Interim Inspection Report

Lanarkshire Acute Hospital NHS Trust
0098

Date of Inspection: 19th and 20th August 2008
Date of Licence Committee: 13 November 2008

Centre Details

Person Responsible	Mr Ian Smith
Nominal Licensee	Dr Alison Graham
Centre name	Lanarkshire Acute Hospital NHS Trust Infertility Department
Centre number	0098
Centre address	Infertility Department Monkscourt Avenue Airdrie Lanarkshire ML6 0JS Tel: 01236 712087
Type of inspection	Interim
Inspector(s)	Allison Cummings (Lead) David Gibbons (External Scientific Advisor) Bhavna Mehta
Fee paid	N/A (interim inspection)
Licence expiry date	30/06/2012
NHS/ Private/ Both	NHS

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About the Inspection:

This inspection visit was carried out on 19th and 20th August 2008 and lasted for 8 hours.

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 licence 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 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.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

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 Lanarkshire NHS Trust Infertility Department is a small centre that provides NHS funded donor insemination treatments to patients from the local area. The centre also became licensed for insemination with partner sperm in July 2007. The centre is based in the Monklands Hospital in Airdrie.

The centre is open 5 days per week, Monday to Friday with treatment services provided between 8:00 am and 4:00 pm.

The last inspection took place on 20 December 2006 to renew the centre's licence. There were no breaches or areas of non-compliance reported. However, a number of recommendations were made. The centre was granted an inspection holiday in 2007.

The person responsible (PR) is also the lead biomedical scientist with overall responsibility for scientific activities. The PR maintains current registration with the Health Professions Council.

Activities of the Centre[1] for the time period from 1 April 2007 to 31 March 2008

Donor insemination (DI)	10
Intra uterine insemination (IUI)	150[2]
Research	No
Storage gametes/embryos	Yes

Summary for Licence Committee

The unit has appropriate premises, suitably qualified and experienced staff and adopts largely appropriate clinical and laboratory procedures. Patients report satisfaction with the treatment that they receive. The centre has been proactive in the development and implementation of a quality management system.

Improvements should be considered relating to the following aspects of the centre's practice:

- Revision of the organisational chart;
- Payment of invoices;
- Control of documentation;
- Welfare of the Child (WOC) assessment prior to the provision of treatment;
- Provision of mandatory update training;
- Provision of treatment outcome information for patients;
- Revision of witnessing documentation;
- Revision of transport protocols.

The inspection team would recommend that progress in addressing the issue outlined should be made within the timescales specified. The executive recommends the continuation of the centre's licence.

[1]This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. 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.

[2] For the time period 5 July 2007 to 31 December 2007

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, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee:

Breach	Action required	Time scale
The organisational chart submitted on the day of inspection did not clearly represent the responsibilities and reporting relationships as required by standard licence condition A.10.1.	The PR should review the organisational chart to ensure that the chart clearly defines accountability and reporting relationships.	To be monitored in the course of the next inspection.
At the time of the inspection, a single third party agreement was outstanding. This was a breach of standard licence condition A.5.1	No action required - following the inspection the PR confirmed receipt of this agreement.	
For the time period to July 2008 the average time taken by the centre to pay HFEA invoices is 43 days. This is a breach of standard licence condition A.16.3.	The PR should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices within 28 days of the date of the invoice. The PR requested that the HFEA send the invoice direct to the PR rather than to the hospital finance department. This instruction has been acted on.	To be monitored in the course of the next inspection.
Not all of the documents reviewed in the course of the inspection were uniquely identifiable as required by S.5.2.6 and A.10.27.	The PR should ensure that all documents can be uniquely identified.	To be monitored in the course of the next inspection.

In one set of patient records reviewed in the course of the inspection there was no evidence of completion of a WOC assessment prior to the provision of treatment. This is non compliant with the requirements of COP standard S.7.1.2. and standard licence condition A.12.4.	The PR should review the circumstances of the non conformity observed in the course of the inspection in relation to the provision of treatment without consideration of the WOC and take appropriate steps to minimise the chance of recurrence.	Review to be completed by 20 December 2008.
At the time of the inspection, not all staff had participated in mandatory annual health and safety or life support update training in compliance with the requirements of standard licence condition A.10.11.	The PR should seek the advice of local health and safety representatives in relation to the requirements for participation in mandatory health and safety training and life support training and ensure that all staff participate as required.	Timeline for completion of required training to be submitted to the HFEA by 20 December 2008.

Non-Compliance

Area for improvement	Action required	Time scale
The inclusion of live birth rate data into patient information leaflets was not complete at the time of inspection, despite that this was recommended at the 2006 inspection.	The PR should assure the HFEA that patients are provided with information about outcomes of the proposed treatment as outlined in COP guidance G.5.3.1 (e).	14 October 2008
On review of the witnessing documentation in a sample of patient records, the witnessing of sperm collection and preparation steps were considered unclear.	The protocol and the laboratory worksheet should be revised so that these documents clearly account for what has been witnessed (COP guidance G.13.1.1 (b) and (c)).	

Recommendations

Area for improvement	Action required	Time scale
The centre's protocol for the transport of gametes is not fully compliant with the recommendations of Alert 21: Transport Hazards.	The PR should review the procedures for transport of gametes in consideration of the	To be monitored in the course of the next inspection.

	recommendations of Alert 21: Transport Hazards.	

Changes/ improvements since last inspection 20 December 2006

Recommendations	Action Taken
To maintain a log book of departmental meetings	It is reported in the pre inspection questionnaire (PIQ) that all staff meetings are now recorded.
To publish the annual successful live birth rates in the patient information leaflets	Live birth rates have not been published. See section 4: information for further detail.
Installation of outstanding cryostorage vessel low nitrogen alarms	All storage dewars are fitted with low nitrogen level alarms and are connected to an auto dial facility.
Purchase/installation of Class II laminar-flow cabinet for the processing of gametes	A flow hood has been purchased.
Revision of laboratory witnessing procedure	Witnessing procedures were reported to have been reviewed shortly after the last inspection.

Additional licence conditions and actions taken by centre since last inspection

The previous licence was issued without 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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
The leadership and management structures within the infertility department are well established. Those providing leadership in the clinical, scientific and nursing and counselling disciplines have been in post for many years. The centre's quality manual contains an organisational chart with clear lines of responsibility and communication. The PR is in overall control of licensed activity but delegates authority to experienced departmental clinical and nursing leads. Scientific matters are dealt with by the PR. The centre has procedures in place for transfer of managerial responsibility during the absence of the PR and systems in place for updating the PR on his return. The PR submitted a completed PR entry programme (PREP) in April 2007: the PR's responses were considered in line with HFEA's suggested responses. The centre has a process for investigating incidents and near misses. The PR reports that this policy promotes a non blame culture and learning to minimise future risk. A file to log all adverse incidents and a reporting policy were reviewed in the course of the inspection. The centre has not had any incidents in the time since the last inspection. All alerts are reviewed by the PR and any appropriate comments are circulated to staff. Computers have shortcut links to allow access to the alerts and PC screensavers remind staff of the latest alert. The centre has a complaints procedure which is publicised to patients via a leaflet in the waiting room. The complaints procedure is also displayed in the waiting area. The PR reports that there have been no complaints in the time since the last inspection.

Information is disseminated to staff through staff meetings and memos.

Patients are provided with an alert card which advises how to contact the department in an emergency.

Areas for improvement

The organisational chart submitted with the pre inspection questionnaire (PIQ) accurately reflected the structure and lines of responsibilities of the centre. However, on the day of inspection, a new organisational chart was provided. The new chart included personnel who were not directly involved in the provision of fertility treatment and the lines of responsibility were considered unclear: this is potentially non-compliant with standard licence condition A.10.1.

Consumables within the NHS Trust are provided by a central department to which all hospitals in the trust have access. However, at the time of the inspection, the centre did not have an agreement with the central supplier. Subsequent to the inspection, the PR reported that the outstanding agreement had been finalised.

For the time period to July 2008 the average time taken by the centre to pay HFEA invoices is 43 days. This is a breach of standard licence condition A.16.3. At inspection the PR requested that the HFEA send the invoice direct to the PR and not to the hospital finance department. This instruction has been acted on.

Areas for consideration

None

Executive recommendations for Licence Committee

The PR should review the organisational chart to ensure that the chart clearly defines accountability and reporting relationships.

The PR should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices within 28 days of the date of the invoice.

Evaluation

Some improvement required

Areas not covered on this inspection

Resource management
Risk management

2. Quality of service

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

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
The centre provided 150 cycles of stimulated IUI treatment in the time period from 5 July 2007 to 31 December 2007. The treatments resulted in 10 singleton clinical pregnancies. For the time period from April 2004 to March 2007 the centres outcomes following donor insemination were in line with national averages for patients in all age bands.
Areas of firm compliance
A copy of the centre's signed quality policy is displayed in the patient waiting area. The centre has a designated quality manager. The centre has a quality manual and is making progress with the implementation and evaluation of a QMS. The centre has established a procedure for document control. A sample of some documents provided in the course of the inspection included document control footers recording the identifier for the document, version number, page number and number of total pages and the name of the author. Information provided in the PIQ records that the review of the QMS has included the following: internal quality control and audits of practice; clinical pathology accreditation inspection of the laboratory; participation in the National External Quality Assurance Scheme (which assesses performance in semen diagnostics); development of a patient feedback questionnaire. The PIQ also documents that practice is evaluated and/or audited against quality indicators for the following: witnessing compliance; pregnancy rates; storage compliance; equipment servicing; consent compliance; patient satisfaction; air quality monitoring. Documentation of the outcome of a sample of internal audits was provided in the course of the inspection and showed that action had been taken in relation to non conformities identified. The centre has gathered feedback from patients in the last year and carried out an interim evaluation of responses. Negative feedback largely related to waiting times for appointments.

The HFEA received feedback from 15 patients who received treatment at the centre in the time since the last inspection. Eleven patients had compliments about the service they had received and no patients had any complaints. Patient responses recorded a high level of satisfaction with the service provided.

Staff are able to make suggestions and provide feedback at team meetings.

Areas for improvement

Of the 15 patients providing feedback to the HFEA on their experiences of treatment at the centre 3 out of 15 patients said that staff did not make them aware of a counselling service; 8 patients said that the clinic did not explain who is legally allowed to know information about their treatment. Individual negative comments were received in relation to the provision of information on side effects of prescribed drugs and delays when waiting for ultrasound scanning probes to be sterilised.

Not all of the documents reviewed in the course of the inspection were uniquely identifiable (the centre's counselling leaflet, semenology training plan, and in-house training documents) as required by S.5.2.6 and A.10.27.

Areas for consideration

In feedback provided to the HFEA 3 patients commented that they could not contact the counsellor directly however it is noted that the centre's counselling leaflet does give the name and direct contact details of the counsellor. Staff also reported that procedures have been developed to ensure that counselling is offered during consultation to all patients. Although uptake is low, the centre is funded for 12 sessions a month. The PR commented that patients presenting for IUI with partner sperm do not often take up the offer of counselling and that the centre has performed very few donor insemination cycles since the December 2006 inspection. Since the last inspection, the counsellor provided 14 sessions between March and April 2007 and 6 sessions since June 2008.

Executive recommendations for Licence Committee

The PR should review relevant procedures in consideration of the feedback provided to the HFEA by patients undergoing treatment.

The PR should ensure that all documents include a unique identifier and record the edition or current revision date, or revision number, the number of pages/total number of pages (where applicable), authority for issue, and author identification.

Evaluation

Some improvement required

Areas not covered on this inspection

None

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
Clinical facilities provide for the privacy and comfort of those seeking treatment; undergoing examination and treatment; and producing semen specimens. Counselling services are provided in quiet comfortable and confidential surroundings. The laboratory facilities were considered well maintained and suitable for purpose: all equipment is designated and maintained to suit its intended purpose. A flow hood, two microscopes with phase option and with heated stages have been purchased this year (2008) and are all still under manufacturer's warranty. Evidence that the flow hood had been tested and validated before use was provided in the course of the inspection. A sample of laboratory equipment (heating block and microscope) had been maintained in the last year. A clean air 'tent' was installed in May 2008 to facilitate compliance with air quality requirements. Service records were made available for inspection that showed that the air quality in the class II hood has been assessed as grade B and background air quality (in the 'tent') as grade C. A specialist company monitors the air quality annually. The centre has purchased a particle counter that monitors the air quality. Evaluation of the air quality using settle plates is also planned. The PR explained that this is a new system and that the results are emailed to an external company for verification. As this system is new, only one set of the particle count results were available for review in the course of the inspection. The centre has six storage dewars; all are fitted with low nitrogen level alarms. Emergency procedures are in place to deal with damage to storage vessels. All records are kept securely within the unit. Access to the whole area is restricted by key and keypad entry out of hours. Counselling records are kept within the unit and are secured by padlock and are accessible only by the counsellor.
Areas for improvement
None
Areas for consideration

None
Executive recommendations for Licence Committee
None
Evaluation
No improvement required.
Areas not covered on this inspection
Staff facilities

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
The centre has documented procedures for the assessment of the welfare of the child (WOC). The PIQ notes that if staff were to be suspicious of factors that may cause physical, psychological or medical harm to either an unborn child or an existing child these concerns would be raised by nursing staff with the consultant who would then investigate via an appropriate agency (social services, counsellor, patients GP). In one set of patient records reviewed in the course of the inspection evidence of completion of a WOC assessment was present and compatible with the provision of treatment. The PIQ documents that there are procedures in place for responding to a patient request for a copy of their medical notes: It is the hospital policy to refer all these requests through the information officer for NHS Lanarkshire. At the time of the inspection only a small number of outstanding errors were reported in registration and treatment forms submitted to the HFEA suggesting that submissions are largely accurate and timely.
Areas for improvement
The inclusion of live birth rate data into patient information leaflets was not complete at the time of inspection, despite that this was recommended at the 2006 inspection. In one set of patient records reviewed in the course of the inspection there was no evidence of completion of a WOC assessment prior to the provision of treatment. This is non compliant with the requirements of COP standard S.7.1.2. and standard licence condition A.12.4.
Areas for consideration
None
Executive recommendations for Licence Committee
The PR should assure the HFEA that patients are provided with information about outcomes of the proposed treatment as outlined in COP guidance G.5.3.1 (e). The PR should review the circumstances of the non conformity observed in the course of the inspection in relation to the provision of treatment without consideration of the WOC and take appropriate steps to minimise the chance of recurrence.
Evaluation

Some improvement required
Areas not covered on this inspection
None

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	2
NMC registered nurses	2.6
HPC registered scientists	1 (5 staff on rota)
Laboratory support staff	pathology support staff as required
Support staff (receptionists, record managers, quality and risk managers etc)	secretary/receptionist available as required
Counsellors	1 (sessional basis as required)

Summary of laboratory audit
A laboratory audit was submitted per inspection: no discrepancies were noted.
Summary of spot check of stored material
No spot check audit was carried out.
Areas of firm compliance
The PIQ documents that processes are in place to monitor and record staff competence and to provide all staff with an annual appraisal. All laboratory staff participating in licensable activity are registered with the Health Professions Council. The PR was able to provide evidence of participation in relevant CPD. The centre has procedures for the documentation of in house training and assessment. Staff were able to demonstrate that their competency to carry out witnessing had been assessed. All nursing staff participating in licensable activity are registered with the Nursing & Midwifery Council. A recently appointed member of the nursing team was able to demonstrate that her competency to perform designated tasks had been assessed.

The centre has access to a registered medical practitioner to oversee medical activities.

The counsellor is qualified to diploma level and is a member of the professional body for counselling and psychotherapy in Scotland (COSCA - Counselling & Psychotherapy in Scotland). The counsellor reported that she participated in relevant CPD in the last year.

The index of procedures provided to the HFEA pre inspection records that the centre has documented clinical procedures for insemination procedures and management of ovarian hyperstimulation syndrome (OHSS). The centre has had no moderate to severe cases of OHSS in the time since the last inspection.

The centre can trace the materials that have come into contact with gametes. Batch numbers and expiry dates are logged on the laboratory internal quality control sheets or in the clinical notes if items are used in a clinical procedure. The centre has documented procedures for the labelling of all samples of gametes requiring the use of the patient's full name and a unique identifier.

The PR has considered the most suitable method of witnessing for their local situation. They have decided to continue with manual witnessing. A risk assessment of their chosen system was documented and provided to the inspection team.

Validation of laboratory procedures has been undertaken.

The centre has a protocol for the transfer and receipt of gametes in compliance with the recommendation of Alert 21: Transport Hazards.

The centre operates a bring-forward system in order to ensure sufficient advance notice of the end of the statutory storage period for gametes or embryos in storage.

Areas for improvement

At the time of the inspection, not all staff had attended mandatory annual health and safety or life support update training.

The centre's protocol for the transport of gametes is not fully compliant with the recommendations of Alert 21: Transport Hazards in relation to the documentation of the requirements for labelling; procedures to be followed if labelling has degraded; and communication of risks of transfer to patients.

On review of the witnessing documentation in a sample of patient records, the scientific inspector considered that witnessing of sperm collection and preparation steps was unclear.

Areas for consideration

None

Executive recommendations for Licence Committee

The PR should seek the advice of local health and safety representatives in relation to the requirements for participation in mandatory health and safety training and life support training and ensure that all staff participate as required in compliance with the requirements of standard licence condition A.10.11.

The PR should review the procedures for transfer of gametes in consideration of the recommendations of Alert 21: Transport Hazards. The protocol and the laboratory worksheet should be revised so that these documents clearly account for what has been witnessed (COP guidance G.13.1.1 (b) and (c)).
Evaluation
Some improvement required
Areas not covered on this inspection
Counselling audit

Report compiled by:

Name……Debra Bloor/Bhavna Mehta…….

Designation…Head of Inspection/ Inspector…….

Date……26 September 2008……

Appendix A: Centre staff interviewed

The PR and three other members of the centre's staff met with members of the inspection team.

Appendix B: Licence history for previous 3 years

Licence Committee 20 June 2007 The Committee approved the change of Nominal Licensee from Dr Browning to Dr Graham. *Licence Committee 14 May 2007* The Committee agreed to vary the centre's licence to incorporate the requirements of the EUTCD. *Licence Committee 16 April 2007* A renewal inspection took place on 20 December 2006. The Committee noted that all of the recommendations by the inspection team have been now implemented by the Person Responsible (PR), as shown by the PR's response to the report at appendix C. The Committee decided to renew the centre's licence for a period of five years, with no additional conditions. *Licence Committee 27 April 2006* An interim inspection took place on 19 October 2005. The Committee agreed that the centre's licence should continue with no additional conditions.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……0098…….

Name of PR……Ian Smith…….

Date of Inspection……19th and 20th August 2008

Date of Response……23/10/08……

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

Signed……Ian Smith……

Name…… Ian Smith……

Date……23/10/08……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

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

Lanarkshire Infertility Unit Centre 0098 **Report response** **Breach 1** The organisational chart submitted on the day of inspection did not clearly represent the responsibilities and reporting relationships as required by standard licence condition A.10.1. **Action required** The PR should review the organisational chart to ensure that the chart clearly defines accountability and reporting relationships.

Response

A chart defining the clear structure and accountabilities has been re-submitted. The chart has been attached as a separate document for approval. (QD-MI-Orgchart2.doc)

Breach 2

For the time period to July 2008 the average time taken by the centre to pay HFEA invoices is 43 days. This is a breach of standard licence condition A.16.3.

Action required

The PR should review the arrangements for payment of invoices and ensure that there are no barriers to the prompt payment of invoices within 28 days of the date of the invoice.

The PR requested that the HFEA send the invoice direct to the PR rather than to the hospital finance department. This instruction has been acted on.

Response

As suggested the invoices will be addressed to myself as the finance department under Lanarkshires standing financial instructions will not approve payment until an authorised signature is present. The invoices on receipt are checked by nursing staff and approved and then signed by myself for payment and sent to finance. In an instance when the payment is approaching or exceded the due payment date I suggest contact with myself again to expidite and rectify would be more beneficial.

Breach 3

Not all of the documents reviewed in the course of the inspection were uniquely identifiable as required by S.5.2.6 and A.10.27.

Action required

The PR should ensure that all documents can be uniquely identified.

Response

The two documents identified at the inspection which were not document controlled were the infertility counselling leaflet (PD-MI-Counselling Info.doc) and a training document. (MF-MI-Training semen.doc) Both documents are now controlled and attached as separate documents.
At present the unit holds all documents electronically but is not currently using any document control software due to security issues. It is hoped that the unit will obtain early next year the newest version of QPULSE which I believe has a greater security aspect and will minimise any potential omissions.

Breach 4

In one set of patient records reviewed in the course of the inspection there was no evidence of completion of a WOC assessment prior to the provision of treatment. This is non compliant with the requirements of COP standard S.7.1.2. and standard licence condition A.12.4.

Action required

The PR should review the circumstances of the non conformity observed in the course of the inspection in relation to the provision of treatment without consideration of the WOC and take appropriate steps to minimise the chance of recurrence.

Response

Following review of the procedure and after discussion we have introduced a step that prior to the intent to offer treatment the nursing staff will check that a welfare of child form has been completed and this will be documented that its presence has been checked and by whom. (CP-MI-Front sheet UI.doc)

Breach 5

At the time of the inspection, not all staff had participated in mandatory annual health and safety or life support update training in compliance with the requirements of standard licence condition A.10.11.

Action required

The PR should seek the advice of local health and safety representatives in relation to the requirements for participation in mandatory health and safety training and life support training and ensure that all staff participate as required.

Response

The two nursing staff who have to complete the ILS (Immediate Life Support) course now have dates organised for 15/12/08
The two nursing staff who have to complete the resuscitation refresher course will have completed this by end of the year (2008)
The manual handling advice for nursing staff in the Infertility unit was that after attending the course that a refresher course was not needed. After consulting the Manual Handling Policy it was noted that this has been modified to advise that a "back awareness session" for half a day is now compulsory after three years. After discussion with the manual handling co-ordinator he has agreed that due to this misinformation that a specific sessions will be arranged to include all Infertility nursing staff before the end of the year (2008)

Non-Compliance items

Area for improvement

The inclusion of live birth rate data into patient information leaflets was not complete at the time of inspection, despite that this was recommended at the 2006 inspection

Action required

The PR should assure the HFEA that patients are provided with information about outcomes of the proposed treatment as outlined in COP guidance G.5.3.1 (e).

Response

We have looked at a different approach to including the live birth rate information for patients.
Previously all leaflets given out to patients had to be through NHS Lanarkshires chosen printers and as the live birth rates changed annually they had to be filled out individually.
These were not always completed and there was always the potential of transcription error when completed individually.
I have now got an electronic version which are controlled documents which we can complete on an annual basis and pre-print to be put into the patient pack
I have already sent the two documents by e-mail to the units inspector as the timescale for this was the 14th October 2008.
I also attach the documents with this response (PD-MI-IUAID Stat.xls**) and(**PD-MI-IUI Stat.xls)

Area for improvement

On review of the witnessing documentation in a sample of patient records, the witnessing of sperm collection and preparation steps were considered unclear

Action required

The protocol and the laboratory worksheet should be revised so that these documents clearly account for what has been witnessed (COP

Response

The witnessing form has been revised to show what the signature is witnessing and is attached as a separate document. (LF-MI- IUI Form.doc)

Area for improvement

The centre's protocol for the transport of gametes is not fully compliant with the recommendations of Alert 21: Transport Hazards.

Action required

The PR should review the procedures for transport of gametes in consideration of the recommendations of Alert 21: Transport Hazards.

Response

The units checklist for transport of gametes did not include giving the individual who was transporting the dry shipper from the unit a safety sheet for Liquid Nitrogen.

This has been included in the checklist and is attached to this response as a separate document. (PD-MI-CRYO SAFETY SHEET.doc)

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

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF