Inspection Report

Date of Inspection: 20 January 2011
Purpose of inspection: Renewal of Treatment Licence
Length of inspection: 5.5 hours
Inspectors: Sara Parlett (HFEA; Lead Inspector)
Helen Kendrew (External; Clinical Inspector)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 10 February 2010 and 1 April 2011.

Date of Executive Licensing Panel: 1 April 2011.

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (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 licence renewal 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 Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Reproductive Medicine Clinic, Bristol
Centre number	0276
Licence number	E0276/2/d
Centre address	Level D, St Michael's Hospital Southwell Street Bristol, BS2 8EG
Person Responsible	Dr David Cahill
Licence Holder	Dr Jacqueline Cornish
Date licence issued	1 July 2008
Licence expiry date	30 June 2011
Additional conditions applied to this licence	None

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Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The centre is a small unit located within St. Michael's Hospital, which is part of University Hospitals Bristol, NHS Foundation Trust. The centre provides outpatient investigation and diagnosis of sub-fertility and Intrauterine insemination treatment to NHS funded couples from the South Bristol and Weston Super Mare area. The centre shares facilities with general and oncology gynaecology services.

The centre does not have facilities for the analysis or preparation of semen for use in treatment on site. This service is provided by the nearby Bristol Centre for Reproductive Medicine (centre 0295). The male partner attends centre 0295 for sample production. Following preparation for insemination, the sample is transported by the male partner to St. Michael's Hospital.

The Person Responsible (PR), Dr David Cahill, is a Reader in Reproductive Medicine at Bristol University and an honorary Consultant in Obstetrics and Gynaecology at St. Michael's Hospital. The PR has successfully completed the HFEA PR entry programme (7th CoP edition).

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period January – December 2009
Intra uterine insemination (IUI)	100

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

Clinical Pregnancy Rates

The centre reported an 18% clinical pregnancy rate for 2009 for IUI.

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- The PR is suitable and he has discharged his duty under section 17 of the HF&E Act 1990 (as amended).
- The premises are suitable.
- The practices are suitable.
- The centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of its licence.
- The centre has submitted an application fee to the HFEA in accordance with requirements.

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

Since the inspection visit on 20 January 2011 the PR has provided evidence that, in the view of the inspection team, provides sufficient information to conclude that the centre is now compliant with, or has given a commitment to implement, the following recommendations:

Major areas of non-compliance

- To establish quality indicators for consent and traceability procedures.
- To carry out audits against compliance with approved protocols, regulatory requirements and quality indicators for consent and traceability procedures.
- To review and revise the agreement with the third party responsible for processing gametes, to ensure compliance with Licence Condition T114.

Other areas of non-compliance

- To document the procedure followed to ensure all relevant data relating to anything coming into contact with gametes are traceable.
- To revise centre documents to ensure that information required for traceability is kept for 30 years.
- To document the procedure to follow upon receipt of an incomplete gamete consignment from the third party responsible for processing gametes.
- To ensure HFEA fees are paid within the required timeframe.

Recommendation to the Executive Licensing Panel

The inspection team considers that, overall, there is sufficient information available to recommend the renewal of this centre's licence for a period of four years without additional conditions.

Details of Inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned appropriately

▶ Witnessing and assuring patient and donor identification (Guidance Note 18)

What the centre does well.

The centre double checks the identification of gametes and the patients to whom they relate at all critical points, ensuring patients receive treatment using the correct gametes (Licence Condition T71).

Sperm samples are produced and processed at the Bristol Centre for Reproductive Medicine (centre 0295). The processed sample is then transported by the patient to the centre for IUI treatment. The centre demonstrates good communication with centre 0295 on all related matters.

The centre has documented Standard Operating Procedures (SOPs) describing a comprehensive witnessing procedure to be followed at all critical stages from the receipt of the prepared semen sample to insemination (Licence Condition T71). Patients are required to supply photographic evidence for identity verification at the time of obtaining consent, upon both delivery of the sperm sample and receipt of the prepared sample at centre 0295 and prior to insemination at the centre (CoP Guidance 5.11).

The senior nurse stated that, on average, two IUI procedures are performed each week. More than one IUI procedure may be performed on any one day, but only one sample is present in the treatment room at a time (CoP Guidance 18.24).

Five sets of patient notes audited at inspection were found to include records of all required witnessing steps, including the date and time of witnessing (Licence Condition T71 and CoP Guidance 18.7 (b)).

Evidence of competence assessments of staff performing witnessing steps was reviewed. Competence assessments were performed in December 2010 and included both theory and practical assessments (Licence Condition T15 (a)).

What the centre could do better.

Nothing noted at the time of inspection.

Patient selection criteria and laboratory tests (Guidance Note 11)

What the centre does well.

Justification for the use of gametes in treatment, based on the patient's medical history and therapeutic indications, was seen documented in patient notes reviewed at inspection (Licence Condition T49).

The PR stated that the laboratories undertaking diagnosis and investigation of patients are accredited by Clinical Pathology Accreditation (CPA) (UK) Ltd. Screening results observed in patient notes at inspection were from CPA accredited laboratories (Licence Condition T21).

What the centre could do better.

Nothing noted at the time of inspection.

Donor recruitment, assessment and screening (Guidance Note 11)
Donor assisted conception (Guidance Note 20)
Only applicable to centres licensed to carry out treatment using donor gametes and / or embryos

What the centre does well.

N/A. This centre does not provide treatment with donor gametes.

What the centre could do better.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)

What the centre does well.

The quality management system: Guidance Note 23

The centre has a comprehensive quality management system (Licence Condition T32), including a quality manual (Licence Condition T33 (a)) and a document control procedure (Licence Condition T34). Quality management system reviews are held frequently and the centre's non conformity and corrective action register was seen to be regularly reviewed and updated.

Monthly unit meetings are held and a sample of meeting minutes was reviewed at inspection. Topics covered included reviews of patient survey results and recent audit results.

The PR confirmed that any HFEA alerts are immediately cascaded to centre staff upon

receipt and are discussed further at the next unit meeting.

All critical procedures conducted at the centre are documented in SOPs, a sample of which was reviewed and found to be comprehensive (Licence Condition T33 (b)).

The centre maintains a patient treatment database and the senior nurse confirmed that pregnancy and abandoned treatment cycle rates are audited frequently. The PR stated that all cancelled treatment cycles are discussed at the centre's monthly meetings to determine if any corrective action is required. The senior nurse explained that there are no specified thresholds under which corrective action would be taken but that any reductions in e.g. pregnancy rates would be discussed with the PR.

A sample of recent audits, performed by an independent auditor, was reviewed, including audits of witnessing and welfare of the child assessment. Evidence of corrective action in response to audit results was seen. Audits of staff compliance with approved SOPs have been performed, including audits of nurses performing IUIs (Licence Condition T36).

The centre's last user satisfaction survey was performed in April 2010 and is due to be repeated in February 2011 (CoP Guidance 23.17). The HFEA has received twelve patient questionnaires since the previous inspection and highly positive comments regarding the centre's services were noted.

Traceability: Guidance Note 19

The majority of records relating to consumables, reagents and equipment that come into contact with gametes are held at centre 0295. The PR explained that discussions had been held with centre 0295 to decide if a copy of these records should be transferred to the centre for retention. It was agreed that this was unnecessary duplication, as centre 0295 is required by its HFEA licence to hold this data.

The only applicable consumable item used at the centre is the IUI catheter. These are bulk delivered from centre 0295 upon request. The senior nurse confirmed that the type of catheter used, expiry date and batch number is recorded in the patient notes, this was confirmed during the patient notes audit (Licence Condition T102).

Validation: Guidance Notes 15 and 26

All critical processing procedures are conducted at centre 0295. The centre regularly evaluates its clinical outcomes and corrective action is taken if required (discussed in quality management systems section above) (Licence Condition T72).

Third party agreements: Guidance Note 24

The centre has a written agreement in place with centre 0295 for the processing of sperm (Licence Condition T111 (a)).

All goods and services that influence the quality and safety of gametes are provided by centre 0295. The PR confirmed that all relevant third party agreements are also managed by centre 0295 (Licence Condition T111 (b)).

Premises and facilities: Guidance Note 25

The premises appeared clean and well organised at the time of inspection (Licence Condition T17).

Air quality requirements were not inspected against because no critical processing of gametes occurs at the centre.

Equipment and materials: Guidance Note 26

The centre does not have critical equipment that requires validation, servicing or monitoring (Licence Condition T24). The senior nurse stated that the centre's scanning machines are serviced and tested for electrical safety on a rolling programme managed by the Trust. The senior nurse confirmed that equipment is cleaned routinely prior to each procedure (Licence Condition T26).

Adverse incidents: Guidance Note 27

Evidence was provided that the centre investigates and learns from adverse incidents.

The centre has a comprehensive checklist for reporting incidents and an "IUI clinic trigger list" giving guidance on what constitutes a reportable incident or adverse event (Licence Condition T118).

The centre has reported adverse incidents to the HFEA since the last inspection. All reporting has been performed in a timely manner in compliance with Directions 0011.

The incidents were comprehensively investigated and corrective action identified. Evidence that corrective action had been implemented was observed at inspection.

What the centre could do better.

The quality management system: Guidance Note 23

Quality indicators have not been established for consent procedures or traceability (Licence Condition T35).

Audits against compliance with approved protocols, regulatory requirements and quality indicators have not been performed in the last two years for consent procedures or traceability (Licence Condition T36).

Traceability: Guidance Note 19

IUI catheter traceability data was observed to be recorded in the patient notes audited. However, the requirement for this is not documented in a SOP (Licence Condition T99).

The centre's "Sample checking prior to IUI" SOP states that patient notes are to be retained for 25 years. Licence Condition T48 requires that records needed for full traceability must be kept for a minimum of 30 years.

Third Party Agreements: Guidance Note 24

The centre's written agreement with centre 0295 for the processing of gametes was reviewed at inspection. The agreement, dated 2 February 2008, does not set out how often the agreement will be reviewed (non compliant with Licence Condition T114 (c)) and refers to the 7th edition of the Code of Practice.

Multiple Births

What the centre does well

The centre is licensed for IUI only and is therefore not required to meet the requirements of Directions 0003. However, the PR explained that the centre had been concerned with the number of multiple pregnancies in 2008 (the centre reported a multiple pregnancy rate of 25% of the total clinical pregnancy rate) and wanted to comply with the spirit of the requirements set by the HFEA. As a result the centre audited its results, identified trends and subsequently revised its clinical protocols to attempt to reduce its multiple pregnancy rate. The centre subsequently reported a multiple pregnancy rate of 11% in 2009. The inspectorate commends the PR's proactive approach.

What the centre could better

Nothing noted at the time of inspection.

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.

Staff: Guidance Note 2

The PR has carried out his duties under section 17 of the HF&E Act 1990 (as amended) and the centre has suitably qualified staff to carry out the services offered.

Centre staff explained that the PR, who is also the registered medical practitioner (Licence Condition T16) is not present at the centre every day, but communicates daily by phone to plan and review treatment schedules. The senior nurse further stated that there is a good working relationship with centre 0295 and if the PR was temporarily unavailable, they could contact the PR there for advice.

It appeared at the time of inspection that personnel are available in sufficient number for the present activity and workload and this was confirmed by the senior nurse (Licence Condition T12).

An organisation chart defining accountability and reporting relationships for the centre was seen (Licence Condition T11). The senior nurse confirmed that the staff recruitment process is handled by the Trust and includes uptake of references and criminal records bureau (CRB) checks for all members of staff (HFE Act 1990 (as amended), Section 17 (1) (a)).

The centre has SOPs describing a comprehensive staff induction process, including teaching of HFEA requirements. The senior nurse explained that part of the induction includes visiting centre 0295 and observing the sperm preparation procedure (Licence Condition T15 (c) and (d)).

The senior nurse confirmed that all staff have annual appraisals, following the NHS Knowledge and Skills Framework. Staff training records reviewed included details of continual professional development undertaken.

Competence assessments are performed and documented in staff competency log books. A selection of staff competence assessments was reviewed, including for witnessing, IUI, giving patient information and welfare of the child (WoC) assessment (Licence Condition T15 (a)).

Staff, where appropriate, were seen to be registered in accordance with the relevant professional and/or statutory bodies (Licence Condition T14). The centre does not perform scientific activities, but the Sister stated that the senior laboratory staff at centre 0295 are available for any advice and scientific input.

What the centre could do better.

Nothing noted at the time of inspection.

Welfare of the Child (Guidance Note 8)

What the centre does well.

Centre staff provided verbal and written evidence that before providing treatment services, account is taken of the welfare of any child (WoC) who may be born as a result of the treatment and of any other child who may be affected by the birth (Licence Condition T56). The centre has a comprehensive WoC assessment SOP (Licence Condition T33 (b)) and a patient information leaflet describing in detail the WoC assessment (CoP guidance 4.2 (b)).

The quality manager demonstrated the centre's commitment to evaluating and improving the WoC process by explaining that the procedure is to be reviewed by the Trust consultant nurse for vulnerable children to identify any further areas for improvement.

The centre has audited their WoC assessment process (Licence Condition T36). Audit reports were reviewed on inspection from September, November and December 2010 all of which demonstrated full compliance with the centre's SOP. The patient notes audited at inspection demonstrated that WoC assessments were being completed.

What the centre could do better.

Nothing noted at the time of inspection.

Embryo Testing – ***only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening)***

- Preimplantation genetic screening (Guidance Note 9)
- Embryo testing and sex selection (Guidance Note 10)

What the centre does well.

N/A for this centre.

What the centre could do better.

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of a costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12) – *if applicable*
- Surrogacy (Guidance Note 14) – *if applicable*

What the centre does well.

Treating people fairly: Guidance Note 29

From overall observations made, and from information provided by the centre, the inspectors consider that the premises are suitable for the licensed treatment provided and that patients are afforded an acceptable level of privacy and comfort. The inspectors also consider that due consideration is given to the dignity of patients and that treatment is offered without discrimination.

The centre is governed by the Trust policy for equality and diversity. Centre staff explained that an equality and diversity impact assessment has been performed on all centre documents and that staff attend Trust training on 'treating each other well' biennially.

Complaints: Guidance Note 28

The centre has a complaints policy that was reviewed at inspection and seen displayed in patient areas. The policy states that the formal complaints file is reviewed annually.

The complaints log is held by the head of midwifery and no complaints regarding the IUI service have been received in the last two years. Centre staff explained that sharing learning from general hospital incidents and complaints is not currently occurring, but that from next month, six monthly learning reports will be cascaded to Trust staff.

What the centre could do better.

Nothing noted at the time of inspection.

Information

- Information to be provided prior to consent (Guidance Note 4)
- Information about storage of embryos (including cooling off periods)
- Information about Intracytroplasmic sperm injection (Guidance Note 21)
- Information about preimplantation genetic testing (Guidance Notes 9 & 10) – *only applicable to centres licensed to carry out preimplantation genetic diagnosis and screening*
- Information about legal parenthood (Guidance Note 6)

What the centre does well.

Information to be provided prior to consent: Guidance Note 4

The centre submitted a suite of patient information prior to inspection, covering the majority of the requirements of the Code of Practice. The PR confirmed that information not provided in leaflets, is provided verbally (e.g. the expected waiting time for treatment). Completed checklists were observed in the patient notes audited on inspection, documenting that the patient has received the centre information pack and post insemination information given after IUI.

The centre provides NHS funded treatment only and is therefore not required to provided a costed treatment plan.

What the centre could do better.

Nothing noted at the time of inspection.

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)
- Consent to legal parenthood (Guidance Note 6)

What the centre does well.

Consent to treatment, storage, donation and disclosure of information: Guidance Note 5

Centre staff provided evidence that written consent is obtained from patients prior to treatment (Licence Condition T57).

The centre uses an in house consent form rather than the HFEA MGI form. The use of the MGI form is recommended, but the PR confirmed that the in house consent covered all consent requirements and the centre preferred to follow the same document style for all centre documents.

Photographic identification is checked prior to obtaining consent and the patient signatures on the consent form are witnessed by a member of staff (CoP Guidance 5.10).

Five sets of patient notes were reviewed during the inspection and found to contain effective consent. Completed checklists were observed in patient notes audited on inspection, to ensure signed consent was obtained prior to treatment.

What the centre could do better.

Nothing noted at the time of inspection.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)]

- Licensed activities only take place on licensed premises
- Only permitted embryos are used in the provision of treatment services
- Embryos are not selected for use in treatment for social reasons
- Embryos are not created by embryo splitting
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman
- Embryos are only stored if those embryos where created for a woman receiving treatment services or from whom a third party agreement applies
- Embryos which are or have been stored are not given to a person, other than in the course of providing treatment services, unless that person is a person to whom a licence applies
- No money or other benefit is given or received in respect of the supply of gametes or embryos unless authorised by the Authority

What the centre does well.

The activities authorised by the centre's licence are carried out at the premises specified in the licence, or at centre 0295 under a written agreement (Licence Condition T1). Copies of the certificate of licence were seen on display at the centre (Licence Condition T5).

What the centre could do better.

Nothing noted at the time of inspection.

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17) – *only applicable for centres licensed to store gametes and / or embryos*

What the centre does well.

N/A for this centre.

What the centre could do better.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15) – *only applicable for centres that has distributed or exported gametes and / or embryos*
- Export of gametes and embryos (Guidance Note 16) – *only applicable for centres that has exported gametes and / or embryos*
- Receipt of gametes and embryos (Guidance Note 15) – *only applicable for centres that has received gametes and / or embryos*
- Import of gametes and embryos (Guidance Note 16) – *only applicable for centres that has imported gametes and / or embryos*

What the centre does well.

The senior nurse described a comprehensive procedure for the transport of sperm samples prepared for insemination and accompanying documentation. The sample is transported by the male partner in a robust container sealed with a label recording the identity of both partners in treatment. The documentation received with the sample for insemination is compliant with all requirements of Licence Condition T110.

The centre stipulates a four hour time limit from sample production to insemination. An audit of time taken from sample production to insemination was performed in 2009 and reviewed at inspection.

What the centre could do better.

The senior nurse confirmed that if gametes for insemination were received with incomplete or incorrect documentation, the PR and centre 0295 would be contacted for advice before the samples would be accepted for use in treatment. However, this procedure has not been documented (Licence Condition T 33(b)).

Use of embryos for training staff (Guidance Note 22) – *only applicable for centres which use embryo to train staff*

What the centre does well.

N/A at this centre.

What the centre could do better.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping • Record keeping and document control (Guidance Note 31)
What the centre does well. All patient records sampled during the inspection were seen to be well organised and clearly documented the patient pathway through the centre from initial investigations to IUI treatment. The centre has a document control procedure which ensures that only current versions of documents are in use. Centre documents are reviewed biennially. The Code of Practice guidance recommends the maximum interval between reviews should be 12 months (CoP Guidance 31.6). However it was explained that SOPs are regularly updated as changes to practice are made. The inspectorate is satisfied that the centre has a suitable system in place to ensure documents are reviewed, revised and reapproved at a frequency that ensures they remain fit for purpose.
What the centre could do better. Nothing noted at the time of inspection.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)] • Obligations and reporting requirements of centres (Guidance Note 32)
What the centre does well. The PR provided all information as required by the application process prior to inspection (Directions 0008). All members of staff cooperated fully with the inspection team and further information requested at the time of inspection was provided in a timely manner.
What the centre could do better. The HFEA finance department reported that the centre was invoiced for the annual EUTD fee on 29 October 2010, but this had not been paid at the time of inspection (Licence Condition T9 (d)). The PR explained that this was a Trust finance department issue that had now been resolved. The HFEA finance department confirmed receipt of payment on 25 January 2011.

Disclosure of information • Confidentiality and privacy (Guidance Note 30) • Disclose of information, held on the HFEA Register, for use in research
What the centre does well. N/A. This centre provides basic partner treatment services only.
What the centre could do better.

5. Changes / improvements since the previous inspection on 10 February 2010.

Area for improvement	Action required	Action taken as evidenced during this inspection
Welfare of the child SOP and process (Licence Condition T33 (b)).	The WoC SOP should be audited against compliance with approved protocols and regulatory requirements to ensure compliance.	The centre's WoC SOP was reviewed at inspection and found to be comprehensive. **No further action required.**
Training and competence to conduct WoC assessments (Licence Condition T15 (a) and (d)).	PR should ensure that staff are trained in the WoC assessment process and can demonstrate appropriate understanding of the process and competence in assessment when required.	A training and competence assessment session for WoC assessment was conducted in July 2010. Records were reviewed at inspection. Audits of the WoC assessment process have been performed and were reviewed at inspection. **No further action required.**
Development of quality objectives and indicators for all key procedures and processes (Licence Condition T35).	Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established.	Quality indicators have not been established for consent procedures or traceability. **Further action is required.**
Audit of key procedures and processes (Licence Condition T36).	The centre should agree a schedule of audit of activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence. The audit should be against compliance with the approved protocols, the regulatory requirements and quality indicators. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented.	Audits against compliance with approved protocols, regulatory requirements and quality indicators have not been performed in the last two years for consent procedures or traceability. **Further action is required.**
The documentation retained in the health care records	It is suggested that the centre should consider an additional	The centre's "Record of progress through IUI including

does not record the signature of the second person witnessing the process on all occasions (Guidance Note 18).	section be added to the witnessing form to ensure the second signature is captured.	identity confirmation" checklist was reviewed and includes space to capture the second signature at all witnessing points. **No further action required.**

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 to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None noted at the time of this inspection.			

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Quality indicators have not been established for consent procedures or traceability. Licence Condition T35.	The PR should ensure quality indicators are established for consent procedures and traceability. 20 April 2011	We noted the discussion that occurred at the inspection visit, and now have a clearer view of what is required of us. The visit and outline feedback was provided at our recent monthly team meeting. Draft documents on these quality indicators will be circulated to senior staff prior to the next team meeting in March, and then, following discussion and amendments, brought into use.	The centre has submitted two SOPs documenting the quality indicators established for consent procedures and traceability. The PR is asked to inform the Executive when these have been approved for use.
Audits against compliance with approved protocols, regulatory requirements and quality indicators have not been performed in the last two years for consent procedures or traceability.	The PR should ensure that audits against compliance with approved protocols, regulatory requirements and quality indicators are carried out for consent procedures and traceability.	Once these are in use, we will then introduce these into our rolling audit programme for 2011. Patient throughput may mean that insufficient numbers will be seen to make a valid assessment by July 20th 2011, but we will work	The Executive is satisfied with the PR's response. It is recommended that the Executive continues to monitor progress of the introduction of consent procedures and traceability into the centre's

Licence Condition T36.	20 July 2011	towards that date.	rolling audit programme by July 20 2011.
The centres third party agreement with centre 0295 for the processing of gametes does not set out how often the agreement will be reviewed and refers to the 7th edition of the Code of Practice. Licence Condition T114 (c)	The PR should review and revise the third party agreement. 20 April 2011	This has already been done, and discussed in draft form with the third parties and sent to them for signature.	The centre has submitted a revised written agreement with centre 0295, covering the requirements of Licence Condition T114. The PR is asked to inform the Executive when the agreement has been signed by both parties.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
IUI catheter traceability data was observed to be recorded in the patient notes audited. However, the requirement for this is not documented in a SOP. Licence Condition T99.	The PR should document the procedure followed to ensure that all relevant data relating to anything coming into contact with gametes are traceable. 20 April 2011	This has been included within the SOP for traceability, to be ratified at the next Team meeting in March.	The centre has submitted a revised "traceability of gametes from procurement to use" SOP, including the requirement to record consumables used in the patient notes. The PR is asked to inform the

			Executive when this SOP has been approved for use.
The centre's "Sample checking prior to IUI" SOP states that patient notes are to be retained for 25 years. Licence Condition T48.	The PR should revise centre documentation to ensure that information required for traceability is kept for 30 years. 20 April 2011	These are all been revised in March but this alteration has been noted and included in the process	The centre has submitted a revised "sample checking prior to IUI" SOP, documenting the requirement to retain patient notes for 30 years. No further action is required.
The procedure to follow if the consignment of gametes with required documentation from centre 0295 is not complete is not documented. Licence Condition T33 (b).	The PR should document the procedure to follow upon receipt of an incomplete consignment from centre 0295. 20 April 2011	This is now included in the SOP "Sample Checking prior to IUI"	The centre has submitted a revised "sample checking prior to IUI" SOP, including the procedure to follow if the consignment is incomplete. No further action is required.
The annual EUTD fee was not paid within the required timeframe. Licence Condition T9 (d) and terms of invoice.	The PR should ensure that annual fees are paid within 28 days. To be monitored	I deeply apologise for this long delay. I will endeavour to ensure that this runs more smoothly on the next occasion.	The Executive is satisfied with the PR's response. No further action is required.

Additional information from the Person Responsible
This is a fair and positive report. I am grateful for the positive and encouraging way in which the inspection team undertook their task at the time of the visit on January 20th, 2011. This was a positive and constructive exercise. I think it is a real pity we cannot have access to the comments of the patients that were collected, as they represent a completely independent view of our clinic, while I recognise they only reflect our own data collected over the past three years ourselves. David Cahill

HFEA Executive Licence Panel Meeting
1 April 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0276 (Reproductive Medicine Clinic) – Renewal Inspection Report (Treatment only)

Members of the Panel: Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Helen Richens, Policy Manager	Acting Committee Secretary for this meeting: Claudia Lally

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 is an IUI centre and that the licence renewal inspection took place in January. The Committee noted the Inspector's recommendation that the centre's licence be renewed for a period of four years.

2. The Panel noted the 18% clinical pregnancy rate for 2009 and also commended the clinic's approach to multiple pregnancy.

3. The Panel noted that the inspection identified three areas of major regulatory non-compliance.

4. The Panel noted the update provided by the Person Responsible (PR) and agreed that the PR had engaged positively with the inspection findings.

Decision

5. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and that the application contained the supporting information required by General Direction 0008.

6. The Panel was satisfied that the character of the PR is such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the Act.

7. The Panel was satisfied that the licence renewal application concerns treatment or non-medical fertility services which relate to gametes intended for human application.

8. The Panel was satisfied that the premises to be licensed were suitable for the conduct of licensed activities based on the evidence provided within the report.

9. The Panel noted that no application was being made to use embryos for training purposes or to store gametes or embryos.

10. The Panel had regard to 'Guidance on periods for which new or renewed licenses can be granted' The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states [The Executive Licensing Panel] will normally only grant a renewal licence for treatments/storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3. On the basis of the PR's responses to the inspection, the Panel agreed that it had no major concerns in relation to the issues set out in paragraph 4.3.

11. The Panel therefore agreed to renew the centre's licence for a period of four years with no additional conditions.

12. The Panel endorsed the recommendations in the inspection report for further action by the Person Responsible, and noted the PR's commitment to comply with these recommendations.

Signed: Date: 7 April 2021

Mark Bennett (Chair)