Interim Inspection Report

Centre Name	Newcastle Fertility Centre at Life
Centre Number	0017
Licence Number	L0017/11/a
Centre Address	Bioscience Centre International Centre for Life Times Square Newcastle upon Tyne Tyne & Wear, NE1 4EP
Inspection date	11 May 2006
Licence Committee Date	16 August 2006
Inspector(s)	Debra Bloor Tony Knox Parvez Qureshi
With Notice	
Person Responsible	Jane Stewart
Nominal Licensee	Mary Herbert
Licence expiry date	30 April 2007

About the Inspection

The focus of this interim inspection will be drawn from issues arising from the last inspection or information received. 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, sixth edition Code of Practice, and also to advise centres to work towards compliance with the EU Tissue and Cells Directive 2004/23/EC where relevant.

The report is used to summarise the findings of the interim inspection highlighting areas 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 continuation of the centre's licence. The report is also available to patients and the public following the Licence Committee meeting.

Inspection teams are drawn from a team of in-house inspectors and generally comprise a scientist, a clinician or nurse and a generalist. Prior to the inspection, the Person Responsible (PR) completes a pre-inspection questionnaire to provide the HFEA with details of any changes since the last inspection and factual information. Patient questionnaires are sent to the centre for distribution to patients so they can tell directly how good they consider the service is. There is also a self-assessment document for the PR to complete so that they and their staff may identify areas needing improvement. Persons Responsible are required to send the HFEA information on all treatments carried out and this information is gathered through an electronic system. All this information is analysed by the lead inspector prior to the visit taking place.

At the visit the inspection team will assess 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.

Evaluations are given to each topic and 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 PRs 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.
There will be an overall judgement made at the end of the five sections.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received.

This inspection visit was carried out on 11 May and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received in the time period between November 2004 and May 2006.

Brief Description of the Centre

The centre is part of the Newcastle upon Tyne Hospitals NHS Trust and provides NHS and self funded treatments to patients largely resident in the North East of England. The centre has an active research programme.

Activities of the centre		
	Licensed treatment cycles	682
	Donor Insemination cycles	215
	Unlicensed treatments provided	Gamete intra fallopian transfer Intrauterine insemination Ovulation induction Surrogacy
	Research	✓
	Storage	✓

Taking into account recommendations of the previous report and submitted documentation the inspection focused on the following aspects of the centre's practice.

1. Training, induction and continued professional development of staff;
2. Laboratory activities including:
    - a sample audit of cryopreserved material;
    - witnessing procedures;
    - audits of outcome;
    - participation in external quality assessment schemes;
3. Implementation of clinical governance strategies including:
    - how the centre links with the Trust;
4. Audits of outcome;
5. The provision of counselling services and review of the counselling audit;
6. Records including an inspection focussing on egg share donors.

Additional licence conditions and actions taken by centre since the last inspection

C	None

Improvements since the last inspection

Patient information and protocols have been revised in accordance with the recommendations of the previous report and Licence Committee.

Summary for Licence Committee

The Newcastle Fertility Centre at Life has been licensed since 1992. The centre offers NHS and self funded treatment to patients from the north east of England.

A number of regulatory issues were identified in the course of the inspection and these are summarised as follows:

- On inspection of the incidents log two breaches of confidentiality were recorded of which the HFEA had not been notified;
- Some counselling is provided to patients by nursing staff;
- The audit of counselling has not been analysed to allow the uptake of the service to be monitored effectively and 6 out of 19 patients providing feedback on their treatment experience at the centre to the HFEA reported that they had found counselling inaccessible;
- No annual audit of sperm samples had been carried out in the time covered by this report;
- The storage of sperm samples for patients who have had treatment that may have impaired their fertility is not split between two locations.

The centre should address these issues as outlined in the report.

Feedback from patients to the HFEA from 19 patients who have received treatment at the centre was very positive. Fifteen patients had compliments about the treatment they have received and only 3 patients had any complaints. The centre has been proactive in responding to the recommendations of the previous report and Licence Committee.

The inspection team support the continuation of the centre's licence.

Breaches of the Act or Code of Practice

Breach	Action required	Time Scale
At the time of the interim inspection, the storage of cryopreserved samples from patients who have had treatment that may have impaired their fertility was not split between two locations. Chair's Letter CH(04)03 states that centres storing gametes and / or embryos for patients whose fertility may be impaired by medical treatment are now expected to divide individual patients' samples into separate storage vessels. All centres are expected to implement this policy immediately for all new patients storing gametes and / or embryos prior to having medical treatment that may affect their future fertility. All centres are expected to split gametes and / or embryos stored for existing patients whose fertility may have been impaired by medical treatment,	The PR should carry out an assessment of the risk of continuing to store material from patients who have had treatment that may have impaired their fertility in single storage vessels. A copy of this assessment should be submitted to the HFEA and the Trust.	Within one month of consideration of the report by a Licence Committee

during the centre's next annual audit of stored material. Therefore, all samples should be divided into separate storage dewars by the end of June 2005.		
Part 9.11 of the COP states that storage centres are expected to carry out reviews, at least annually, of the status of stored gametes and embryos. Failure to audit sperm samples in the last year is a breach of this requirement.	An audit of stored sperm samples should be completed as a matter of urgency to comply with the requirements of the COP and the possibility of splitting oncology samples within existing storage vessels during the course of the audit should be considered. If this procedure is considered to carry a risk then this should be assessed and a copy submitted to the HFEA and the Trust.	Within three months of consideration of this report by a Licence Committee

Non-Compliance

Area for improvement	Action required	Time scale
During inspection of the incidents file, it was noted that two breaches of confidentiality caused by administrative errors had not been reported to the HFEA.	The PR agreed to review the incident reporting protocol and to ensure that staff, particularly members of the administration team, are made aware of the requirement to report incidents to the HFEA.	Not specified
Implications and support counselling is provided by clinical and nursing staff	The PR should distinguish between provision of counselling and information giving and ensure that counselling is provided by suitably qualified staff.	Not specified
Six of the 19 respondents (31%) providing feedback to the HFEA commented that counselling services are inaccessible. The Licence Committee considering the 2005 interim report commented a counselling uptake of 8% appeared disproportionately low.	The PR should consider how the uptake of counselling can be more effectively monitored to reflect the different patient groups (donors, new patients, existing patients etc) using the service. A more detailed audit should then be used to inform the centre's decision making in relation to a review of the accessibility and provision of the service.	Not specified

Proposed licence variations

None

The effectiveness of the provision

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 of:

- Organisation of the centre
- Risk management
- Incident management
- Clinical governance
- Payment of treatment fees
- Contingency arrangements

Areas of firm compliance
Inspection documentation was provided promptly suggesting that the centre is well organised. The centre adopts the clinical governance strategies of the Trust. The 2002 CHI review[1] assessed the Trust as having achieved level III in clinical risk management. The report commented that there was a good strategic grasp and substantial implementation of clinical risk management strategies and alignment across the strategic and planning level, and the operational level of the Trust. The Trust is part of the Clinicial Negligence Scheme for Trusts and achieved a level 2 risk management assessment in February 2005[2]. The centre maintains a log of incidents and this was made available to the inspection team. Incidents are reported using the Trust's clinical governance procedures and it was reported by the PR that any incident reports are reviewed at monthly multi-disciplinary meetings. Clinical staff are available to patients out of hours and can admit patients as necessary. The average time to pay HFEA invoices over the last 6 months has been less than 60 days.
Areas for improvement
During inspection of the incidents file, it was noted that a breach of confidentiality caused by an administrative error had not been reported to the HFEA. This was discussed with the PR who agreed to review the incident reporting protocol and to ensure that staff, particularly members of the administration team, are made aware of the requirement to report incidents to the HFEA.
Executive recommendations for Licence Committee
None
The quality of service provided by the centre

[1] Clinical Governance Review Report Published by the Commission for Health Improvement, February 2002
[2] As reported on the NHS Litigation Authority website.

Requires no improvement
Areas not covered on this inspection
Leadership and management Organisation of the centre Resource management Business planning

Data analysis/success rates

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
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services

Areas of firm compliance
The PR confirmed that outcomes are audited and reviewed at the monthly management meetings. Evidence of this was seen in minutes of the management meetings. The centre maintains a log of complaints and this was reviewed by the inspection team. The centre adopts the Trust's complaints policy and responds to complainants within locally specified timeframes. Counselling is provided without charge. The counsellor has completed a diploma in counselling and is working towards accreditation with the British Association of Counselling and Psychotherapy (BACP). The counsellor reported that she is a member of the British Infertility Counselling Association and the BACP and that her practice is supervised. The counsellor provides therapeutic counselling. Counselling records are stored securely and are accessible only to the counsellor. A counselling audit was submitted with the interim application. The audit showed that a total of 91 sessions were provided for 50 patients between November 2004 and October 2005. No further analysis of the figures was performed and it is not possible to estimate the percentage of patients using the service from this information. Feedback from patients to the HFEA from 19 patients who have received treatment at the centre was very positive. Fifteen patients had compliments about the treatment they have received and only 3 patients had any complaints.
Areas for improvement
The counsellor reported that implications and support counselling is provided by clinical and nursing staff at the centre. Part 7 of the 6th Code of Practice (COP) states that it is expected that counselling will only be provided by qualified counsellors and part 7.1 states that counselling is expected to be clearly distinguished from (i) information which is to be provided to all relevant parties in accordance with guidance in Part 5 of this Code of Practice (ii) the normal relationship between clinical staff and the potential donor or seeker of storage or treatment (including the giving of professional advice). The PR should distinguish between provision of counselling and information giving and ensure that counselling is provided by suitably qualified staff.

Feedback from patients to the HFEA from 19 patients who have received treatment at the centre was very positive. In relation to counselling however, six of the 19 respondents (31%) commented that counselling services are inaccessible. The Licence Committee considering the 2005 interim report commented that the uptake of counselling by 8% of patients in the period from October 2003 to September 2004 was, in their experience disproportionately low. The PR should consider how the uptake of counselling can be more effectively monitored to reflect the different patient groups (donors, new patients, existing patients etc) using the service. A more detailed audit should then be used to inform the centre's decision making in relation to a review of the accessibility and provision of the service.
Executive recommendations for Licence Committee
None
The quality of service provided by the centre
Some improvements required.
Areas not covered on this inspection
'Welfare of the Child' arrangements Choice of treatments Privacy and dignity of patients Donor selection Egg sharing and surrogacy Protection of children arrangements (for patients under 18yrs) Confidentiality (including safe storage of patients' records)

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
- Safe storage of embryos and gametes
- Safe equipment, servicing and maintenance

Areas of firm compliance
The centre's embryology laboratory is currently situated in separate licensed premises at the Royal Victoria Infirmary pending the completion of the refurbishment of the laboratories at the Centre for Life. Cryostore facilities are situated within the andrology laboratory at centre 0017. Access to the laboratory is restricted to centre staff only. Dewars are fitted with low nitrogen level alarms and are connected to an auto dial system. The andrology laboratory is equipped with an oxygen depletion monitor. The alarms are checked on a weekly basis and a log of this was seen during the inspection. It was also reported that tanks are routinely monitored for nitrogen use and evidence of failure. Screened and unscreened samples are kept in separate dewars and the centre has a spare dewar for emergency use. No discrepancies were found during a spot check audit tracking two embryos from records to dewar and from dewar to records. The report of the 2004 interim inspection recommended that the centre develop a protocol for responding to low nitrogen level alarms. This was made available to the inspection team. Evidence of annual maintenance of key pieces of laboratory equipment was seen in the course of the inspection. The senior embryologist reported that an audit of stored embryos had taken place since the last inspection and that no discrepancies were found. A copy of the audit report was made available to the inspection team. The senior andrologist reported that no audit of the stored sperm samples has been carried since the last inspection in November 2004. It is planned that an audit will be carried out on completion of the current refurbishment programme which is expected to be in October 2006. At this time the centre will transfer stored sperm samples from liquid to vapour phase storage tanks. No discrepancies were observed during a spot check audit of two sperm samples from records to dewars and from dewar to records.
Areas for improvement
The centre stores samples for patients who have had treatment that may have impaired their fertility. At the time of the interim inspection, the storage of these samples was not split between two locations. This is a breach of Chair's Letter CH(04)03. This was discussed with the PR and accredited consultant and it was reported that the HFEA has been informed of the planned delay. The splitting of samples has been delayed pending the replacement all of liquid nitrogen storage dewars with vapour phase dewars. The accredited consultant did not

consider that the capital outlay for new liquid nitrogen storage vessels could be justified when these would be replaced with vapour phase storage vessels within a short time period.

Part 9.11 of the COP states that storage centres are expected to carry out reviews, at least annually, of the status of stored gametes and embryos. Failure to audit sperm samples in the last year is a breach of Part 9.11 of the COP.

Executive recommendations for Licence Committee
The PR should carry out an assessment of the risk of continuing to store material from patients who have had treatment that may have impaired their fertility in single storage vessels. A copy of this assessment should be submitted to the HFEA and the Trust. An audit of stored sperm samples should be completed as a matter of urgency to comply with the requirements of the COP and the possibility of splitting oncology samples within existing storage vessels during the course of the audit should be considered. If this procedure is considered to carry a risk then this should be assessed and a copy submitted to the HFEA and the Trust.

The standard of the premises and equipment within the centre
Some improvement required.

Areas not covered on this inspection
Prevention of incidents/ accidents Disposal of gametes / embryos

4. Information

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

Summary of findings from inspection:

- Information provided to the HFEA
- Record keeping (including consents)

Outcome of audit of records

Areas of firm compliance
Documentation of witnessing practices was tracked in five sets of patient records. All the records showed documentation of relevant witnessing steps. Consent forms and documentation relating to welfare of the child assessments were reviewed in 11 sets of patient records. All consents were correctly completed and were compatible with treatment including consents in a single set of records from a patient who had donated eggs in an egg share arrangement.
Areas for improvement
None
Executive recommendations for Licence Committee
None
The standard of information provided by the centre
Some improvement required
Areas not covered on this inspection
Protocols Information for patients and donors Information management

5. Laboratory and Clinical Practice

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

Summary of findings from inspection:

- Staff competence, qualifications, training and CPD
- Laboratory processes and practice

Staff

Clinicians	7 (including 2 consultants, 1 clinical assistant, 2 specialist registrars, 2 research registrars)
NMC registered nurses	9 (including 1 senior nurse, 6 staff nurses, 1 theatre nurse and 1 research sister)
Nursing support workers	2
HPC registered scientists	3 (2 senior and 1 qualified)
Trainee scientists	2
Counsellors	1
Medical technical officers	3
Research scientists	7 (including 1 scientific director, 1 clinical research associate, 1 junior research associate, 2 PhD students, 1 placement student, 1 research assistant)
Support staff (receptionists, record managers, quality and risk managers etc)	8

Highlighted areas of firm compliance
All clinical staff are registered with the General Medical Council. All embryologists are registered with the Health Professions Council with the exception of two trainee embryologists who are working towards registration through the completion of the Association of Clinical Embryologists certificate. All members of the nursing team are registered with the Nursing and Midwifery Council. The PR reported that training records for clinical staff are not maintained on site but confirmed that all mandatory training had been completed with the exception of basic life support training. This training is planned imminently. The PR also reported that following a review of policies and procedures, staff are to be provided with a formal training record. The continued professional development (CPD) of the PR and other members of the consultant clinical staff is monitored by the Royal College of Obstetrics and Gynaecology. A newly appointed member of the nursing staff was able to demonstrate participation in a comprehensive induction programme and of training in IVF specific duties. Two senior and one junior member of the embryology/andrology team provided evidence of appropriate training and CPD in the last year. Laboratory protocols are version controlled and show evidence of revision. A protocol for

responding to a dewar alarm has been developed as requested in the 2005 interim inspection report.
Areas for improvement
None
Executive recommendations for Licence Committee
None
The standard of laboratory and clinical practice provided by the centre
No improvement required
Areas not covered on this inspection
Assessment of patients and donors Safe handling systems Procedures in practice Clinical practice Recruitment and retention of staff These areas of the centre's practice were reviewed at the time of the renewal inspection when they were considered appropriate.

Breaches of the Code of Practice or Act

Compliance with additional conditions and requests

Conditions

The previous licence was issued without any additional conditions or recommendations.

Actions requested in previous report

Action	Timeframe	Centre's action
The centre should modify its protocol for monitoring liquid nitrogen levels in storage vessels and should prepare a protocol for response to alarms	None specified	Completed, protocol reviewed in course of the inspection
The centre should modify its protocol for assessment of the welfare of the child to reflect that the assessment will be repeated inline with the 6th Code of Practice	None specified	Completed
The centre should update patient information as follows • egg sharers can know outcomes with appropriate consents; • HFEA address update; • 'CHILD' now 'Infertility Network'	None specified	Completed
The centre should again consider reviewing practice of not completing the 'consent to storage' section of consent forms in advance of treatment	None specified	The PR considers this practice appropriate and patients continue to consent to storage only when it is known that there are embryos suitable for freezing.
The centre should update its protocol for egg 'sharer-provider' consent in line with the 6th Code of Practice (ie two consents should be completed, one for own treatment and one as a donor).	None specified	Evidence seen of compliance with this recommendation in the course of the review of patient records.
The centre should revise consent forms to reflect that it is normal practice to transfer two embryos (Licence Committee recommendation)	None specified	Completed

The inspection team

List the inspectors identifying the lead inspector and support inspectors.

Debra Bloor	Chair, Inspector, HFEA
Tony Knox	Inspector, HFEA
Parvez Qureshi	Inspector HFEA

Report compiled by:

Name…Debra Bloor…….

Designation…Inspector, HFEA……..

Date……23 May 2006……

Appendix A: Centre Staff interviewed

Jane Stewart, PR Five other members of the centre's staff met with members of the inspection team.

Appendix B: Licence history for previous 3 years

Licence	Type	Active From	Expires
L0017/11/a	Treatment with Storage	01/09/2005	30/04/2007
L0017/10/b	Treatment with Storage	11/08/2004	30/04/2007
L0017/10/a	Treatment with Storage	01/05/2004	30/04/2007
L0017/9/d	Treatment with Storage	07/07/2003	30/04/2004

L0017/11/a

No conditions

Recommendation

- That the Person Responsible should get written confirmation that the witnessing protocols in use at the Hexham transport centre are in line with those protocols in use at Centre 0017.

L0017/10/a/b and **L0017/9/d**

Conditions

- The PR must ensure that the centre has made all reasonable efforts to satisfy itself that the GP of each prospective parent knows no reason why either of the parents are not suitable for the treatment to be offered (including anything which might adversely affect the welfare of any resulting child or child of the family.)
- The PR must ensure that consent to treatment/storage/use is given in accordance to the HF&E Act 1990 and the Code of Practice for the time being in force, and that the patients after death wishes are clearly stated.

Recommendations

- That patients undergoing ICSI should receive the information sheet from the Centre, suitably updated to take account of the latest published evidence, plus the latest version of the HFEA leaflet on ICSI.
- That the Person Responsible ensures that the documentation used by the transport centre is reviewed with particular regard to consent to disclosure and Welfare of the Child assessment.
- That the Person Responsible must ensure that the patient's consent is obtained before approaching his or her GP and that consent to disclosure forms are signed as soon as it has been agreed to proceed to treatment. To facilitate this the consent to disclosure form should be separated form the consent to treatment form.
- That the centre amends the patient information to incorporate the points raised in section 8 of the inspection report, viz.
    - Epilepsy be listed separately to mental disorders;
    - Health Authorities changed to read Primary Care Trusts;

- Year of the HFE Act be corrected to 1990;
- Cytomegalovirus be written in full;
- No mathematical signs for greater than or less than used
- That the Person Responsible should endeavour to ensure that couples consent to posthumous use is compatible, and that all consent forms are completed fully and dated.
- That the Person Responsible reports all adverse incidents to the HFEA in line with section 2.24 of the Code.

L0017/8

Conditions

- The centre should ensure that no information is passed to any individual for whom prior written consent to disclosure has not been given by the patient.

Recommendations

- The centre should consider making reference in their patient information to the requirement for an assessment of the Welfare of the Child to be made.
- The centre should include reference to the assessment of the Welfare of the Child in the initial letter to the GP.
- The centre should routinely write to GPs with reference to the Welfare of the Child.
- The centre should review the patient information on embryo freezing and consider whether the recommendation to patients to store for only 1 year is in the best interests of patients.
- The centre should consider a general review of their patient information for spelling, grammar, consistency, and accuracy, including data presentation. The centre should also address the recommendations of the previous licence committee in respect of patient information.
- The centre should update protocols to reflect that nurses and not clinicians carry out embryo transfers

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO 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

Breaches of the Act or Code of Practice.

Retrospective splitting of long term storage samples

Enclosed is a copy of the Risk assessment pertaining to this issue as requested.

Sperm storage audit

This will be carried out as instructed and the report forwarded to the Inspector.

Counselling

PART 2, also Pages 4/5/6/9

There appears to be disproportionate repeated emphasis being placed on the discussion regarding counselling.

We distinguish quite clearly between therapeutic counselling which is undertaken by an independent and suitably qualified counsellor (Barbara Thomson) and implications "counselling" which relates to specifics of treatment or procedures/processes being undertaken by suitably qualified nurses and doctors within the unit. It is our view that implications counselling is best carried out in the first instance by individuals who are well versed in and involved in clinical practice and it is arguable that individuals whose specialty is therapeutic counselling are in the best position to discuss those implications or that information. This was the opinion acknowledged by TK at the PR interview during the inspection and at previous inspections and I am sorry therefore that without seeking further discussion this point seems to have been carried over by the inspection team into the report as an area for improvement.

All couples undertaking licensed treatment at NFC-LIFE receive the appropriate implications counselling; the Inspectors have copies of the specific reference sheets which ensure that all aspects are covered and documented in the notes. In addition all couples undertaking treatment are given/offered information on how to contact Barbara Thomson independently and this practice is reflected in the IVF counselling sheet where there is a specific tick box recording this fact. Donors and recipients similarly will receive implications counselling and are offered therapeutic counselling should they wish it. In fact this facility is available to all of our patients whether or not they are undertaking licensed treatment.

Thus the uptake for counselling available from Barbara Thomson's data reflects the uptake of therapeutic counselling only and one might argue that a low uptake there reflects the quality of advice and information and support being provided within the unit. The uptake for "counselling" relating specifically to implications of treatment is of necessity 100% since treatment does not go ahead until this has been completed.

We have measures in place to ensure that there is no conflict between donor and recipient implications counselling since they are specifically done independently of each other.

Considering the HFEA patient questionnaire data

Whilst we acknowledge the importance of independent patient views, with regard to the 6 patients who found counselling inaccessible there are two points;

1. a sample size of 19 hardly reflects the workload of the unit where we see 1000 new couples per year and perform 500+ cycles of treatment and there is a risk that there is a significant self selection bias in the couples who fill in the form albeit that they were substantially complimentary.

2. The nature of a closed question in the HFEA questionnaire with a yes or no answer means that there will always be the appearance of dissatisfaction even if that is not the intention. If all 19 couples were undertaking treatment then in fact they are mistaken if the general term of "counselling" (ie not just denoting therapeutic counselling) is considered since they will all have received

implications discussions.

We were not given access to the data from the patient questionnaire for comment at the inspection (I received a copy on 16th June) it would be helpful if the limitations of this data were acknowledged if such emphasis is to be placed on the negative points.

As a result of this discussion and the Inspectors recommendations we will devote a portion of our forthcoming re-audit of patient satisfaction to the subject of both implications and therapeutic counselling in our clinic.

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

Signed……

Name……..

Date……

2. 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 this section of the report to:

Dr Marion Witton
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