframes set out in the inspection report:

- The PR should ensure that all critical equipment (technical devices) and critical procurement, processing and storage procedures are validated. The PR has submitted an action plan listing all critical procedures and equipment that require validation and the anticipated timescales for completion of validation. The PR should also submit quarterly reports to the inspector on the progress of validation until the action plan is complete. Licence Condition T72

- The PR should ensure that the laboratory that carries out diagnostic semen analysis obtains accreditation by CPA (UK) Ltd or another body accredited to the equivalent standard. The PR has provided an action plan to the inspector outlining the anticipated timescales for obtaining accreditation and then quarterly reports on the progress in becoming accredited. Licence Condition T21

- The PR should ensure that all HFEA fees are paid within 28 days. Licence Condition T9(a) Chairs letter CH(10)02

The Licence Committee is asked to note that this interim inspection has afforded the PR the opportunity to update the centres progress following an incident in October 2009. The PR and staff at the unit have worked diligently to ensure that the incident reported in October 2009 was recognised, investigate and managed well. The PR complied with all the requirements of the HFEA Code of Practice (8th Ed) for reporting and managing incidents and has ensured continued service for patients undergoing other care and treatment at the unit.

Details of Inspection findings

Brief description of the centre and its licensing history:
The Assisted Conception Unit has held an HFEA licence since 1993; no additional conditions have been attached the licence.

The unit is a self contained facility based at the King's Healthcare NHS Foundation Trust and provides a range of fertility services to both NHS and privately funded patients. Fertility services are provided under contract primarily for Lambeth, Lewisham, Southwark, Greenwich, Bexley and Barnet Primary Care Trusts and to some self funded patients. The unit also provides transport service arrangements with St Helier Hospital in Surrey.

The Person Responsible (PR) is a Consultant Obstetrician and Gynaecologist at King's College Hospital NHS Foundation Trust and completed the Person Responsible Entry Programme in 2010.

Additional information relating to this interim inspection:
In October 2009 staff at the centre identified that there had been a noteworthy fall in pregnancy rates across all age groups: outcomes for intra uterine insemination (IUI) treatments were unaffected. This coincided with the start of significant building work on the floor below the unit. Although the air quality in the laboratory remained consistently within regulatory requirements the PR and consultant embryologist took the decision to stop egg collection, embryology and embryo transfer in the unit. The PR immediately informed the HFEA that they were invoking their contingency arrangement with a neighbouring HFEA licensed assisted conception unit at Guy's & St Thomas' Hospital NHS Trust (centre 0102). An incident report was then filed with the HFEA in line with requirements of Licence Condition T120 and following an investigation Licence Condition T121. The PR kept the inspectorate fully informed of all changes as required by Licence Condition T9 (a) and (f)

At the time of this inspection the assisted conception unit, Guy's & St Thomas' Hospital NHS Trust are carrying out egg collection, embryology and embryo transfer according to their own protocols including embryo selection criteria, multiple birth minimisation policy and reporting treatments to the HFEA. Some of the Assisted Conception Unit's scientific and clinical staff are working across both sites to ensure continuity of patient care. All other elements of the patient pathway including providing information and taking consent, follow up post treatment and IUIs are carried out at and by the staff of the King's ACU.

At the time of inspection the building work on the floor below has been completed, cleaning of the laboratory had started and the PR and consultant embryologist are beginning to plan the repatriation of egg collection, embryology and embryo transfer back to the unit.

For more detailed information please see:
Annex A: Serious incident report – Assisted Conception Unit, King's College Hospital.
Annex B: Incident investigation report – Assisted Conception Unit, King's College Hospital.

Because of these changes and developments the inspectorate extended the interim inspection to include: storage of gametes and embryos; premises and facilities, validation of processes and equipment and traceability.

Activities of the Centre:

Activity quoted here is for the period 31 August 2008 to 01 September 2009 as activity from October 2009 to the time of the inspection has been carried out at another centre.

Type of treatment	Number of treatment cycles for the period 31/08/2008 & 01/09/2009
IVF	282
Intra Cytoplasmic Sperm Injection(ICSI)	302
Donor Insemination	75
IUI (2009)	34

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	N/A
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

*These data were extracted from the HFEA register for the period 31/08/2008 – 01/09/2009 and are subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

Updated actions since the centre was inspected on 10 June 2010

Since the interim inspection on the 10 June 2010 staff at the unit have repatriated egg collection, embryology and embryo transfer back to the Kings site. Activity has been gradually increased to 15 cycles a week with plans to achieve 20 cycles later in the year. It is too early to provide meaningful data on clinical pregnancy rate but the biochemical pregnancy rate is currently 40% (14/35)

The PR has consistently provided updates on their progress to the lead inspector following repatriation of services.

Of the five areas of non compliance and five areas that required improvement identified at inspection the PR has provided evidence of compliance with seven areas and has provided action plans and details of imminent compliance with three areas. As described on page 3 of this report.

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood

What the centre does well

Information to be provided prior to consent: Guidance Note 4 - 4.3
Before treatment, storage or both are offered, staff at the unit provide a personalised costed treatment plan for each patient. *(Doc: Self-Funded Treatment Prices from April 2010)* It was observed at the time of inspection that the plan details the main elements of the treatment proposed and any necessary investigations and tests.
The unit provides a "cost package" that details all costs any additional tests or investigations are included in the package. No extra charges are added once the cost package has been agreed.

During the inspection staff said that patients are given the opportunity to discuss the plan before treatment begins, at the first consultation and throughout their treatment pathway.

What they could do better.
N/A

Consent - particularly consent to disclosure to researchers and consent to storage

What the centre does well

All staff who take consent at the unit are provided with mandatory training in consent taking by the King's College Hospital NHS Foundation Trust. The PR described how, as part of the local induction process, medical and nursing staff observe the process of information giving and consent taking and then move on to being supervised and, when appropriate, signed off as competent.

Consent to the disclosure of information
The unit has a detailed procedure in place and a comprehensive checklist to be completed when patients/partners are provided with information prior to providing consent to disclosure of their information to relevant parties. Patients are given the opportunity to decide what identifying information should be disclosed and to whom. Written consent is documented before disclosing any identifiable information relating to their treatment. (Guidance 5.27)

Staff at the unit do seek consent to disclosure of information to medical or other researchers Guidance 5.27(d). HFEA records show that the unit is submitting this information as part of the EDI reporting system and the consent is also stored in the patient's records.

In a joint audit by the inspectorate and quality manager it was noted that all consent to disclosure of information forms had been appropriately completed and signed by the relevant parties.

Consent - particularly consent to disclosure to researchers and consent to storage continued

Consent to treatment and storage
Consent to treatment, use and storage of gametes is taken by medical and nursing staff. Consent forms are completed by the nursing staff at the first nursing consultation. The PR demonstrated a detailed process and a series of checklists to be completed to ensure that consent to treatments and storage of gametes and embryos is compliant with regulatory requirements.

During discussion the consultant embryologist confirmed the assertion on the unit's Self Assessment Questionnaire that all material currently in storage is within the limit of the statutory period. The inspectorate carried out an audit of four laboratory records of cryo preserved material. All indicated storage in line with statutory storage period with no discrepancies (Licence Condition 79)
See storage of gametes and embryos on page 13 for further details.

What they could do better.

Cooling off period
The standard operating procedure for storage does not reference the steps to be taken in relation to the cooling off period if one partner withdraws consent to storage (HFE Act 1990 (as amended) Schedule 3) or procedures for dealing with disputes that may arise when one gamete provider withdraws their consent to the use or storage of gametes or embryos in treatment. (Guidance 5.35).

Multiple births

What the centre does well

Multiple Births: Guidance Note 7
The PR reported an overall multiple pregnancy rate in 2009 of 27%. This is not indicative of present activity as patient and embryo selection criteria, treatment and reporting is done via the Guy's and St Thomas' ACU.

The PR provided evidence that the King's unit is compliant with the mandatory requirements of Directions 0003.

The strategy sets out how the unit aims to reduce the multiple birth rate and how to ensure that the rate does not exceed the maximum rate specified by the HFEA.

The strategy also includes a section identifying suitable cases for single embryo transfer (SET), including criteria in relation to embryo assessment and patient selection criteria. Directions 0003 Section 5(a) (b).

Multiple births continued

The unit also maintains a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer as set out in the strategy. (Directions 0003 Section 3(c))

Where more than one embryo has been transferred the unit has recorded in patients health records an explanation of the reasons for transferring more than one embryo in that particular case and a note confirming that the risks associated with multiple pregnancy have been fully discussed with the patient. (Directions 0003 Section 7(a) (b))

Until September 2009 the unit carried out regular audits and evaluations of the progress and effectiveness of the strategy. Evidence of this was seen in the unit's multiple birth minimisation audit report. (Directions 0003 Section 3(b)

Once patient treatment is repatriated to the King's unit all treatments will be provided with the units own strategy, patient and embryo selection and be monitored and reported accordingly.

The PR has complied with the requirements of Directions 0003. Until September 2009 the unit applied this policy and selection criteria to patients undergoing treatment within the King's unit.

NB
From October 2009 all patients transferred for treatment have been treated under the Guy's and St Thomas' (0102) policy and selection criteria. This unit demonstrated full compliance with the requirements of Directions 0003 during inspection on 26 January 2010.

What they could do better.
N/A

Witnessing

What the centre does well.

Witnessing: Guidance Note 18
The unit has a standard operating procedure for checking the identity of patients/partners and donors at the beginning of treatment/donation. It was observed that passport photographs, national insurance numbers and signatures are recorded in the patient records at the time of the first consultation at the unit. The fertility nurse said that the patient's identity is check against these records prior to treatment. (Guidance 18.7)

The unit has documented standard operating procedures for the processes to be followed for witnessing laboratory and clinical processes. The procedures identify where patient identification and all the critical points of the clinical and laboratory processes require witnessing by two members of staff. (Licence Condition T71).

A witnessing standard operating procedure, discussions with laboratory staff and an audit of patient and laboratory records demonstrated that witnessing checks appeared to be completed and signed by a member of staff when the relevant clinical or laboratory process/procedure took place and a record kept in each patient's records. A record is kept of the name, status and signature of the person performing the activity and the witness in the patient's records. (Licence Condition T71)

The consultant embryologist provided documented evidence of their recent audit (March 2010) of witnessing practice against compliance with the approved standard operating procedure and corrective actions required. (Licence Condition T36)

Staff are asked to sign to confirm that they have read the witnessing standard operating procedure and consider themselves competent. The consultant embryologist then assesses their competence and signs to confirm their competence in witnessing. (Licence Condition T15(a))

What they could do better.

The PR has not established quality indicators or objectives relating to witnessing. During discussion the consultant embryologist and quality manager described how these are to be established. (Licence Condition T35)

At the time of inspection that the consultant embryologist had not had her competence to carry out witnessing assessed or documented. (Licence Condition T15(a))

Witnessing - continued

What they could do better.

The inspection team noted that the unit's witnessing practice is non-contemporaneous at some stages of sperm preparation. Unit staff explained that they cross check information on all the sperm preparation tubes and the sperm pot at the beginning of the procedure but thereafter, witnessing checks are not performed each time the sperm sample is moved between tubes. The final tube is then witnessed against patient identity and patient records at the time of treatment.

Guidance at 18.30 acknowledges that as part of a risk assessment for sperm preparation, centres may consider witnessing the cross-checking of information on tubes only at the start and end of the procedure, not at every stage however, in compliance with guidance

provided at 18.25

An audit of five records showed that on a small number of occasions the time of the witnessing step was not recorded. Guidance18.7 (b).

Legal Parenthood

What the centre does well.

Legal parenthood: Guidance Note 6
Legal parenthood requirements are documented in the units "the law and conception in using donor sperm" information (Licence Condition T60). This document explains: husbands/partner/second parent rights relating to parenthood; the procedures to follow and the consent forms to be completed. The patient leaflet also contains information about what rights donors have, information that can be shared and the rights that a child born as a result of donor treatment has.

This document also explains the procedures to be followed when a patient or their partner withdraws their consent to parenthood. The process of taking routine (non parenthood issues) consent also explains how to withdraw consent. (Licence Condition T64 and T65).

Patients/partners are asked to confirm they have received this information and have the opportunity to discuss it with a relevant member of staff.

What they could do better.
N/A

Equipment and materials and premises and facilities.

What the centre does well.

Although there has been a limited service within the embryology laboratories staff have ensured that all equipment and materials have been maintained to a compliant standard. During discussion the consultant embryologist described the regular cleaning and disinfection of equipment. A template for documenting the outcome was provided to the inspection team.(Licence Condition T26)

Air Quality
Staff at the unit provided documented evidence that the areas where processing of gametes and embryos takes place is an environment with Grade A air quality with a background environment of a Grade D air quality. (Licence Condition T20)

Detailed documented evidence was provided of air quality testing with particle counts and settle plates. Results from June 2009, October 2009, May 2010, and June 2010 for the operating theatre showed the required minimum grade D environment. Testing results in the laboratory (environment) for May 2010 and June 2010 demonstrated grade D. The laboratory air flow hood and ICSI hood demonstrated consistent grade A air quality.

The PR provided documented evidence of the maintenance and regular inspection of equipment. Servicing records showed that the units centrifuge had recently been serviced and that the air flow hoods are due for service.

Diagnostic sperm analysis
Staff received training and provided evidence of assessments demonstrating their competence to carry out sperm analysis. The consultant embryologist provided verbal evidence during discussion of their participation in external quality assessment through the UK National External Quality Assessment Scheme (UKNEQAS)

What they could do better.

Validation of critical equipment and processes
Although the process of validation has begun not all critical equipment (technical devices) and procurement, processing and storage procedures have been validated (Licence Condition T72).

Equipment and materials and premises and facilities - continued

What they could do better.

CPA Accreditation
The consultant embryologist explained that the unit performs diagnostic semen analysis for patients referred by local GPs as well as semen analysis for their own fertility patients; however the laboratory is not CPA accredited. (Licence Condition T21)

Traceability

What the centre does well

Traceability: Guidance Note 19
The consultant embryologist provided evidence that gametes and embryos are traceable from procurement of gametes to patient treatment or disposal. (Licence Condition T99)

The consultant embryologist demonstrated that it is possible to track all of the equipment and materials used in the course of procurement and processing of gametes intended for treatment via a laboratory spreadsheet/log. This includes which incubator has been used during processing, which storage tank has been used and the batch numbers of any consumables and materials used.(Licence Conditions T22 and T87)

The unit has a documented standard operating procedure to ensure traceability and during discussion provided evidence of receipt of training in traceability procedures. (Licence Condition T75) An audit of traceability at the time of inspection for IUI treatments demonstrated no discrepancies.

What they could do better.

The PR has not established a procedure to ensure that data necessary for traceability is stored for a minimum of thirty years.
The PR should ensure that there is a procedure established to ensure data necessary for traceability is stored for a minimum of thirty years: and for such longer period as may be specified in Directions. (Licence Condition T103)

The unit has not established quality indicators or objectives relevant to traceability.
The PR should establish quality indicators or objectives relevant to traceability.
(Licence Condition T35).

Storage of gametes and embryos

What the centre does well

Storage of gametes and embryos: Guidance Note 17
The consultant embryologist provided a detailed standard operating procedure for the storage of gametes and embryos. (Licence Condition T33(b)) The PR has established quality indicators relevant to storage e.g. post thaw survival rates. (Licence Condition T35).

Storage procedures have been audited against compliance with approved protocols and the consultant embryologist provided a copy of the audit document complete with discrepancies and implementation of corrective actions. (Licence Conditions T36) The discrepancies were seen to be small in number and largely administrative and were considered by the inspector to be suitably resolved.

Staff provided documented evidence of the assessment of competence in the storage of cryopreserved material (Licence Condition T15(a))

The consultant embryologist confirmed the assertion on the unit's Self Assessment Questionnaire that all material currently in storage is within the limit of the statutory period. An audit of four laboratory records of cryo preserved material demonstrated that all were stored in line with statutory storage period with no discrepancies (Licence Condition 79)

All storage screening tests are carried out by the, (UK) CPA Accredited, King's College Hospital NHS Foundation Trust pathology laboratory. (Licence Condition T21). Prior to storage all providers of gametes are screened in accordance with Licence Condition T50 as described in the unit's standard operating procedure. An audit of five sets of patient records demonstrated compliance with this requirement. If results of screening are not known prior to storage samples are stored in quarantine in a transport shipper until the results are confirmed. The unit does treat some patients who are viral positive for which they have separate tanks for gamete and embryo storage.

Auto dialler and alarms
At the time of inspection the alarm auto dialler which contacts on call staff if there is a storage tank failure was not working. On the 16 of June 2010 (six days post inspection) the consultant embryologist provided a technical service report to show that the alarm auto dialler had been fixed, tested and signed off by the technician as working.

What they could do better.

Quarantine storage tanks
The unit provides long term storage of samples for patients undergoing cancer treatment. Some of these samples are cryostored urgently prior to the start of treatment. Where results of the required screening are not known prior to storage samples are stored in quarantine in one of three dedicated storage tanks until the results are confirmed (1-2 days) These storage tanks are not fitted with alarms.

These storage tanks are monitored and used following manufacturer's instructions which include regular priming and weekly moving of samples to a freshly primed dry shipper.
A risk assessment has been carried out by the consultant embryologist.

2. Changes / improvements since the last inspection on 15th April 2008

Area of practice	Reference	Action required	Timescale for action	On inspection 10 June 2010
The HFEA Finance Department noted that the Unit takes an average 59 days to pay HFEA invoices, which is an additional 31days to the payment terms of 28 days.	*A.16.3 7th CoP*	The PR should review whether there are any barriers to the prompt payment of HFEA invoices and take steps to ensure the fees are paid within 28 days.	By June 30 2008	For the financial year 1 April 2009 to 31 March 2010 the unit took an average of 86 days to pay its invoices over the year, For the period 1 April 2010 to 11 June 2010 the unit is taking an average of 65 days The PR should ensure that all HFEA fees are paid within 28 days in compliance with the requirements of T9 (d).
It was noted during the inspection that the embryologists when assisting with embryo transfers are performing the ultrasound scanning. There was no evidence of training or competence assessment.	*S.6.2.2 (b) 7th CoP* Licence Condition T15 CoP 8th Ed	The embryologist must be able to demonstrate training competence assessments for ultrasound scanning.	By August 31 2008	The PR has established a training programme for embryologists and a signed training record demonstrated a certification of competency. The consultant embryologist said at the time of inspection that there will be a refresher course before the service at King's is resumed. No further action required
Area of practice	**Reference**	**Action required**	**Timescale for**	**On inspection 10 June 2010**

			action	
It was noted that there is no third party agreement in place with the courier who provides transport for cryo-preserved material.	*S.4.2.10 7th CoP* Licence Condition T111 CoP 8th Ed	A documented third party agreement is required with a person or entity which provid products to a licensed centre that has the potential to affe the quality and safety of gametes or embryos	By August 31 2008	A compliant third party agreement has been established and sent to the third party courier. This has yet to be returned to the unit. The PR has ensured that the third party agreement is completed and a copy sent to the inspectorate. No further action required
The figures reported for the annual records of clinical ICSI were found not to be accurate.	*S.5.2.7 7th CoP*	All annual ICSI data to be reviewed by the Senior Embryologist and correction reported to the HFEA.	By 31 of June 2008	All annual ICSI data is reviewed by the consultant embryologist but there is no longer a requirement to submit these data to the HFEA. No further action required.
Not all service user consent documentation from the transport centre was complete or had signatures	S.7.5.4 (c) 7th CoP Licence Condition T52 CoP 8th Ed	The PR should review the consent process with staff at the transport centre to ensure all service user cons valid and documentation is complete	By the 31 of August 2008	The PR and quality manager have reviewed the consent process with staff at the transport centre to ensure all service user consent is valid and documentation is complete. No further action required
Area of practice	**Reference**	**Action required**	**Timescale for**	**On inspection 10 June 2010**

			action	
It was observed during the inspection that three dewars were not fitted with alarms.	*S.6.4.2 (b) 7th CoP* Licence Condition T 24 CoP 8th Ed	Alarms should be fitted to all dewars.	A timescale for the installation of alarms to the HFEA by 15 June 2008.	All the main storage dewars are now fitted with an alarm. No further action required
Not all polices and procedures or laboratory Standard Operating Procedures (SOPs) are written and in place	A.10.24 7th CoP Licence Condition T33(a)	The centre should implement a system that results in clearly defined and effective documentation and authorised standard operating procedures (SOPs), for the activities for which a licence has been granted	31 May 2008	The SOPs described in the previous report have been completed and approved No further action required.
During review of service user health records it was noted that on two occasions the doctors 'witness' signature was missing from the embryo transfer section of the records. It was noted that a number of embryologist signatures were not in the appropriate boxes on witnessing documentation.	S.7.8.15 7th C Licence Condition T71	Centres shall have witnessing protocols in place 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. These checks shall be comp and recorded at the time the clinical or laboratory process procedure takes place.	Immediate	The PR has carried out an audit of records using the HFEA witnessing audit tool. (February and March 2010) No discrepancies were found. See page 3 of this report for further information on witnessing

3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
All areas of concern have inspected and reported in the main body of this report.		

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 require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
N/A					

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- 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	Reference	Action required	Timescale for action	PR Response	Executive Review
The PR has not established quality indicators or objectives relating to witnessing or traceability.	Licence Condition T35	The PR should ensure that quality indicators or objectives relating to witnessing and traceability are established.	By the time of the next inspection. The PR should provide quarterly reports to the inspector on their development and implementation.	A number of quality indicators regarding witnessing and traceability are already in place and have been audited. Audit results will be submitted to the inspector	Audit results have been submitted to the inspector. No further action required
At the time of inspection that the consultant embryologist has not undergone competency assessment of witnessing.	Licence Condition T15(a)	The PR should ensure that the consultant embryologist's competence to perform witnessing is assessed and documented.	31 September 2010	The senior embryologist to assess and document the consultant embryologists' competencies in witnessing. To be completed by end of August 2010.	Competency assessment completed and submitted to the inspector. No further action required

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Not all critical equipment (technical devices) and procurement, processing and storage procedures have been validated.	Licence Condition T72	The PR should ensure that all critical equipment (technical devices) and critical processing procedures have been validated as described during inspection. The PR should submit an action plan listing all critical procedures and equipment that require validation and the anticipated timescales for completion of validation.	By the time of the next inspection. Validation plan submitted to the inspector by 10 August 2010 The PR should submit quarterly reports to the inspector on the progress of validation until the action plan is complete.	Consultant embryologist and senior embryologist will develop a validation plan and submit to HFEA by the end Aug 2010	The submitted action plan for validation will be monitored via the compliance cycle.
Area of practice	**Reference**	**Action required**	**Timescale for**	**PR Response**	**Executive**

			action		**Review**
The consultant embryologist explained that the unit performs diagnostic semen analysis for patients referred by local GPs as well as semen analysis for their own patients; however the laboratory is not CPA accredited.	Licence Condition T21	By the time of the next inspection the PR should ensure that the laboratory that carries out diagnostic semen analysis obtains accreditation by CPA (UK) LTD or another body accrediting to the equivalent standard.	The PR should provide an action plan by 31 September 2010 to the HFEA outlining the anticipated timescale for obtaining accreditation and then quarterly reports on the progress in becoming accredited	We are currently working with the pathology department to develop a process and time scale for obtaining accreditation. Action plan to be submitted by the end of Sept 2010	The submitted action plan will be monitored via the compliance cycle
Area of practice	**Reference**	**Action required**	**Timescale for**	**PR Response**	**Executive**

			action		Review
The unit provides long term storage of samples for patients undergoing cancer treatment. Some of these samples are cryostored urgently prior to the start of treatment. Where results of the required screening are not known prior to storage samples are stored in quarantine in one of three dedicated storage tanks until the results are confirmed (1-2 days) These storage tanks are not fitted with an alarms. .	Licence Condition T24 and guidance 17.5	A risk assessment has been carried out by the consultant embryologist.	10 August 2010	This risk assessment has already been submitted	A Trust based risk assessment has been conducted and submitted to the lead inspector. The risk assessment demonstrates a low risk of harm. The PR has decided that based on the fact that the centre have been unable to source a alarm that fits the dedicated storage tank and the outcome of the risk assessment an alarm will not be fitted.

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 good practice.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
The inspection team noted that the unit's witnessing practice is non-contemporaneous at some stages of sperm preparation. Unit staff explained that they cross check information on all the sperm preparation tubes and the sperm pot at the beginning of the procedure but thereafter, witnessing checks are not performed each time the sperm sample is moved between tubes. The final tube is then witnessed against patient identity and patient records at the time of treatment.	Licence Condition T71 Guidance 18.4 (e) and 18.30	Guidance at 18.30 acknowledges that as part of a risk assessment for sperm preparation, centres may consider witnessing the cross-checking of information on tubes only at the start and end of the procedure, not at every stage however, in compliance with guidance provided at 18.25 it is recommended that the unit should assess whether there are any risks associated with the procedure used for the witnessing of sperm preparation. The unit should implement any steps considered necessary to mitigate any risks identified and submit the assessment and any report of the implementation of corrective actions to the inspector.	31 September 2010	This is not accurate. All sperm preparation tubes and the sperm pot are cross checked by two embryologists at the beginning and the end of the sperm preparation. In addition only one sample is kept in the hood at any one time until preparation is complete. Also a formal risk assessment can be undertaken if you feel that this is necessary	The PR has considered the process and is content with following the guidance18.30 This is compliant with guidance No further action required
Area of practice	**Reference**	**Action required**	**Timescale for action**	**PR Response**	**Executive Review**

The standard operating procedure for storage does not reference the steps to be taken in relation to the cooling off period if one partner withdraws consent to storage or procedures for dealing with disputes that may arise when one gamete provider withdraws their consent to the use or storage of gametes or embryos in treatment.	(HFE Act 1990 (as amended) Schedule 3) (Guidance 5.35)	The PR should review the relevant procedures to ensure that they reflect the current requirements and guidelines and ensure that all staff are aware of the revisions and their implications	31 September 2010	All relevant staff are aware of actions required when there is dispute or one partner withdraws consent to storage but the standard operating procedure is being updated and will be completed by end Aug 2010.	No further action required
An audit of five records showed that a small number of omissions in the time being recorded of a witnessing step. When a procedure takes place a record should be made of the date and time of the procedure.	Licence Condition T71 Guidance18.7 (b).	The PR should ensure that the time is recorded of each witnessing step	Immediately	Relevant quality indicators are being set up and an audit will be undertaken to ensure that all steps are witnessed appropriately.	No further action required
Area of practice	**Reference**	**Action required**	**Timescale for action**	**PR Response**	**Executive Review**
The unit has not	Licence	The PR should ensure that	31 September	The current	SOP has been

established a procedure to ensure data necessary for traceability is stored for a minimum of thirty years.	Condition T103	there is a procedure in place to ensure that data necessary for traceability is stored for a minimum of thirty years: and for such longer period as may be specified in Directions	2010	traceability SOP will be updated by end of Aug 2010	submitted. No further action required
For the financial year 01/04/09 to 31/03/10 the unit took an average of 86 days to pay its invoices over the year. For the period 01/04/10 it is 65 days	Licence Condition T9(d) Chairs Letter CH(10)02	The PR should ensure that all HFEA fees are paid within 28 days.	31 September 2010	The service manager to the ACU has communicated with Hospital Finance dept reiterating the need to pay invoices within 28 days.	Will be monitored via the compliance cycle.

Additional Information from the Person Responsible
No addition information was added by the Person Responsible.

HFEA Licence Committee Meeting

30 September 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 02

Centre 0109 (Assisted Conception Unit, Kings College Hospital) – Interim and Grade A Incident

Members of the Committee:	Committee Secretary:
David Archard (lay) – Chair Anna Carragher (lay) Sally Cheshire (lay) Jane Dibblin (lay) Sue Price (Professional)	Terence Dourado Legal Advisers: Graham Miles, Morgan Cole

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

The following papers were considered by the Committee:

- Interim inspection report
- Incident report
- Licence Committee minutes: 7 July 2008 Renewal inspection report
- Licence Committee minutes: 11 February 2010 variation to change licence holder (LH)
- Licence Committee minutes: 11 February 2010 variation to change person responsible (PR)

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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 Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Tabled documents:

- Executive Summary for Licence Committee, Tue 28th Sept
- Correspondence

Background

1. The Committee was presented with a Grade A incident report alongside an interim inspection report for Centre 0109. It noted that the interim inspection was targeted to support the incident investigation.

2. The Committee noted that the incident involved a drop in the Centre's Clinical Pregnancy Rate (CPR) during a period when building work had taken place beneath the Centre's premises. It noted that, to some degree, the close proximity of the building work affected the performance of the Centre's Intracytoplasmic Sperm Injection (ICSI) equipment during treatment, which consequently may have affected the Centre's CPR at that time.

Consideration

3. The Committee considered the interim report and was satisfied there was sufficient information to recommend the continuation of the Centre's licence without additional conditions. Furthermore, the Committee supported the Executive's recommendation that the Centre's Person Responsible (PR) complies with the following recommendations within the prescribed timeframes:

    - The PR should ensure that all critical equipment (technical devices) and critical procurement, processing and storage procedures are validated. The PR has submitted an action plan listing all critical procedures and equipment that require validation and the anticipated timescales for completion of validation. The PR should also submit quarterly reports to the inspector on the progress of validation until the action plan is complete (Licence Condition T72);
    - The PR should ensure that the laboratory that carries out diagnostic semen analysis obtains accreditation by CPA (UK) Ltd or another body accredited to the equivalent standard. The PR has provided an action plan to the inspector outlining the anticipated timescales for obtaining accreditation and then quarterly reports on the progress in becoming accredited (Licence Condition T21);
    - The PR should ensure that all HFEA fees are paid within 28 days. Licence Condition T9(a) Chairs letter CH(10)02.

4. The Committee considered the incident investigation report and noted the Executive's recommendations. It endorsed the subsequent actions and monitoring/evaluation arrangements put in place by the PR:

    - The pregnancy rates will be monitored on a weekly basis;
    - Air quality will be monitored;
    - The Centre inspector will be informed of progress on a weekly basis.

Decision

5. In light of all the evidence received, the Committee decided to continue the Centre's licence with no additional conditions. Furthermore, it noted that the Centre's PR and staff worked diligently to ensure that the incident was recognised, investigated and managed efficiently and promptly.

Signed:  Date: 6.10.2010

David Archard (Chair)