Central Manchester University Hospitals NHS
NHS Foundation Trust

Person Responsible Dr Cheryl Fitzgerald's response to issues raised within HFEA report St Mary's Hospital, Manchester. Centre 0067 written in March 2010

Inspection January 2010

1. Staff competencies

    a. Clinical competencies
        i. Clinicians are only allowed to practice independently once deemed competent to practice – for clinic performance, oocyte recoveries, embryo transfers.
        ii. All clinicians undergo a strictly controlled training programme, the time to achieve competence varies between individual practitioners.
        iii. Biannual monitoring of individual clinician outcome for oocyte recovery and embryo transfer to assess ongoing competence.
        iv. Complications of individual treatments are examined, via incident reporting within the Trust scheme and action taken if there is evidence of poor practice.
        v. All clinicians undergo annual appraisal where all aspects of their practice is examined. This can be referenced on the trust Organisational Development & Training spreadsheets.
        vi. All clinicians are members of the RCOG and complete CPD in line with RCOG guidelines.

    b. Nursing competencies –
        i. All nurses within the department of Reproductive Medicine had their annual KSF (key skills and framework) assessment in the summer of 2009 incorporating the health and well being domains related to assessment ,care planning implementation and evaluation of all care/treatment provided.
        ii. All new band 5 staff who commenced in the Autumn of 2009 were inducted in all areas including placements in a ward and theatre environment with set learning objectives.
        iii. All nursing staff in line with Trust policy have undertaken annual competency assessments of aseptic non touch techniques (ANTT) assessments in venepuncture, Hand washing, and early warning scores.
        iv. All nursing staff have attended annual corporate and clinical mandatory training.
        v. All staff have undertaken annual basic life support training.

vi. All Nursing and Clinical support workers have undergone a competency based training program to perform venepuncture and are assessed annually.
vii. Band 6 nurses with the exception of one new starter (December09) have undergone training to undertake new patient clinics. Incorporating assessments to take a history decide on investigations and complete consents for treatment. All staff who have undertaken this training have been assessment as competent by a consultant within the department and a competency document completed.
viii. All clinical support workers are working towards NVQ level 2 certificate in care.
ix. Band 6 nurses who perform IUI have undergone a competency assessed training program and will be assessed annually.

c. Laboratory competencies

i. All staff undergo annual appraisal within their KSF (Knowledge and Skills Framework) review.
ii. All embryologists are full ACE members or trainees undertaking the ACE Certificate in Embryology. All andrologists and embryologists are registered with the Health Professions Council (HPC). All embryologists have taken or are planning to take the new RCPath Embryology part 1 exams, Greg Horne and Daniel Brison were two of the first five embryologists in the UK to pass part II and become FRCPath. Professor Brison is an examiner for RCPath.
iii. Prior to inspection
    1. Each member of laboratory staff reviewed all Standard Operating Procedures (SOP) pertaining to their areas of responsibility. This was recorded initially by signing each SOP, but the process for confirmation has been superseded by Qpulse.
    2. All ICSI practitioner results were assessed annually and submitted to the HFEA.
    3. Department KPIs were monitored monthly, including a number monitored by individual practitioner through a team meeting session that takes place once per month.
        a. number of IVF / ICSI cycles fresh and frozen
        b. IVF and ICSI fertilisation rates
        c. embryo implantation rates (fresh and frozen)
        d. positive and clinical pregnancy rate per treatment started, oocyte collection and embryo transfer

iv. New protocol for laboratory competencies
    1. Critical SOPs have been identified that will be assessed by an annual examination audit. The three areas responsible are IVF laboratories, andrology laboratories and the NEQAS scheme. (See below)
    2. The examination audits will be completed by 1st June 2010.

3. Monitoring of individual KPIs will be increased. Individual KPIs for ICSI fertilisation rates, ICSI damage rates, embryo implantation rates (per ET) will be assessed quarterly, rather than every six months.

2010-2011	area
IVF culture system set up	IVF
Egg collection	IVF
Sperm preparation	IVF
ICSI	IVF
IVF insemination	IVF
Fertilisation and cleavage checks	IVF
Embryo grading	IVF
Embryo transfer	IVF
Embryo Cryo	IVF
Vitrification and warming	IVF
Embryo thawing	IVF
sperm cryo in straws	IVF
Entering data on ACUBase	IVF
Anti-sperm antibody test	ANDROLOGY
Hypo-osmotic swelling test	ANDROLOGY
Pregnancy test	ANDROLOGY
Sperm cryo in ampoules	ANDROLOGY
Semen analysis	ANDROLOGY
Distribution of semen analysis specimens	NEQAS
Distribution of motility DVD	NEQAS
Packaging and postage of distribution	NEQAS
Specimen collection	NEQAS

d. Administrative staff competencies
    i. All administrative staff have an annual KSF review which includes assessment of competencies and training.
    ii. SOP in place for data inputting will now be subject to an examination audit.

e. Counselling staff competencies
    i. Quality assessment – patient evaluations (copy given to inspectorate). Patients are given evaluation forms at the end of counselling and are asked to return them anonymously.
    ii. Counselling service protocols (given to inspectorate). Strict guidelines which are adhered to be all counsellors. Guidelines reviewed annually.
    iii. KSF review. All counsellors work within the Knowledge and Skills Framework as set out in all NHS establishments. This is reviewed annually against their job description for Infertility Counsellors.
    iv. BICA accreditation. Jenny Dunlop our most senior counsellor was one of the first counsellors to gain the SAMBICA. Ann Curley is about to gain her AMBICA. Beverley Loftus will apply for accreditation once she has accrued sufficient supervised practice hours.
    v. Audit of counselling service 2009 (given to inspectorate) Audit of counselling service work last year. Included additional activities completed by counselling team and CPD update.
    vi. Audit of initial referrals for counselling. Audit of referrals in 2009, presented at departmental meeting.

f. Competency of staff to take consent has not been assessed / recorded.
    i. All staff are fully trained to take consent before they are allowed to take consent.
    ii. Training consists of
        1. Completion of the Trust's consent training. This is recorded via ICON.
        2. A formal teaching session for HFEA consents and in house specific assisted conception consents, with the Person Responsible. Lists of staffing attending recorded.
        3. Observing consent taking within the clinic session by sitting in on three clinics.
        4. All consents obtained during a staff member's first ten clinics are checked by either the PR or one of the other clinical consultants.
    iii. Following the above, staff can be deemed competent to take consent.
    iv. If issues are identified, staff will undergo further training and will not be allowed to take consent independently until appropriately trained. There have not been any issues that required this in the last 12 months.

2. Data submission

    a. This is a significant issue and has been for the past two years.
    b. The unit feels great regret that no progress has been made since last year in addressing this issue.
    c. There have been ongoing issues with the IT system which have prevented improvement. The provider of Acubase needs to ensure certain fields are mandated and remove some system errors such as adding up of columns incorrectly. This work is ongoing with N Pulsford.
    d. A protocol is in place for data submission and this has been reviewed recently following the recent HFEA audit.
    e. The new protocol has clear details regarding "ownership" of each step.
    f. The Trust has carried out a review of all IT systems within the department and is currently working with IT to enable improvement of the access to programmes within the department.

3. Clinical pregnancy rates

    a. The report states that this has been an ongoing issue over the past three years.
    b. The report gives "relative success rates" only for the period 2005 to 2007; no data is within the report for more recent years, despite publication on the HFEA website of live birth data for the first quarter of 2008 and clinical pregnancy data for the first quarter 2009.
    c. The unit has instigated numerous changes over the past three years to try to improve live birth rates.
    d. The report states that the unit has pregnancy rates below national average for fresh pregnancies <35 years, fresh pregnancies 35-37 years and frozen pregnancies <35 years. Clinical pregnancy data (HFEA website) for Q1 2009, shows that the unit is now within national average for all groups except fresh pregnancy for <35 years.
    e. The unit has always had an aggressive single embryo transfer policy for women under 35 years for minimisation of multiple pregnancy. This is confirmed by a below national average multiple pregnancy rate within the group, which has affected fresh pregnancy rates within this group. This reduction is, we believe, offset by frozen embryo pregnancies.
    f. HFEA published live birth data per embryo transferred in Q1 2008, data published in an attempt to offset the advantage to pregnancy rates caused by multiple embryo transfer. These data confirm the St Marys results are within national average.
    g. The report states that some outcome measure declined between 2007-2008. Published data show that pregnancy rates increased at this time.
    h. The report queries outcome variation from month to month. We have examined this and with the relatively small numbers being treated each month, this variation is not statistically significant.
    i. We believe the above do confirm improving pregnancy rates over the last three years and reflect effective change instigated by the PR.

j. We invited external reviews last year to consider any additional factors as part of our ongoing commitment to improving outcome. We have carefully considered the recommendations.
k. Imminent plans include the improvement of oocyte and embryo selection. The team in Manchester was involved in drawing up the ACE national grading scheme published in 2008. Professor Brison recently took part in an international (Alpha / ESHRE) consensus workshop on oocyte and embryo grading and practice at St Marys will be updated.

4. Nursing issues

a. Nursing management

Following the standing down of the band 7 nurse manager in January 2009 the department has two band 6 nurses job sharing the acting role of nurse manager. The band 7 role is line managed by a band 8b Lead Nurse for Gynaecology. The delay to appoint to the vacant post was intentional as an external review of nursing services was requested in early 2009. Unfortunately the external review in the summer of 2009 did not inform the management team sufficiently with robust recommendations of how to take the nursing team forward; therefore a further external review was commissioned. This took place in December2009 and the report received on the 6th January 2010.

b. Poor maintenance of emergency trolleys
    i. See comments from PR in "PR response" sheet.
    ii. Trust resuscitation document available on request
    iii. All staff spoken to with regards to accountability and responsibility in daily checking resuscitation equipment.
    iv. All nursing staff made aware of importance of escalating and resolving missing equipment or replacing used equipment with as soon as possible.
    v. All staff issued with a copy of Trust guidelines re checking availability of resuscitation equipment (Resuscitation Policy 2009)
    vi. Nurse in charge of shift aware of responsibility for ensuring that all resuscitation equipment within the facility has been checked.
    vii. All nursing to be competency assessed annually to check resuscitation equipment.

c. Keys left in the drugs cabinet
    i. All nurses have access to the Medicines Management Policy which is available on request.
    ii. All nurses have been spoken to about this incident by the Lead Nurse for Gynaecology.
    iii. Nursing staff are aware that this is a disciplinary incident within the Trust.
    iv. This is the clear responsibility of the nurse in charge for the day within the unit.
    v. There has been no recurrence of this since the inspection.

5. Lack of quality indicators and audits.

    a. *T33*

    The following documentation must form part of the quality management system:

    a. a quality manual

    b. standard operating procedures (SOPs) for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence

    c. guidelines

    d. training and reference manuals, and

    e. reporting forms

    Background:

    T33 found not compliant with regard to SOP to describe the process of data entry at the centre. A draft SOP was provided for the inspectors which details the steps taken for data entry by the nursing and administrative staff. An SOP is in place for the entry of data by the Embryology staff. We have been awaiting delivery of a training manual from the database provider before implementing the active SOP.

    Corrective/preventive action to clear non-compliance:

    Training manual has been previously requested from database provider. Until this is provided nursing and administrative staff will work from the draft SOP. The Operational manager is carrying out daily and weekly checks to ensure that the correct data is being submitted to the HFEA. Please see enclosed pathway document.

Other documentation is in place as listed above, which is continually reviewed and revised as part of the document control lifecyle. A register of documentation has been previously supplied to the inspectors.

    b. *T35*

    Required standards of quality and safety, in the form of quality indicators for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, must be established.

    Background:

    T35 Not compliant with regard to quality indicators named in the inspection report. These are being addressed by the senior management team. All actions, timescales and

responsibilities will be recorded as part of the quality management system. With specific reference to areas of quality management the following corrective action is being carried out:

QMS: No annual review performed for the 08-09 period. As we explained to the inspectorate, the unit was closed for four months last year and this coincided with our quality manager being absent for maternity leave. We therefore took the decision to delay the QM review until the unit was fully operational and the Quality manager had returned. This was a deliberate decision to ensure that the annual review would address any additional issues raised following the restructuring of the unit. This review took place on 3rd March 2010

Internal audits: Traceability, Witnessing, Consent taking and Provision of information will be prioritised for audit in the forthcoming year. SOPs are in place for traceability and witnessing and are reviewed as part of document control. Consent taking for nurses has been assessed using a checklist and examination audit, an example of this has been provided to the inspectors. Information provided is currently under review for updates as part of the normal document control lifecycle.

c. T36

Trained and competent persons must audit the activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence against compliance with the approved protocols, the regulatory requirements and quality indicators. These audits must be performed in an independent way, at least every two years. Findings and corrective actions must be documented.

Background:

T36 Not compliant with regard to internal audits not performed for specific areas named in the inspection report. The internal audit calendar is planned by the quality manager and prioritised in conjunction with the quality leads. For the 2008-2009 period 6 internal audits were carried out by the acting quality manager but these did not cover the areas named in the report.

Corrective/preventive action to close non-compliance:

The audit calendar going forward will be reviewed by the quality manager and leads to ensure that the areas named in the inspection report, namely witnessing, traceability, provision of information and data submission will be prioritised over the forthcoming year. See audit calendar attached.

All quality leads will be either updated or trained in carrying out internal audits to ensure sufficient manpower to carry out the audits is available.

6. No annual management meeting in 2009to assess staffing levels etc.

a. An annual management meeting took place in September 2009 as we informed the inspectorate. Minutes are available from this.

7. Embryo stored beyond limit
    a. As explained to the inspectorate, this incident occurred due to inability to locate patient records during the move of our patient records store.
    b. We brought this matter to the attention of the inspectorate during the inspection.
    c. The incident was reported to HFEA immediately after the inspection.
    d. We give assurance that there are no embryos in store beyond their limit.
    e. Old and new SOPs attached (INS/DRM/EMB/003)
    f. Incident report and HFEA response available on request.

8. Need to update patient information booklet
    a. Revision of our patient information booklet was deliberately delayed as the patient pathway has recently changed significantly, with the refurbishment of the department and achievement of the 18 week pathway.
    b. Revision of the booklet is happening currently.

9. No audit of consent taking
    a. See audit calendar.

10. Some information sent with SAQ were not current versions
    a. We wish to apologise that incorrect versions of some information was sent.
    b. At the time of submission of the SAQ, we were asked to submit in hard copy, rather than electronically.
    c. I, as PR, asked a member of the administrative staff to print copies of the requested SOPs etc and failed to notice that some of these were not the current versions.
    d. On the day of the inspection, all up to date copies were shown to the inspectorate.

11. Lack of electrical PAT testing on some equipment.
    a. An immediate assessment of all electrical equipment was carried out.
    b. All remedial works have been completed.
    c. This continues to be covered by the Trust policy.

12. Door to records room left open.
    a. During our recent refurbishment we have moved our notes store to facilitate all assisted conception notes being kept in a single room.
    b. On the day of the inspection, we were at the end of moving and re-filing all notes.
    c. During this movement, the door was left open. However, staff were in the room at the time so the risk of a breach of confidentiality was minimal.
    d. All staff are aware of the need to ensure that this door is secured at all times.
    e. Since the inspection the door has been secured at all times.

13. Issues in relation to low oxygen alarm

a. We regret that on the day an individual member of staff failed to follow the agreed policy. The individual concerned has been retrained.
b. Protocol available on request

14. Difficulties encountered by inspectorate in gaining access to unit.
    a. We apologise for inconvenience caused to the inspectorate.
    b. As explained to the inspectorate information has been sent by the Trust to all patients with appointments, detailing all issues in relation to relocation of the entrance to the assisted conception unit and gynaecology unit.
    c. This has recently been rectified as planned by the opening of the original entrance to the old St Marys building on Oxford Road.