Interim Inspection Report

Hewitt Centre for Reproductive Medicine
0007

Date of Inspection: 1 February 2007
Date of Licence Committee: 3 September 2007

TRIM: 06/3141

CENTRE DETAILS

Centre Address	Liverpool Women's Hospital Crown Street Liverpool, L8 7SS
Telephone Number	0151 702 4301
Type of Inspection	Interim
Person Responsible	Charles Kingsland
Nominal Licensee	Body Corporate of the Liverpool Women's NHS Foundation Trust
Licence Number	L0007-13-b
Inspector(s)	Debra Bloor Janet Kirkland Parvez Qureshi Stephanie Sullivan
Licence expiry date	31 August 2008

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About the Inspection:

An interim inspection was carried out on 1 February 2007 and lasted for 7½ hours. A further follow up visit on 26 April lasted 3 hours. The report covers the pre-inspection analysis, the visit and information received in the time period between May 2005 and April 2007. Analysis of HFEA-held register data for the time period from 31 March 2002 to 1st April 2005 and non verified outcome data (which may be subject to change) for the period from 1 January 2005 to 31 December 2006 is included.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

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 Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The centre is part of the Liverpool Women's NHS Foundation Trust and provides NHS and self funded treatments to patients from the North West of England. The centre provided 1532 cycles of IVF and ICSI treatment in 2005 and 1820 cycles of IVF and ICSI treatment in 2006.

The PR has held the post since1998 and has appropriate experience and qualifications.

Activities of the centre

	2005	2006
Licensed treatment cycles	1532	1820
Donor Insemination	204	99
Unlicensed treatments	GIFT IUI Ovulation induction Surgical sperm retrieval	
Research	no	
Storage	✓	

Summary for Licence Committee

The centre increased its workload by approximately 19% in 2006 when compared to 2005. To accommodate the increase the unit undertook a comprehensive review of staffing, clinical practices, equipment and premises.

A small number of regulatory issues were noted in the course of the inspection but where possible, the centre implemented relevant changes immediately post inspection.

The HFEA received feedback from 58 patients who received treatment at the centre in the time since the last inspection. Feedback was generally very positive with 41 respondents having compliments about the care that they had received while only four had any complaints. Feedback received on the day was also favourable. The centre has a relatively high counselling uptake and attained International Standardization Organization (ISO 9001) certification in September 2006.

Risk Assessment

Risk Assessment: 16% (low)

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	✓	

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		✓	
2. Quality of the service		✓	
3. Premises and Equipment		✓	
4. Information		✓	
5. Laboratory and clinical processes		✓	

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
A number of adverse clinical events reported internally to the Trust related to the inadvertent disclosure of information about patient treatment as a result of administrative errors. This is a breach of section 33 of the 1990 Human Fertilisation and Embryology Act (HF&E Act).	No retrospective action was required in relation to the breaches of confidentiality. It was recommended that the PR review adverse incident reporting procedures.	Evidence was provided in the course of the inspection that action had already been taken to minimise the risk of reoccurrence of the incidents. Action in relation to reporting of adverse incidents was taken immediately post inspection.
The identity check at egg collection was carried out by a lone member of the embryology team. This is a breach of directions D 2004/4.	It was recommended that the PR review witnessing procedures.	Changes to witnessing procedures were implemented immediately post inspection.
The centre did not have written agreements with transport units at the time of the interim inspection. This is a breach of directions D2000/3	Agreements with transport units should be established.	Copies of the required agreements have been provided to the HFEA.

Non-Compliance

Area for improvement	Action required	Time scale
During inspection of the incidents file, it was noted	It was agreed that the team would seek guidance on the	Changes were implemented immediately post inspection

that a number of incidents which had been reported and investigated internally had not been reported to the HFEA.	reporting of incidents to the HFEA. The PR should also review the incident reporting protocol and ensure that staff are made aware of the requirement to report incidents to the HFEA.	
Since May 2005, 12 three embryo transfers were carried out in patients aged between 28 and 39 years old. This is a breach of guidelines as outlined in part 8.20 of the 6th COP	It was recommended that the PR provide information on the circumstances and outcomes of the three embryo transfers that were undertaken.	A review of the circumstances and outcomes of some of the three embryo transfers was provided to the HFEA post inspection. The review is appended at appendix C of this report.

Recommendations	**Time scale**
The PR should assess all aspects of practice that give rise to risk.	Not specified. The centre confirmed that the Trust is in the process of establishing a risk register.
Not all staff were able to demonstrate participation in mandatory health and safety training. The PR should ensure that all staff receive the training annually as required and that the training is documented.	To be monitored in the course of a future inspection.
The PR should review patient information packs as a matter of some urgency to ensure that patients are provided with appropriate information as outlined in guidance provided in the 7th Code of Practice.	Within one month and to be monitored in the course of future inspections.

Proposed licence variations

None

Changes/ improvements/actions since last inspection

Recommendation	**Action taken**
At the time of the last report the centre was considered to be operating at full capacity. The centre was asked to submit an action plan to the HFEA providing details of how the expected increase in workload was to be managed.	The centre carried out a comprehensive review of workload and evidence of this was provided to the HFEA subsequent to the 2007 inspection.

At the time of the 2005 renewal inspection the centre's documentation required updating in a number of areas. It was recommended in the renewal report that a complete set of revised documents should be submitted to the HFEA on completion of the review.	Patient information packs were provided in April 2007 but some revisions are still required.
The centre should review the security of its records stores and the cryostore.	The records store off the main waiting area has been fitted with a key pad operated lock. Issues relating to the security of the cryostore were discussed in detail in the course of the inspection.
The centre should consider how counselling by an appropriately qualified member of the team could be made available to oncology patients.	The provision of counselling to oncology patients was discussed in the course of the inspection and is considered suitable.
The centre should consider developing suitable procedures and information for children or young people seeking the storage of gametes prior to treatment that may impair their fertility.	No additional information has been developed to date although it was reported that efforts would be made to communicate with other centres providing this service in an effort to share best practice.
The centre should consider including the trust complaints officer on the HFEA licence	The complaints officer was included on the centre's licence.
All staff should maintain written records of training activities and new staff should have an opportunity to take part in an induction programme.	Staff interviewed in the course of the inspection were able to demonstrate participation in induction training.

Additional licence conditions and actions taken by centre since last inspection

The current licence was issued without any additional conditions.

Report of Inspection findings

1. Organisation

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Clinical governance
- Contingency arrangements
- Business planning
- Payment of treatment fees

Areas of firm compliance
The centre has comprehensive documentation that shows evidence of revision and version control. It was reported by the PR and other senior members of the team that considerable efforts have been made since the last inspection to manage resources effectively. The centre has employed a business manager who has reviewed procedures and practices extensively in order to achieve the efficiency savings that have allowed the increase in workload to be accommodated. The centre adopts the clinical governance strategies of the Liverpool Women's NHS Foundation Trust. In October 2004 the Trust was assessed as achieving level three in the clinical negligence scheme for trusts[1]. The centre has systems in place for clinical governance and quality management with a designated risk management team and written protocols for the reporting and management of adverse clinical events. Clear lines of reporting have also been established. The log of adverse clinical events was reviewed in the course of the inspection and the risk manager was able to talk through areas where analysis of adverse events had led to changes of practice. Evidence of regular discussion and learning from incidents was observed. It was reported that some key performance targets have been established and that these will continue to be developed. Performance against these targets is monitored on a monthly basis. Information from HFEA Alerts is discussed in the course of team meetings and evidence of this was seen in a meeting agenda.

[1] NHS Litigation Authority website

The centre has a written contingency plan and an informal agreement with another unit for the treatment of patients in an emergency. However, the unit has a large number of staff and unexpected absences can usually be covered by the existing team.

Following the interim inspection, the centre developed written agreements with transport centres. The agenda of a meeting in January 2006 attended by representatives from transport centres was provided to the inspection team and showed evidence of discussion of key issues. Minutes of meetings held in the course of visits to transport centres showed that: Leighton Park was last visited by representatives of the primary centre in September 2004 and Chester fertility Unit in November 2003. The centre no longer provides satellite or transport services to Arrow Park and Whiston.

The centre attained International Standardization Organization (ISO 9001) certification in September 2006

The average time to pay HFEA invoices over the last 6 months has been less than 60 days.

Areas for improvement

While the centre was able to demonstrate that action had been taken in relation to recommendations made in the 2005 renewal report, no action plan or revised documentation was submitted prior to the interim inspection. The PR should ensure that there is a robust system in place for the implementation and reporting of activities carried out in response to regulatory advice.

At the time of the interim inspection the centre did not have written agreements with transport centres. This is a breach of directions D 2000/3[2]. Agreements were developed post inspection and copies were submitted to the HFEA.

In the course of the review of the incidents log it was observed that a number of incidents that were reported and investigated internally should also have been reported to the HFEA. It was agreed that retrospective reporting of the incidents would not be requested but that in future, the unit would seek guidance from the HFEA when deciding whether to report an incident. Failure to report incidents within prescribed timeframes is a breach of part 2.23 of the 6th Code of Practice (COP).[3] Changes to the incident reporting procedures were implemented immediately post inspection.

Executive recommendations for Licence Committee

As noted above

Areas not covered on this inspection

Business planning

[2] Centres offering transport or satellite IVF to other centres should have a written agreement between that centre and each of the satellite centres.

[3] Centres must report all adverse incidents occurring at the treatment centre to the HFEA by telephone within 12 working hours of the identification of the incident and submit an Incident Report Form within 24 working hours.

Evaluation
Some improvement required

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

- Live birth rates
- Confidentiality (including safe storage of patients' records)
- Privacy and dignity of patients
- Patient feedback and satisfaction
- Complaint handling
- Counselling facilities and services
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates

The centre provided 1533 cycles of IVF and ICSI treatment for 1202 patients in 2005 and 1820 cycles for 1387 patients in 2006. This represents an increase in workload of approximately 19% in 2006 when compared to 2005. The centre reported a 25% twin birth rate in 2005 and a 15% twin birth rate in 2006. No higher order pregnancies were reported. Live birth rates for 2004 and clinical pregnancy rates for 2005 and 2006 are summarised below.

	IVF	FET after IVF	ICSI	FET after ICSI	DI
Clinical pregnancy rate per treatment cycle 2006	26%	14%	24%	12%	16%
Clinical pregnancy rate per treatment cycle 2005	20%	18%	23%	21%	12%
Live birth rate per treatment cycle 2004	112 (19%)	8 (7%)	131 (24%)	20 (17%)	15 (9%)

Analysis of outcomes from the time period from 31 March 2002 to 1 April 2005 and comparison to national averages shows that the centre's outcomes for IVF, ICSI and DI treatments are in line with national averages with the following exceptions:

- For patients aged below 35 years and 35-37 years, outcomes following IVF or ICSI treatment were significantly lower than national average;
- For patients aged 37-39 outcomes following frozen embryo transfer were significantly lower than national average.

In consideration of these data the PR commented that an estimated 14% of patients under 35 years old achieve a pregnancy while waiting for NHS funded treatment. This cohort of patients might be considered to be only marginally infertile and in units where similar patients receive immediate treatment, it could be expected that outcomes would be higher than those in units, like the Hewitt Centre, where there is a delay in the provision of treatment.

Areas of firm compliance
Patient records are stored in a secure room off the main waiting area and in filing cabinets behind the nurse's station. Records of counselling are kept securely and separately from clinical records. Two couples receiving treatment at the centre on the day of the inspection met with a member of the inspection team and reported that they felt that their privacy and dignity had been respected. They were very positive about the centre, describing the staff as a friendly caring team and referring to them as "smashing and handpicked" The HFEA received feedback from 58 patients who received treatment at the centre in the time since the last inspection in May 2005. This represents approximately 3% of the patients treated in that time period (total number estimated to be approximately 2158). Of the 58 respondents, 41 had compliments and only four had any complaints about the care that they had received. The only significant number of negative comments related to the accessibility of counselling services: 20 respondents (34%) reported that they had found the counselling service inaccessible. Nationally, 31% of patients providing feedback to the HFEA make his comment. Counselling is provided by three counsellors who can provide a total of 52 hours of counselling per week. There has been no increase in the number of counselling hours provided per week since the last inspection. Counsellors' continued professional development (CPD) is partially funded by the centre and evidence of mandatory training and attendance at British Infertility Counselling Association (BICA) courses was seen during the inspection. All members of the counselling team are supervised and it was reported that a member of the team attends multi disciplinary meetings. An audit of counselling provision showed that between May 2005 and April 2006 a total of 324 patients were seen, for a total of 481 sessions. Over this time period the centre treated an estimated 1341 patients (including 103 patients receiving treatment with donated gametes or donating gametes). This represents a counseling uptake of approximately 24%. It was reported that patients can contact the counselling team directly. Counselling services are referenced in patient information and the centre has written counselling protocols. In the course of the inspection a counsellor reported that counselling services are provided by transport centres and this is also reflected in the written agreements with transport centres. It was reported that regular meetings are held between the counsellors at centre 0007 and those at the transport centres. Taking into account the provision of information, systems in place for contacting the counselling team and the level of uptake for the service, the inspection team was satisfied with the centres counselling services, including efforts to make the service accessible. Patients attending for cryopreservation of sperm are seen by a seminologist and are offered an appointment to see the consultant andrologist or/and a counsellor. The centre does occasionally treat young people who are referred to the centre for sperm storage before the commencement of treatment that could impair their fertility. The centre has a clinical protocol

for treating these patients. All patients under 16 years old are seen by the consultant andrologist who assesses Gillick competence. It was reported that a member of the counselling team has received child protection training.

The centre has a designated complaints officer and patients are also advised that complaints can be made directly to the Chief Executive of the Trust. The complaints log was reviewed in the course of the inspection and it was reported that all complaints are responded to in a time frame in line with Department of Health recommendations. The complaints log documented a number of complaints related to difficulties in contacting the centre and similar comments were made by some patients providing feedback to the HFEA. It was reported that the centre is currently attempting to address this issue.

Areas for improvement
A number of adverse clinical events reported internally to the Trust related to the inadvertent disclosure of information about patient treatment as a result of administrative errors. This is a breach of section 33 of the 1990 Human Fertilisation and Embryology Act (HF&E Act). The incidents were investigated fully and measures were taken to moderate the risk of reoccurrence. The centres reporting procedures were revised immediately post inspection.
Executive recommendations for Licence Committee
As noted above
Areas not covered on this inspection
'Welfare of the Child' arrangements Choice of treatments Egg sharing and surrogacy Donor selection

Evaluation
Some improvement required.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance

Areas of firm compliance
On the day of the inspection the premise and facilities appeared well maintained and suitable for purpose. The cryostore is fitted with a key pad operated lock and all dewars are locked individually. Sperm storage dewars are housed in the seminology laboratory which is accessible to licensed personnel only and all dewars are locked individually. All dewars are alarmed and the rooms in which they are kept are fitted with low oxygen level alarms. There is a written protocol outlining procedures for monitoring performance of laboratory equipment. Monitoring of key equipment is carried out using an automated system. There is resuscitation equipment in the unit. The equipment had been checked on the day of the inspection. The hospital has a designated team who would be called if a patient required resuscitation. It was also reported that some members of the clinical team have received intermediate life support training.
Areas for improvement
The door to the cryostore was left open when the room was unoccupied on two occasions on the day of the inspection despite the display of a prominent notice asking staff to lock the door when leaving the room. This was discussed with the scientific director who acknowledged the requirement for the cryostore to be secure and accessible to licensed personnel only. However, the senior embryologist considers that as dewars are locked individually and because of the close proximity of the cryostore to the nursing station, gametes and embryos are secure even if the door to the cryostore is open and/or unlocked during working hours. The scientific director has assessed the benefits and risks of the door remaining unlocked and a copy of the assessment has been submitted to the HFEA.
Executive recommendations for Licence Committee
As noted above
Areas not covered on this inspection
Servicing and maintenance

Evaluation
Some improvement required.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent

Areas of firm compliance
The centre has comprehensive documentation that shows evidence of version control and revision dates. A robust system for identifying the expiry of consent of storage for cryopreserved material was demonstrated in the course of the inspection. The centre has submitted fewer than 3% of chargeable treatment forms late in the time period from 2005. The last operational audit was carried out in January 2005. The audit report concluded that the unit has robust systems for reporting; reporting is accurate and timely; welfare of the child issues were considered; consents to treatment were in place.
Areas for improvement
At the time of the renewal inspection in May 2005 a number of revisions to patient information were recommended. As the centre's documentation was undergoing review in preparation for ISO certification at that time it was also recommended that a complete set of revised documentation be submitted to the HFEA on completion of the review. Information for patients undergoing donor insemination (DI) and IVF was provided in the course of the visit in April 2007. The information in both packs should be reviewed in consideration of the following: • The HFEA does not require all patients to be screened for HIV and hepatitis prior to treatment. This was highlighted in the report of the renewal inspection in May 2005; • The importance of informing the centre of the outcome of treatment; • The cost of treatment; • The statutory storage period for stored embryos and/or gametes and the risks of storage. The information for patients undergoing IVF requires review in consideration of the following: • The availability of counselling. The unit has a separate leaflet on counselling that was not included in the sealed pack; • Information on outcomes is presented in terms of clinical pregnancy rate per embryo transfer. This is in breach of guidelines[4] which require that outcomes are reported in terms of live birth rate per treatment cycle;

[4] Guidance at section G.5.3.1(e) of the 7th COP states that data provided in all relevant patient resources should include the centre's own most recent live birth rate per treatment cycle as verified by the HFEA, and the national live birth rate per treatment cycle.

- The risks of egg collection;
- The risks of multiple pregnancy;
- Possible side effects of treatment including ovarian hyper stimulation syndrome (OHSS).

The information for patients undergoing DI requires review in consideration of the following:

- The information pack contains no written information documenting the availability of identifying and non identifying information and states “the woman and the donor never meet and never find out each other’s identities”;
- Information on legal parentage;
- Information on the maximum number of families that can be created with a single donors sperm;
- Information about the patient’s and donor’s right to withdraw consent and the implications of this;
- Donor from relevant ethnic backgrounds may be screened for sickle cell anaemia, thallassaemia and Tay-Sachs;
- Information collected for the HFEA register.

The information pack provided referenced information on ovulation induction for the benefit of patients undergoing stimulated DI but did not contain the information leaflet. The pack did contain a checklist suggesting that some of the information listed may be provided verbally.

The PR should review the information packs as a matter of some urgency to ensure that patients are not provided with misleading information and that they are provided with appropriate information as outlined in guidance provided in the 7th Code of Practice. The provision of information should be documented in the patient records.

Executive recommendations for Licence Committee
As noted above.

Areas not covered on this inspection
Audit of records Consent Protocols Record keeping

Evaluation
Some improvement required.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- Staff competence, qualifications, training and CPD

Full time equivalent staff – staff numbers/ FTE's at May 2005 shown in parentheses

GMC registered doctors	3.25 (7.6 FTE)
NMC registered nurses	12.53 (13)
Nursing support staff (health care assistants, auxiliaries etc)	3.31 (3)
HPC registered embryologists	5.4 (9)
Embryologists working towards registration	4.75 (2)
Seminologists	3
Trainee seminologists	1
Medical laboratory assistants	1
Counsellors	1.6
Support staff (receptionists, record managers, quality and risk managers etc)	15.04 (11)

Summary of spot check of stored material
A spot check audit tracking two embryos and a sperm sample from records to dewar and from dewar to records was carried out. No discrepancies were observed.
Areas of firm compliance
A senior member of the embryology team provided evidence of completion of a 5 yearly cycle of Association of Clinical Embryology (ACE) accredited continued professional development. A recently appointed member of the embryology team was able to demonstrate that she was working towards registration with the Health Professions Council (HPC) by participation in the ACE training scheme. She was able to provide evidence of training in laboratory procedures and that her competency in laboratory procedures is monitored and assessed. A recently appointed member of the administration team was able to demonstrate participation in induction training. A member of the counselling team was able to provide evidence of mandatory training and attendance at BICA lead courses. The written training records of three members of the nursing team were reviewed. The records showed evidence of training in egg collection and embryo transfer and of assessment of competency. The records also showed evidence of participation in continued professional development. Witnessing was reviewed in one set of patient records and with the exception of the

witnessing carried out at the time of the identity check at egg collection, documentation of witnessing was in line with the requirements.

Egg collection is carried out under conscious sedation administered by a member of the clinical team. Sedation is managed by a member of the clinical or nursing team. The PR reported that the procedures for the administration and management of conscious sedation have been reviewed by an appropriate specialist from the Trust[5]. A consultant anaesthetist has been recruited to support the service from June 2007.

Areas for improvement

Since May 2005, 12 three embryo transfers were carried out in patients aged between 28 and 39 years old. This is a breach of guidelines as outlined in part 8.20 of the 6th COP.[6] The centre provided a report of the three embryo transfers that were undertaken and it was reported that no higher order pregnancies resulted from any of the treatments. The PR reported that the final decision on the number of embryos to transfer is made by him in his role as lead clinician. The notes of a patient who had received a three embryo transfer were reviewed and contained brief notes on the rationale for the transfer. Subsequent to the review of the draft report the centre submitted additional information relating to the three embryo transfers carried out in 8 patients: an anonymised version of this information is included in Appendix C.

At the time of the interim inspection it was observed that the identity check at egg collection was carried out by a lone member of the embryology team. This is a breach of directions D 2004/4[7]. This was discussed with the senior embryologist who agreed to immediately revise the procedure to ensure that a second person witnesses the identity of the patient. A witnessing sheet reviewed in the course of the spot check audit was not completed as required. A single sheet may not be representative but the senior embryologist should consider undertaking spot check monitoring of witnessing practices to ensure that procedures are being undertaken according to protocol.

Not all staff were able to demonstrate participation in mandatory health and safety training. The PR should ensure that all staff receive the training annually as required and that the training is documented.

Executive recommendations for Licence Committee

As noted above

Areas not covered on this inspection

Assessment of patients and donors
Safe handling systems

[5] The guidelines on safe sedation recommend that each hospital should nominate two consultants, one an anaesthetist and the other a user of sedation, to collaborate in the local implementation of guidelines.
[6] In circumstances where women are using their own fresh or frozen eggs or embryos, centres are expected to ensure that: (i) Women aged under 40 at the time of transfer receive no more than either two eggs or embryos in any one cycle, regardless of the procedure used.
[7] The schedule to directions D2004/4 states that at egg collection, the witness should ask the patient her name and date of birth in the presence of clinician, nurse and embryologist.

Recruitment and retention of staff

Evaluation
Some improvement required.

Report compiled by:

Name…Debra Boor…….

Designation……Inspector…….

Date……27 February 2007…….

Appendix A: Centre Staff interviewed

The Person Responsible and 15 other members of the unit's staff met with the inspection team.

Appendix B: Licence history for previous 3 years

First licensed 1992

Status	Licence	Type	Active From	Expires
Active	L007/13/b	Treatment with Storage	01/08/2006	31/10/2008
Expired	L0007/12/a	Treatment with Storage	01/09/2005	31/10/2005
Replaced by New Version	L0007/A/b	Treatment with Storage	03/09/2004	31/10/2005
Replaced by New Version	L0007/A/c	Treatment with Storage	09/06/2004	31/10/2005

L007/13/b

No conditions

L0007/12/a

Conditions

- The centre should submit to the Authority within 28 days an action plan demonstrating how the centre will contact all relevant patients to advise them of the Deceased Father's Act 2003. The date for completion of this contact should be no later than 31 March 2005. This plan should also include procedures for ensuring regular annual contact with patients with regard to their stored material (as required by the Code of Practice 9.1).
- The centre should ensure that when they permit a man to provide sperm produced at home, there is full compliance with section 8.14 of the Code of Practice.

Recommendations

- That the centre ensure that the keys for the dewar padlocks are not left on display if the cryostore door is left open.
- That the ventilation in the cryostore be improved to remove the perceived requirement that any work in the store be conducted with the door open.
- That the centre update and implement a witnessing protocol to better reflect compliance with current HFEA Directions, and submit this updated protocol to the Authority.
- That the centre produce a written protocol for how it traces what happens to individual embryos, eggs and sperm samples from the date of collection.
- That the centre's patient information be updated in the light of the sixth Code of Practice and the removal of donor anonymity.
- That the Person Responsible read the independent report conducted on behalf of the Department of Health by Professor Toft.

L0007/A/b

No conditions

Recommendations

- The centre should change its protocols in accordance with the altered practice of handing sperm samples to a member of staff, instead of leaving them on a trolley outside the sperm preparation room.
- The centre should ensure that the Consent to Disclosure form specifies a named GP as detailed in the HF&E (Disclosure of Information) Act 1992 33(6C) and Chief Executive's Letter CE(01)01.
- The centre should ensure that when a sperm sample is produced away from the centre, it must be documented that the centre is satisfied that the sperm has been produced by that man, not more than two hours previously, and that it has not subsequently been interfered with.

L0007/A/a

No conditions

Recommendations

- The centre's annual audit of stored gametes and embryos should consist of the following:
    - an inventory of all gametes and embryos located in the storage dewars;
    - an audit of all patient records to ensure that all gametes and embryos documented to be in storage are located in the storage dewars
    - a cross-check to ensure that all stored gametes and embryos are stored with the correct / valid consent.
- The experienced embryologists at the University Hospital, Aintree could provide additional embryology cover at Centre 0007.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……

Name of PR……

Date of Inspection……..

