Licence Renewal Inspection Report

Care Sheffield

Centre 0061

Date of Inspection: 19 June 2008

Date of Licence Committee: 11 September 2008

CENTRE DETAILS

Centre Name	Care Sheffield
Centre Number	0061
Licence Number	L0061-13-a
Licence Expiry Date	31 December 2008
Centre Address	24 – 26 Glen Road, Sheffield S7 1RA
Type of Inspection	Licence Renewal
Person Responsible	Mrs Rachel Smith
Nominal Licensee	Dr Simon Fishel
Inspector(s)	Mrs Gillian Walsh Dr Victoria Lamb Ms Janet Kirkland
Fee Paid – up-to-date	Yes
NHS/Private/ Joint	Private

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About the Inspection:
This inspection visit was carried out on 19 June 2008 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between August 2007 and May 2008.

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 renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the 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.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. 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

This Centre is part of the Care group and offers a comprehensive range of assisted conception treatments to both self funding and NHS commissioned patients drawn largely from the local and neighbouring counties.

The Centre was last inspected by the HFEA in August 2007 following which it was recommended that the Centre's licence be continued without condition.

Application to vary the licence to reflect a change of Person Responsible (PR) was granted by Licence Committee in May 2008 on the return of the substantive PR following a period of maternity leave.

The PR is also the Senior Embryologist and Laboratory Manager for the Centre and is appropriately qualified and experienced to hold this post and as successfully completed the HFEA Person Responsible Entry Programme.

The Centre is registered with the Healthcare Commission (HCC) and was last inspected jointly with the HFEA in July 2005. The most recent HCC Regulation Assessment Statement states that analysis of the Annual Self Assessment submitted indicate that the Centre did not require on site inspection during the period 1 April 2007 to 31 March 2008.

Activities of the Centre[1] for the time period from 01/04/07 to 31/05/08

In vitro fertilisation (IVF)	161
Intracytoplasmic sperm injection (ICSI)	290
Frozen embryo transfer (FET)	50
Donor insemination	10
Research	No
Storage gametes/embryos	Yes

Summary for Licence Committee

The centre appears well organised and many improvements and developments have been made since the last inspection.

The Executive supports the renewal of the Centre's licence for the period of five years.

Evaluations from the inspection

[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. The figures are representative of treatment cycles commenced.

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
Routine diagnostic and investigative procedures such as semen analysis and standard blood tests are being performed either in the centre's laboratory or using the automated blood analysis equipment in the centre (S.7.8.2).	The PR should seek advice on the requirement for clinical pathology accreditation (CPA) of the blood diagnosis facilities.	The outcome of the review should be communicated to the HFEA by 19 October 2008. If accreditation is considered required then a timeline for completion of accreditation should also be submitted to the HFEA.

Non-Compliance

Area for improvement	Action required	Time scale

Recommendations	Time scale
The Centre should ensure that the HFEA patient information publications on display at the Centre and on their website is the most current version available as per the HFEA website to download.	Immediately.
The Centre should implement their competency assessment programme.	To be monitored at next inspection.

The Centre should ensure that the information contained within their policies and other documentation is current and in accordance with current guidance and legislation	To be monitored at next inspection.

Proposed licence variations by last L.C.

Licence Variation to reflect change of Person Responsible.

Changes/ improvements since last inspection

Recommendations	**Action Taken**
Validation of key process and procedures had not been established.	Validation process has begun as a corporate wide initiative.
Late submission of EDI data	Resolved.
Information on the Centre's website did not reflect that a charge had been introduced for counselling sessions beyond three.	Any reference to cost for counselling has been removed from the corporate website.
Patients and couples were reported to be waiting up to six weeks for counselling appointments.	Additional counselling time has been implemented.
Review the centre's requirements of the counsellor in the assessment of patients to assure independence of the clinical decision making process.	This has been reviewed and was seen to satisfactory on inspection.
Training and competency assessment of those seeking valid consent to be reviewed.	The extent of training has been reviewed and further development of the competency framework has begun.
Health and Safety review and risk assessment of the cryostore and laboratory office area for space and access.	Risk assessment completed and adjustments made accordingly.

No additional licence conditions were imposed following last licence committee.

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:

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees

Areas of firm compliance

Leadership and management
The Person Responsible (PR) has completed the HFEA PR entry programme. The PR satisfied the Executive that she is fully conversant with the scope of his responsibilities as PR and her reporting obligations to the HFEA. (S.4.1.4 / 5 /7 / 8 / 9 / 11)

Activities of the Centre are lead by the PR, the HCC Registered Manager and the Medical Director, who is the nominated registered medical practitioner. (S.4.1.1 A.10.2) The Person Responsible is based at the centre throughout the working week.

Organisation
An up to date organisation chart was seen to be in place, demonstrating accountabilities and reporting relationships. (S.4.2.5 & S.4.2.6).

The centre appears well organised, with good communication within the team at all levels. (S.4.1.1) (S.4.1.1) Evidence of effective communication was seen in minutes of meetings. (S6.2.13)

The PR stated that staffing was to establishment and that she felt confident the Centre had sufficient staff of the appropriate skill mix to fulfil the activity planned.

Risk management
There is a Care wide corporate risk management strategy in place and a number of the Centre staff have been trained in Risk Assessment. The Executive saw a number of completed risk assessments for the laboratory and clinical areas and some evidence of positive action in changing and monitoring practice following risk assessment. (S.7.8.10 S.9.4.3)

Incident management
The centre's standing operating procedure (SOP) for the management and reporting of incidents and the incident log were reviewed in the course of the inspection. 2 incidents had been reported to the HFEA since the last inspection, both of which are now closed. Evidence of appropriate reporting, investigation and consequent changes and monitoring was seen.

Responses to Incidents and HFEA Alerts from all Care centres are collated and published internally in the Embryology Health and Safety report. Locally, Centre staff demonstrated a good understanding of the HFEA incident reporting requirements and of HFEA Alert system, stating that formal response is required from relevant staff members confirming that they have read the Alert and what action has been taken if required. S.4.1.8, S.4.2.9, S.6.4.3, S.7.7.1 S.7.7.8, S.9.4 and A.4). .

Contingency arrangements
The Centre has contingency plans in place with sister Care centres, the closest of which is with Care Nottingham, in the event of any disruption to service. There is a system in place to alert nominated members of the team to an alarm being activated in the laboratory out of hours.
A member of the senior nursing team carries an 'out of hours' mobile phone when the Centre is closed or at weekends when, dependant on activity, only a receptionist and an HCA and possibly someone from the lab team are in attendance. If required, the 'on call' nurse would then contact the Consultant who is on call for the Centre at that time. Patients are given details of how to contact the Centre urgently out of hours and this number is also on the Centre's answerphone when the Centre is closed. Patients are also given written instructions on what to do if they are significantly unwell and are unable to contact the Centre.

Clinical governance
The Centre feeds into the Care wide corporate clinical governance agenda.

Payment of fees
The finance department of the HFEA report no issues of concern.

Areas for improvement

No real areas for improvement identified.

Areas for consideration

Executive recommendations for Licence Committee

None at this time.

Areas not covered on this inspection

Business planning.

Evaluation

No 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:

1. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates

Live Birth Rates

Outcome data extracted from the HFEA register for the period 1st April 2004 to 31st March 2007 for this Centre is in line the national averages.[1]

The Centre's activity year to date is comparable with the same period in the preceding year.

Areas of firm compliance

Quality management system
The centre has implemented a comprehensive quality management system. The is a nominated 'Quality Lead', who is also the HCC Registered Manager who is also part of the Care wide Corporate Quality Management Team. (S.4.2.1 S.4.2.7)

A corporate Quality Policy and Quality Manual, which also reflected local Quality and Policy information was seen to be in place. Evidence was also seen of local contribution to the Quality Manual by staff from all areas of the Centre's activity. All information was seen to be accessible to staff via the newly implemented electronic corporate document management system (S.4.2.3 / 4).

As part of the Quality Management review process, the Quality Manager (QM) stated that key staff, representative of all work streams within the Centre, would shortly be undergoing formal training in audit to facilitate in house 'exchange' audit of departments to enhance the scope of the in house audit programme in place. The Centre also participates in 'inter Care Centre' audits in certain areas, evidence for all of which was seen by the Executive. (S.4.2.9)

A comprehensive list of third party agreements was seen and sample agreements viewed appeared to be appropriate.

Monitoring and resolution of complaints.
The centre has an appropriate complaints policy (Care corporate) and procedures for making a complaint (including to the HFEA) are publicised on the notice board in two patient's waiting areas. The is a person nominated to whom complaints should be directed. The complaints log was reviewed in the course of the inspection, evidence of appropriate investigation and

resolution measures were seen.(S.9.2.2)

Document control
A comprehensive number of Centre policy documents both in hard copy and electronic form were available to view on inspection.

Documents were seen to be of a good standard and were, version controlled (S.5.2.5). The Quality Manager stated that the implementation of a new corporate wide, electronic document management system will facilitate accurate version control and monitoring of document review dates.

There is also a system in place to ensure any change in policy or procedure is communicated to relevant personnel and is confirmed and acted upon as required.

Areas for improvement

It was noted that information relating to donor anonymity contained within one Counselling policy was no longer current. The Quality Manager assured the Executive that this was an oversight and would be corrected without delay.

Areas for consideration

A number of policy and procedure documents seen had a prescribed review schedule of three years. Standard 5.2.5 requires that the maximum interval between reviews should be twelve months. The Quality Manager stated that as documents are being transferred to the electronic system the review schedule is being revised to reflect that they will be revised annually.. Evidence of this was seen on sample electronic documents.

Executive recommendations for Licence Committee

The Centre should be vigilant in ensuring the information contained within their documentation accurately reflects current practice and legislation.

Areas not covered on this inspection

Staff suggestions – good evidence of exchange was seen in meeting minutes.

Evaluation

Some small 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:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Areas of firm compliance

General suitability of premises

In the opinion of the Executive, the general premises, clinical and laboratory facilities are suitable for the activities for which the Centre is licensed and provides a physically safe working environment for patients, staff and visitors. (S.6.3)

The centre is located within the heart of a quiet residential area and is housed within a large, former domestic dwelling which has been adapted and extended for the purpose. The nature of the building dictates that the available space is broken up in to a number of small areas connected by communicating corridors. Whilst space constraints are evident, provision for disabled access has been considered.

There is a central reception area at the entrance to the Centre. Patients and partners are directed to one of two waiting areas, dependant on their appointment type. There are a number of consulting rooms used for doctor consultation, nurse appointments or counselling in on this level.

On the day of inspection the premises and facilities appeared well maintained and suitable for purpose. Clinical and waiting areas were well equipped, clean and aesthetically pleasant. Equipment appeared to be of a good standard and well maintained.

Access to non patient areas is controlled via standard or key pad locks.

The centre's current HFEA license plus Healthcare Commission and ISO certification were on display in the waiting area, information on how to make a complaint internally or to the HFEA was also displayed.

Clinical facilities

There are two ultrasound sound scanning rooms and a number of consulting rooms. There is also a dedicated phlebotomy room.

Routine blood analysis is conducted using an automated analysis machine by attendant nursing staff. In house training has been given to users and instruction manuals are available. Cleaning and decontamination of the equipment appeared to be in accordance with manufacturer and best practice guidance. More complex blood tests are sent to a Clinical Pathology Accredited (CPA) laboratory with whom the Centre has a third party agreement.

There is a small, private room set aside for the production of semen. A 'buzzer' type button in the room alerts laboratory staff that the specimen is ready for collection. Laboratory staff stated that the specimen is then collected from the room immediately. (S.3.4.(a) iii)

The Centre's treatment room is spacious, and appeared to be well equipped. Equipment for use in the even of an emergency was seen to be available in this room. Staff stated that procedures are conducted under light, oral sedation and analgesia only and patients walk to and from the treatment room.

There are two pleasant, simply furnished rooms in which patients recover from their procedures, one of which is also used for administering acupuncture. It was noted that there was no means of summoning assistance or a 'nurse call' system in these rooms.

Staff stated that patients are usually accompanied by a companion or their partner when recovering and rarely attend alone. Staff stated that regular checks are made on the patient and help would be easily accessible should it be required should the patient call or their companion be concerned.

In the event of that a patient should become unwell, basic emergency equipment was seen to be available. In the event of a serious emergency, staff are instructed to dial 999 for paramedic assistance. Signs seen in the ultrasound scanning room support this.(S.6.3.4 (b)). It was noted that there is a policy listed in the Quality Manual to support this but was not seen on the day.

Counselling facilities
Counselling is conducted in one of two rooms, both of which are comfortable and private. (S.3.5)

Laboratory facilities
The laboratory appeared to be appropriately equipped for the treatments offered. It also appeared to be clean and well maintained. (S.6.3.6) Access to the laboratory is keypad controlled and is limited to licensed personnel only.

Air Quality
Gametes are processed in an environment of the appropriate air quality. Evidence of quarterly environmental air quality monitoring using settle plates and annual particle count testing was seen and was within acceptable range. Documentation of air quality monitoring in the critical work area was not seen but staff gave verbal confirmation that last assessment was acceptable. This is conducted by the analysis of settle plates placed monthly and air particle testing conducted every six months. (S.7.8.5 (a b)).

Storage facilities
Facilities for the storage of cryo preserved samples was seen to be appropriate for use.

(S.6.3.7 / 8)
Appropriate alarm and monitoring mechanisms were seen to be in place, as was a policy directing action in the event of an alarm being activated. .(S.6.4(b)).

There has been significant improvement in the organisation of this area since last inspection following risk assessment. Facilities for storage were seen to be appropriate for use. There is a designated, secure cryostore. Cryopreservation dewars are fitted with appropriate low nitrogen level alarms and the store is fitted with a low oxygen level alarm with an audible alarm and an automatic 'dial out' system to alert nominated laboratory staff to an alarm out of hours. The nominated person would then attend the Centre if required. The Centre states that there is sufficient space remaining within their storage capacity to accommodate samples should there be a storage dewar failure.

Staff facilities
There is a separate, comfortable staff rest room adjacent to the main Centre building where staff my take breaks completely away from patient areas and store personal effects securely. Access to this area is restricted to Centre personnel only and also provides a forum for meetings and such. (S.6.3.9/ 10)

Management of equipment and material
Key electrical equipment is connected to an uninterrupted power supply (UPS) S.6.3.1 / 2).

Evidence of scheduled, preventative maintenance of laboratory and other equipment was provided in the course of the inspection. Equipment seen was 'CE' marked. (S.6.4.1/2) and were seen, Portable Appliance Test (PAT) was current.

Control of records
The majority of patient health records are held in a secure room, which sits behind the reception area. Access to this area is restricted by keypad lock. (S.5.2.7 G.10.2.1).

Risk assessment
Evidence of risk current risk assessment was seen.

Areas for improvement
It was noted that when the inspector entered the vacant 'production room' a semen sample awaiting collection was in the room. The sample was not collected for some while, during which the inspector was unaccompanied. The Centre should review this practice to safeguard the integrity of the sample and timely receipt into the laboratory.
Areas for consideration
Executive recommendations for Licence Committee
Areas not covered on this inspection
All areas covered.

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:

1. General Information
2. Meetings and communication
3. HFEA Alerts
4. Welfare of child
5. Confidentiality and access to health records
6. Traceability and coding
7. Information for service users/consents
8. Donor registration and information requirement of the HFEA
9. Surrogacy
10. Procurement, distribution and of receipt of gametes and embryos
11. Home procurement report documentation

Areas of firm compliance

General Information

General information regarding the Centre, opening times, facilities and location are available via the Centre's websites and in written pre appointment information.

Comprehensive written patient information is readily available within the Centre and also via the Care websites. Information relating to patient support groups and local meetings was displayed in patient waiting areas.

Meetings

Evidence of effective communication and exchange of views within the Centre was seen in minutes of meetings. Evidence was also seen of attendance at regular scheduled Care wide meetings which involve different clinical work streams within the organisation, such regular embryology and laboratory meetings, a quality management group and project groups working on the development of competency frameworks for different disciplines. (S6.2.13)

HFEA Alerts

An effective mechanism for the distribution of HFEA Alert system information, which required recipients to confirm they had received and acted on the information when required, was seen to be in place. S.4.1.8, S.4.2.9, S.6.4.3, S.7.7.1 S.7.7.8, S.9.4 and A.4). .

Welfare of the child consideration

When asked, staff were able to confirm that welfare of the child consideration is addressed at both doctor consultation and nurse consultations throughout the treatment process. Staff asked were able to appropriately describe the next steps to take should issues that may be of concern arise.

Welfare of the child considerations were also discussed with the Counsellor for the Centre and the Executive were satisfied that her current practice is appropriate and is conducted within professional guidelines. (S.7.1.2/3 S.7.6.2 /4)

A record, without detail, simply stating that welfare of the child implications had been

discussed and considered during both nurse and counsellor sessions was seen in sample patient notes.

Confidentiality and access to heath records
Active health records not being held within the Centre's main records store, were seen to being held securely, with access restricted to appropriate personnel when unattended and handled confidentially when in immediate use. A audit of randomly selected patient records conducted by the Executive on the day of inspection showed appropriate consents in place in all records viewed.

Traceability and coding
Procedures have been implemented to ensure the traceability of all materials that come into contact with gametes and embryos. Evidence of recording batch information on culture media and consumables used in the assisted conception process was seen to be effective. (S.6.4.2)

Information for service users and consent
Written information for those considering treatment, donation or egg sharing provided by the Centre appeared to be clear, comprehensive and easily understood. (S.7.4.1 G.5.1.1)

A couple currently in treatment interviewed by the Executive stated that they felt the information they had received so far was 'excellent, everything was explained step by step' and that they had been given time to 'go away and chew things over and could call anytime with a question'. Having been discussed with the Doctor, patients given their consent forms to take away to consider.

Following medical consultation, patients considering treatment will then meet separately with an experienced nurse and are asked to bring their consent forms to this appointment. The senior nurse stated that at this point the proposed treatment plan is discussed and the opportunity to ask further questions or seek clarity on any matters is presented. The Nurse will give medication tuition and will seek consent having satisfied herself that the person has fully understood the information received and can give valid consent. (Training and the assessment of competency for which was seen). (S.7.5.1/2)

Donor registration and treatment information required by HFEA
The registration department report that they currently have no issues regarding the content of timeliness of information received from the Centre.

Procurement and distribution
The centre operates a donor and egg share programme. The sperm donor recruitment is still at a early stage but egg share and egg donation are established services for this centre. There is a dedicated donor coordinator in post. The co-ordinator will manage the process for referrals requiring a donor and for potential egg share or egg donors. Two people will conduct the matching process.

Home procurement
Laboratory staff state that the vast majority of semen samples are produced at the Centre, however, a documented home procurement report was seen by the Executive and thought to be appropriate. (S.7.7.9)

Areas for improvement
HFEA published information It was noted that a number of HFEA produced patient information leaflets on display were no longer current and have been superseded, in addition to which, the address for the HFEA cited on one leaflet is incorrect. It was noted that the address and telephone number for the HFEA displayed on the Centre's website, in the section illustrating the Centre's own with national average outcome data is incorrect.
Areas for consideration
It was noted that the Nurse Consultation appointment is described by the Centre as 'Nurse Counselling', the Centre may wish to reconsider this title as it was felt by the Executive that this could lead to some confusion by inferring that this appointment constituted support counselling. It was noted that the room in which this is normally conducted is also labelled as such and again, may cause some confusion.
Executive recommendations for Licence Committee
The Centre should ensure that the information available for distribution at the Centre or for view on the website relating to the HFEA is accurate and contemporaneous.
Areas not covered on this inspection
Surrogacy – this is not facilitated at this centre.

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:

1. Staffing and competency
2. Selection and Validation of laboratory procedures and processes
3. Laboratory and clinical documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing

Full time equivalent staff

GMC registered doctors	2
NMC registered nurses	4.5 Fertility Nurses
HPC registered scientists	1.4 (.4 person about to go on maternity leave) I of which is PR
Scientists working towards registration	2 (1 of which is very close to registration)
Support staff (receptionists, record managers, quality and risk managers etc)	1.5 Health Care Assistants 1 Quality Manager (also the HCC Registered Manager 8 (some partime)
Counsellors	1 part time

Summary of laboratory audit / Audit of records

The most recent three embryo transfer log was submitted to the HFEA and was seen to be in line with guidance.

5 sets of randomly selected patient records were audited by the Executive on the day of inspection, in all of the records reviewed, consents were present and compatible with the treatments provided

Areas of firm compliance

Staffing and competency
Staffing appears stable, with a high proportion of staff having several years service.

The PR stated that the Centre is currently staffed to establishment, with one part time member of the laboratory team now on maternity leave and one nurse having recently joined.

The Quality Manager stated that there was a specific budget for clinical professional development. Staff asked said they felt recent access to training was good. However, only one nurse has attended a recognised scanning course. Nurses conducting ultra sound scanning continue to receive in house training from doctors and more experienced nursed. The Senior Nurse stated that it is intended that competency from this experiential learning will be assessed by Ultrasonographers at Care Nottingham.

The Senior Nurse, who has been with the Centre since it opened, is due to retire within the year. It is understood that succession planning for this role is in hand. Staffing appears to be

of appropriate skill mix and number for the current workload. (S.4.1.3 S.6.2.1/2)

Evidence of clinical and laboratory competency assessment was seen to have been conducted but not all assessments had been formally documented. It was positively noted that the laboratory manager underwent refresher procedure assessment on return from maternity leave.

A member of the embryology team was able to provide evidence of participation in Association of Clinical Embryologists continued professional development (CPD) training programme and a member of the nursing team was able to provide evidence of learning in preparation for competency assessment for Intra Uterine Insemination.

Evidence of staff participation in mandatory health and safety training and basic and intermediate life support training for relevant staff was seen.

The Quality Manager stated that key staff from all workstreams would shortly be undertaking formal audit training to fully facilitate in-house interdepartmental audits.

It was noted by the Executive that significant work had been undertaken on developing an formal competency assessment framework across all workstreams at the Centre. All staff now have competency folders in which supporting evidence of learning and assessment of competence will be recorded. Whilst the process is not yet fully implemented, it was seen that significant progress had been made in areas of practice that did not previously have a structured framework of assessment.

Laboratory processes.
The laboratory's procedures examined by the Scientific Inspector were considered to be conducted in compliance with current professional guidelines, legislation and regulations. (S.7.8 S.9.5 S.9.2.4 / 6).

Selection and validation of laboratory processes
The Scientific Inspector observed that the validation of laboratory processes has begun.

Evidence of participation in inter Care laboratory comparisons and participation in the National External Quality Assessment Service (NEQAS) was provided in the course of the inspection. One member of the team successfully completed a semen analysis course.

The Centre has an effective system for recording and responding to non-conformity, evidence of this was seen relating to an alarm being triggered the previous day.(S.7.8.13 a/b)

Storage
A rolling audit of stored material is conducted by the centre, the latest results for which were submitted to the Executive and were deemed to be in order by the Scientific Inspector.

A spot check of samples from tank to records and records to tank was conducted on 5 samples in storage, no discrepancies were found and appropriate consents were seen to be in place.

Provision of counselling

There is an appropriately qualified Counsellor in post. An audit of the counselling service has recently been conducted by the centre and was available to the Executive. The Counsellor receives regular professional supervision. She attends Centre meetings at which she feels there is 'always the opportunity for exchange' and at other times her usual first point of contact is the Quality Manager, who is also the Centre's registered manager.

The Counsellor is currently at the Centre on two fixed days for a period of 11 hours altogether, which is an increase in hours since the last inspection. The Counsellor stated that to address the long waiting period experienced by new patients at the time the last inspection, the Counsellor at Care Nottingham saw some of those patients. The waiting time for new patient is now stated to be less that one week. Patients make appointments via the Centre reception desk.

Witnessing
The Scientific Inspector was able to observe a sample of witnessing process activities and witnessing documentation directly and was satisfied that this was being conducted in accordance with HFEA guidance. (S.7.8.15). It was stated that at weekends and occasionally other times, nurses or HCA's will perform witnessing checks for which they have received training.

Areas for improvement

Diagnostic testing.
Routine diagnostic and investigative procedures such as semen analysis and standard blood tests are being performed either in the Centre's laboratory or using the automated blood analysis equipment in the Centre which is not accredited with a suitable body such as the Clinical Pathology Accreditation (S.7.8.2).

Areas for consideration

Executive recommendations for Licence Committee

The PR should seek advice on the requirement for clinical pathology accreditation (CPA) of the diagnostic facilities. The outcome of the review should be communicated to the HFEA by 19 October 2008. If accreditation is considered required then a timeline for completion of accreditation should also be submitted to the HFEA.

Areas not covered on this inspection

All areas covered.

Evaluation

Some improvement required

Report compiled by:

Name…….

Designation…….

Date……

Appendix A: Centre Staff interviewed

The Person responsible

6 members of the team

2 patients

Appendix B: Licence history for previous 3 years

24/04/08
Licence Variation to reflect a change of PR (return from maternity leave).

21/1107
Consideration of Interim Report – continuation o f licence with no additional conditions.

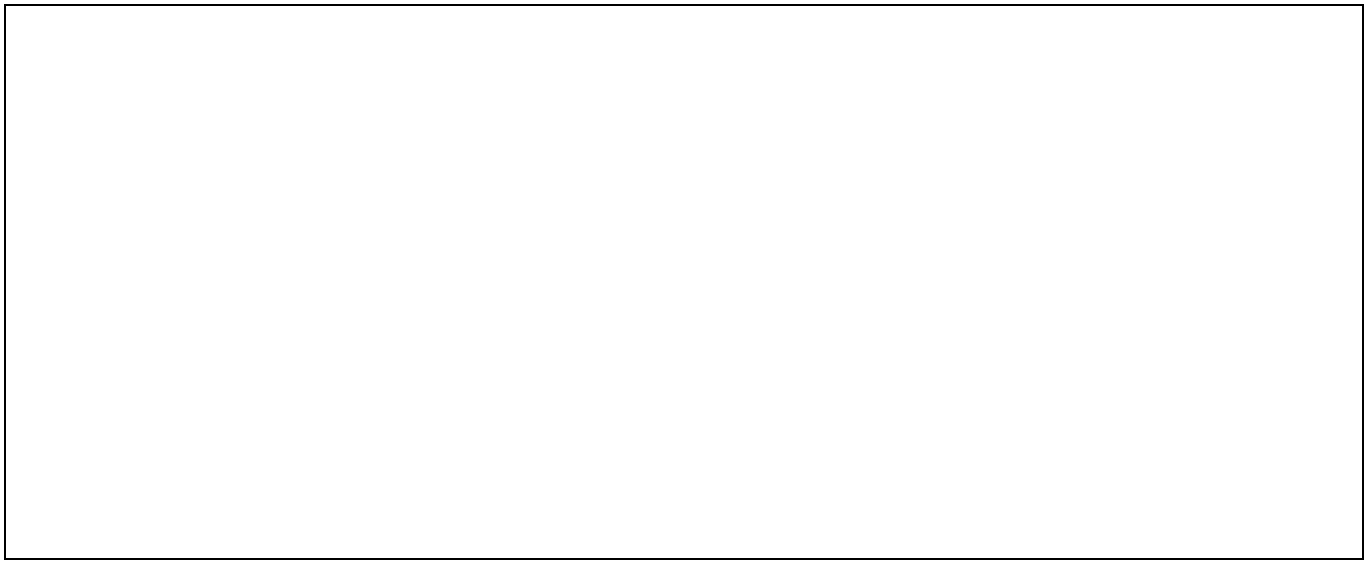
26/04/07
Licence Variation pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007

16/04/07
Licence Variation to reflect a change of PR (maternity leave cover).

10/07/06
Licence Variation to reflect a change of Centre name.

19/01/06
Licence Variation to reflect a change of PR

30/11/05
Licence renewal for three years with the addition of egg storage



Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number……

Name of PR…….

Date of Inspection……..

Date of Response……

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

Signed……

Name…….

Date……

1. 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).

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

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

Licence Committee Meeting

21 November 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 5

CARE Sheffield (0061)
Interim Inspection

Members of the Committee:	In Attendance:
Anna Carragher, Lay Member – Chair	Trish Davies, Director of Regulation / Deputy Chief Executive
Rebekah Dundas, Lay Member	Stephanie Sullivan, Interim Head of Inspection
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary	Claudia Lally, Committee Secretary
	Providing Legal Advice: Sarah Ellson, Field Fisher Waterhouse

Conflicts 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 (32 pages)
- 4 papers were tabled:
    - Success Rate Assessment
    - Patient Questionnaire Assessment
    - Regulation Risk Assessment
    - Action plan submitted by the Person Responsible

1. The papers for this item were presented by Gill Walsh, HFEA Inspector. Mrs Walsh informed the Committee that this is a long established centre offering a full range of treatments. The centre has a low risk score of 11%. The current Person Responsible is covering maternity leave and is new to the PR role at this centre though has considerable previous experience and works full time at the centre.

2. Mrs Walsh discussed an issue which arose at the inspection in connection with the counselling service which was a concern that the counsellor was also providing a medical assessment of patients. Mrs Walsh read from the action plan submitted by the Person Responsible which agreed to review the role of the counsellor and change counselling information to ensure that there is no

suggestion that the counsellor will be medically assessing patients. The Committee noted that this issue had arisen at previous inspections of the centre and welcomed the fact that positive action will be taken by the Person Responsible. The Committee asked the Executive to monitor the issue closely and ensure that the agreed actions take place before January 2008.

4. Mrs Walsh also highlighted the issue of training for the nursing team, as discussed at page 16, 17 and 19 of the inspection report. She explained that patients are taken through the consent process by nurses who are very experienced but have not had formal training. Furthermore, ultrasound scanning is conducted by nurses but only one nurse has completed a recognised ultrasound course since the last inspection. The Committee agreed with Mrs Walsh that it was important for members of the nursing team to participate in formal training in these two areas and asked the Executive to monitor this issue.

5. Mrs Walsh summarised the inspection report and discussed the recommendations listed at page 7 of the inspection report. Mrs Walsh then read the action plan submitted by the Person Responsible. Mrs Walsh informed the Committee that on the basis of this action plan she is satisfied that the centre are in the process of addressing all of the areas for improvement identified by the inspection team.

6. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed…… … Date……..
Anna Carragher (Chair)