Interim Inspection Report

Date of Inspection: 21 January 2010
Length of inspection: 6 Hours
Inspectors: Gill Walsh and Bryan Woodward

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between November 2009 and January 2010.

Date of Licence Committee: 21 April 2010

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice and 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 Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	Fertility Unit Craigavon Area Hospital
Centre Number	0294
Licence Number	E0294-2-b
Centre Address	Infertility Unit Craigavon Area Hospital 68 Lurgan Road Portadown Craigavon Northern Ireland BT63 5QQ
Person Responsible	Mr Richard Noel Heasley
Licence Holder	N/A
Licence expiry date	31/08/12
Additional conditions applied to this licence	None

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Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

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

In considering overall compliance, the Inspectorate 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 has largely discharged his duties effectively under Section 17 of the HF&E Act 1990 (as amended)
- centre staff acting under the supervision of the PR are suitably qualified for their designated roles and are currently of sufficient number for safe clinical and laboratory practice
- the premises and equipment inspected are largely suitable for the treatment procedures for which the centre is licensed
- the centre demonstrates appropriate practices in respect of laboratory, clinical and administrative procedures to minimise risk and optimise outcomes for patients and offspring
- prospective and current patients appear to be treated fairly and all licensed activities conducted in a non-discriminatory way
- the centre respects the privacy, confidentiality, dignity and well being of prospective patients
- proper account is taken for the welfare of any child born as a result of licensed treatment or of any child who may be affected by that birth

The inspectorate also recommends that the Executive Licensing Panel requires that the Person Responsible complies with the following recommendations within the prescribed timeframes set out in the inspection report:

- the formulation and agreement of quality indicators reflecting the centre's activities should be incorporated into the overall audit schedule
- the organisational chart for the centre requires updating to reflect current staffing
- air quality measurement methodologies should be validated
- all critical equipment should be subject to regular maintenance and validation of critical parameters
- a number of the centre's standard operating procedures (SOPs) require updating to reflect current practice and should be audited against current regulatory requirements and guidelines
- all professional staff should have appropriate access to clinical professional development

Details of Inspection findings

Brief description of the centre and its licensing history:

This centre is set within the general gynaecology service of Craigavon Area Hospital, Co. Armagh, Northern Ireland and is part of the Southern Health and Social Care Trust. The centre shares resources with the general gynaecology and maternity outpatient department with two rooms being 'ring-fenced' specifically for the centre's use. Semen analysis and preparation for insemination is conducted in a laboratory within the hospital, but is located in another building. Male partners attend the laboratory for sample analysis and for the preparation of samples for use in treatment. Photographic identification is required. Approximately 90% of all male partners produce their samples at home. There is provision for the production of samples on site, but because of shared accommodation and space constraints the location is not ideal. The prepared sample plus accompanying documentation is transported to the centre with a member of centre staff and the male partner.

The centre provides services for the investigation and diagnosis of sub fertility and treatment for couples who may benefit from stimulated and un-stimulated cycles of partner sperm intrauterine insemination (IUI). The centre operates Monday to Friday from 7:30 to 13:00 hours for licensed treatments, with medical cover available via on call arrangements in place at all other times

The Person Responsible (PR) has held the post since the centre was first licensed. He is registered with the General Medical Council and is a Consultant Gynaecologist at the hospital and has a special interest in sub-fertility. The PR has successfully submitted his Person Responsible Entry Programme to the HFEA.

This centre has provided a service to the community for the past 17 years and has been licensed with the HFEA since June 2007, with the implementation of EUTD. The centre was last inspected by the HFEA in February 2009 for renewal of its licence which was granted by licence committee for a period of three years without condition. Licence Committee requested that the centre be visited in early in 2010 (interim) to assess progress with issues arising from the licence renewal report.

Outcome data for the centre indicates that the centre's success rate is consistent with national averages across all age ranges treated.

The centre submitted its outcome data for the period to February 2009 in a timely manner and data for the period to February 2010 has also been submitted.

There have been no significant changes to personnel, to the premises or the working of the centre since the last report.

The finance department of the HFEA report no issues with the payment of licence fees to date.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01/01/08 – 31/12/08
Partner Insemination	335 (approx)

*This data was extracted from the HFEA register for the period 01/01/08 - 31/12/08 - . 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.

Age	Pregnancies per treatment cycle	Predicted chance of an average patient having a pregnancy	How does this clinic compare to the national average?
Under 35	19 out of 182	Predicted chance between 5.3% and 19.5% most likely around 10.4%	Consistent national average pregnancy rate of 12.4%
35-37	5 out of 55	Predicted chance between: 5.3% and 34.3% most likely around: 14.5%	Consistent with national average pregnancy rate of 11.8%
38-39	5 out of 48	Predicted chance between: *2.8% and 63.1%* most likely around: 18.2%	Consistent with national average pregnancy rate of 11.8%
40-42	4 out of 50	Predicted chance between: *0.0% and 34.7%*	No national average data

*These data were extracted from the HFEA register for the period 28/02/2009 – 09/02/2010.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.

1. Focus of inspections for 2010-12

Witnessing
Evidence of how the centre demonstrates compliance with the requirement 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. **Guidance Note 18: Witnessing and assuring patient and donor identification**. Evidence was seen at the time of inspection that the identification of samples and the patients to whom they relate are witnessed contemporaneously by two members of staff at all critical points of the laboratory and clinical process (Licence Condition T71). It was seen on inspection that a record is kept in each patient's records of the name, status and signature of the person carrying out the procedure and that of the witness. (Licence Condition T71). The requirement for witnessing is detailed in the IUI standard operating procedure (Licence Condition T33b). Witnessing procedures have been audited against compliance with the unit's SOP. No non-conformities were noted. (Licence Condition T36). Relevant laboratory staff have training and assessment of their competence in andrology. Documented evidence of training and competence assessment to carry out witnessing for all relevant staff was seen. A list of staff signatures for those trained and competent to witness was available in the laboratory. (Licence Condition T15a). The Inspectorate considers that the PR and staff have achieved compliance for all requirements of Guidance Note 18 and associated Licence Conditions.
What the centre does well. Staff in the unit have been proactive in their approach to improving the witnessing processes. The scientific inspector was able to observe practice during the inspection and was satisfied that it was compliant with T71. Evidence of laboratory audit of witnessing procedures was seen as was a clinical audit of witnessing procedures which had been undertaken. The results of audits conducted in April 2009 showed no non-conformities.
What they could do better. As the andrology laboratory and clinical areas are set apart, there is some evidence of separate audits being conducted for different elements of the witnessing process from semen preparation to transfer to clinical area, and then in the clinical area to final insemination. The centre should consider conducting joint audit of witnessing processes to capture the entire pathway of samples used in treatment from receipt to insemination.

Parenthood

Evidence of how the centre demonstrates compliance with the requirements in relation to legal parenthood The unit does not provide donor insemination and this theme is therefore not relevant to this centre.
What the centre does well. N/A
What they could do better. N/A

Information about the cost of treatment
Evidence of how the centre demonstrates that it has introduced personalised costed treatment plans for all patients This centre does not provide treatment to self funding patients.
What the centre does well. N/A
What they could do better. N/A

Patient consent to the disclosure of information, held on the HFEA Register, for use in Research
Evidence of how the centre demonstrates that it provides information to patients about the use of information, held on the HFEA Register, for use in research. The HFEA does not hold information relating to specific IUI patients and this theme is not relevant to this centre.
What the centre does well. N/A
What they could do better. N/A

Consent issues in relation to the storage of embryos (including cooling off period)
Evidence of how the centre demonstrates compliance with the requirements relating to the withdrawal of consent to storage of embryos intended for use in treatment. The unit does not create or store embryos and this theme is therefore not relevant to the centre.
What the centre does well. N/A
What they could do better. N/A

2. Changes / improvements since the last inspection on 25 February 2009

Critical area of non compliance - None

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 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	Executive Review as verified on Inspection
Laboratory procedures and critical processing procedures and critical equipment have not yet been fully validated.	S.7.8.3 of the Code of Practice (COP) and standard licence conditions A.10.13 A.11.11. **T72 (8th Ed)**	A plan for validation should be drawn up. This should take into account the particular needs of the unit and validation of those processes considered to be the most likely to impact on the quality of service should be prioritised.	Progress to be monitored at the next inspection.	The validation process is partially complete and is ongoing.
Area of practice	**Reference**	**Action required**	**Timescale**	**Executive Review**

			for action	as verified on Inspection
A review of the quality management system has not yet been conducted.	Code of Practice Standard 4.2.8 and 4.2.9 T32/T36 (8th Ed)	The quality management system should be reviewed.	Progress to be monitored at the next inspection.	No further action required Confirmation that this has been conducted was seen on inspection.
The most recent air particle count conducted in march 2008 showed that the background air quality in the laboratory had fallen below the required Grade D.	A.10.19.	The centre should monitor air quality as a matter of urgency and document measures to be implemented to ensure that the critical parameters are maintained within acceptable limits at all times and relevant corrective actions in compliance with S.6.4.2.	June 09	Further action required The method of choice for assessing background air quality in the andrology laboratory has changed since the last HFEA inspection. The results now demonstrate a significant improvement in the quality of the background air to grade B/A.
Key equipment and processes, including those for air quality monitoring had not been validated.	A.10.13 and A.11.11	Procedures should be validated in accordance with professional guidelines and should be based on previously published studies, or retrospective evaluation of the centre's own data. Records of all validations should be kept.	Sept 09	Further action required Validation process has begun but does not yet cover all areas of activity, process continues.
Not all third party agreements were in place.	S. 4.2.10 a.5	One third party agreement required agreement.	June 09	No further action required. On inspection, all third party agreements seen to be in place and reviewed in a timely manner.

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 considered 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
Availability / uptake of clinical professional development. T15	Laboratory staff asked stated that access to and opportunities for appropriate fertility and andrology related clinical professional development and update training are poor.	Further action required. This was discussed with the PR on inspection who agreed to take this forward with those responsible for pathology staff training and professional development. To be monitored.
Air Quality in the laboratory.T20	The method of choice for assessing background air quality in the andrology laboratory has changed since the last HFEA inspection. The results now demonstrate a significant improvement in the quality of the background air to grade B/A.	The current method of air quality measurement is by microbiological testing whereas previous testing was by particulate testing. There has been no material change to the environment in which testing takes place, and indeed building works surrounding the area have increased, which may indicate that there is little change to the air quality. Whilst both testing methods are acceptable means of measuring air quality, as there is such a significant difference between the results form both testing measures it was discussed that perhaps the centre should repeat the particle count air quality assessment and validate the results.
Area of concern	**Inspection findings**	**Assessment of whether the action**

		taken meets requirement or whether any further action is required
Establishment of quality objectives and quality indicators. T35	The centre has formulated and agreed quality indicators for a significant number of clinical and administrative processes, there are however areas that still require quality objectives and indicators to be agreed and implemented.	Some further action required. The centre should continue the process of establishing objectives and quality indicators for all key aspects of their licensed and unlicensed activity using evaluation techniques including audit, user satisfaction surveys and management review, to find opportunities for improvement through corrective or preventive action. To be monitored in the course of the next inspection.

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
None identified					

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
Audit processes Procurement and processing procedures have not been audited.	Schedule 3A (10) 2006/86/EC T36 Audit of procurement and processing procedures against compliance with regulatory requirements and quality indicators in the last two years	Audit of procurement processes against the centre's own quality indicators and regulatory requirements to be conducted. The SOP for the preparation of semen for therapeutic use should be audited against compliance and best practice and validated accordingly.	July 2010	An audit of procurement and processing procedures for the preparation of semen for therapeutic use has been conducted.	
Air Quality monitoring validation	G15.16/18 G25.9 T 20 It must be documented that the chosen	The centre should have appropriate procedures to ensure premises comply with relevant requirements for safety and air quality, and these procedures	June 2010	Retesting has been arranged and the results will be validated accordingly.	

	environment achieves the quality and safety required. (GMP_ Annex 1 and Directive 2003/94/EC)	should be validated.			
Formulation and review of standard operating procedures.	T33 Requires that documented SOPs be in place 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.	Overall the quality of the centre's document control and SOPs were considered to be very good. However, a small number of SOPs required formulation to reflect practice or review and to reflect current best practice, namely: Validation of new or repaired equipment (T25) and to document the traceability process being conducted (T99) SOP for sperm procurement requires amendment to reflect all steps in the process undertaken for transporting prepared samples from the laboratory to the clinical area.	June 2010	A review of the SOPs noted has been conducted.	

Access to appropriate clinical professional development	T15 Adequate opportunity for relevant professional development must be provided	The PR should review any barriers to staff being able to participate in appropriate clinical professional development and make adjustments to facilitate this accordingly.	July 2010	The PR has written to the Head of Laboratory Services to highlight the need for staff participating in assisted reproductive therapies to have proper access to appropriate professional meetings and professional development. It is hoped that the temporary suspension of study leave funding imposed by the Trust will be reinstated in the new financial year.	
The LED display on one incubator in use was found to be faulty and did not accurately reflect the actual working temperature of the incubator. However the centre is testing and recording	T26 Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment and premises must	The centre should ensure that all critical equipment in use or available for use is regularly maintained as per licence condition T26 or if no longer required should be decommissioned.	June 2010	Appropriate repair and maintenance / servicing of this equipment has been arranged.	

the actual working temperature of the incubator which indicates that it is working within acceptable temperature parameters. This incubator and one centrifuge (not currently in use) are not part of the scheduled maintenance programme. Reports were seen for the maintenance schedules and maintenance having been conducted for all other equipment observed.	be performed regularly and recorded accordingly.				

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
Organisational	T11 The centre must have	Requires minor updating	April 2010	This has been	

chart	an organisational chart which clearly defines accountability and reporting relationships.	to reflect current staffing and reporting lines.		updated	
Quality Management - joint working re lab and clinical	G23.2 The centre should ensure that its quality management processes, including the interaction between them, are effective and continually improved.	The responsibility for quality management is currently divided between laboratory and clinical personnel. Both areas are demonstrating significant commitment to the quality management process but it appeared that the two areas were not working in partnership. The centre may wish to consider how the two areas may be more closely aligned in the management of the quality system.	To be monitored.		

Additional Information from the Person Responsible

I wish to confirm that the report is an accurate reflection of the inspection visit and of our centre's activity.

HFEA Executive Licensing Panel Meeting

21 April 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – item 5

Craigavon Area Hospital (0294), Interim Report

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Juliet Tizzard, Acting Director of Strategy & Information	Committee Administrator: Joanne McAlpine

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:

- papers for Licence Committee (25 pages)
- no tabled papers for this item

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel considered the papers which included an interim inspection report and previous licence committee minutes.

2. The Panel noted that the inspection took place on 21 January 2010 and lasted for six hours.

3. The Panel noted that the centre is set within the general gynaecology service of Craigavon Area Hospital, County Armagh, Northern Ireland and is part of the Southern Health and Social Care Trust.

4. The Panel noted that the centre shares resources with the general gynaecology and maternity outpatient department with two rooms being 'ring-fenced' specifically for the centre's use.

5. The Panel noted that the centre was last inspected in February 2009 for its licence renewal.

6. The Panel noted that the centre has carried out 335 partner insemination treatments January - December 2008.

7. The Panel noted that in the previous Licence Committee minutes the Committee was concerned with background air quality. The Panel noted on page 11 of the current inspection report that air quality had significantly improved and that further retesting has been arranged.

8. The Panel noted that the inspectorate recommends the continuation of the licence without any additional conditions and that the PR complies with the recommendations set out on page 4 of the report.

The Panel's Decision

9. The Panel agreed to the continuation of the centre's licence with no additional conditions, and endorsed the inspector's recommendations and accompanying timescales within the report.

Signed.....Peter Thompson.....Date.....5/5/10.....
Peter Thompson (Chair)