Date of Response……

Please state any actions you have taken or are planning to take following the inspection with time scales

Summary of 9 three embryo transfers carried out in 2006

Age 35
Two previous IVF cycles with 2 fresh embryo transfers (of 2 embryos)
One abandoned cycle (OHSS)
Five FET cycles with 2 embryos each
Total 7 embryo transfers
Eight embryo transfer → 3 frozen-thawed embryos → <u>not pregnant</u>
<u>Summary:</u>

* IVF	(02)	-	ET x 2	-	not pregnant
	(02)	-	FET x 2	-	not pregnant
	(03)	-	FET x 2	-	not pregnant
	(03)	-	FET x 2	-	not pregnant
* IVF/ICSI	(04)	-	A/C	-	(OHSS)
	(04)	-	ET x 2	-	not pregnant
	(05)	-	FET x 2	-	not pregnant
	(06)	-	FET x 3	-	

Age: 32
One previous IVF cycle with fresh embryo transfer (of 2 embryos)
Following FET cycle → 3 frozen-thawed embryos → <u>not pregnant</u>
<u>Summary:</u>

* IVF	(05)	-	ET x 2	-	not pregnant
	(06)	-	FET x 3	-	not pregnant

Age: 37
One fresh IVF cycle with embryo transfer (2 fresh embryos)
Followed by FET cycle with 2 embryos
Third embryo transfer → 3 frozen-thawed embryos → not pregnant
Fourth embryo transfer following second IVF cycle → 2 fresh embryos → <u>not pregnant</u>
<u>Summary:</u>

* IVF	(05)	-	ET x 2	-	not pregnant
	(06)	-	FET x 2	-	not pregnant
	(06)	-	FET x 3	-	not pregnant
* IVF	(06)	-	ET x 2	-	not pregnant

Age: 39
Four IVF cycles with four fresh embryo transfers (2 embryos each time)
Additional FETs (notes not available from previous treatment elsewhere, patient can not recall the exact number)
Following FET cycle → 3 frozen-thawed embryos → <u>not pregnant</u>
<u>Summary:</u>

IVF x 3 by 05		-	not pregnant		
+ FETs					
* IVF	(05)	-	ET x 2	-	not pregnant
	(06)	-	FET x 3	-	not pregnant

Age: 39
Fourth IVF cycle
Previously, three fresh embryo transfers and three FETs
Sixth embryo transfer, 3 embryos → <u>singleton pregnancy</u>
<u>Summary:</u>

* IVF	(01)	-	ET x 1	-	not pregnant
* IVF/ICSI	(02)	-	ET x 2	-	not pregnant
	(03)	-	FET x 1	-	not pregnant
	(03)	-	FET x 2	-	not pregnant
	(04)	-	FET	-	not pregnant
* IVF/ICSI	(04)	-	ET x 2	-	not pregnant
* IVF/ICSI	(06)	-	ET x 3	-	Pregnant – Singleton

Age: 40
Two previous IVF cycles, one fresh embryo transfer (of 2 embryos)
Three previous FETs
Fifth embryo transfer, 3 frozen-thawed embryos → <u>singleton pregnancy</u>
<u>Summary:</u>

	(01)	-	Freeze all		
	(02)	-	FET x 2	-	not pregnant
* IVF	(02)	-	ET x 2	-	not pregnant
	(05)	-	FET x 2	-	not pregnant
	(05)	-	FET x 1	-	early pregnancy (ges sac seen) - missed miscarriage
	(06)	-	FET x 3	-	Pregnant – Singleton

Age: 39
Fourth treatment cycle
Three previous fresh embryo transfers and 3 FETs all with 2 embryos
Seventh embryo transfer → 3 embryos → <u>not pregnant</u>
<u>Summary:</u>

(2 x ICSI) by 2001					
5 ET					
* ICSI	(01)	-	ET x 2	-	implan
* ICSI	(06)	-	3 embryos (agreed by Cons)	-	not pregnant

***Age* 35**
Fifth IVF cycle
Previous 6 DI cycles
Seventh embryo transfer → 3 embryos → <u>not pregnant</u>
<u>Summary:</u>
(3 x IVF) by 05
* DI X 6

* IVF/ICSI	(05)	-	ET X 2	-	not pregnant
	(06)	-	Stim FET		
			ET x 3	-	negative pregnancy test
* IVF/ICSI	(06)	-	ET x 3	-	not pregnant
			(agreed by Cons)		

I have read the inspection report and agree to meet the requirements of the report.

Signed……

Name……..

Date……

Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF