Interim Licensing Report

Centre name: **CARE Sheffield**
Centre number: **0061**
Date licence issued: **01/01/2009**
Licence expiry date: **31/12/2013**
Additional conditions applied to this licence: **None**
Date of inspection: **12/09/2012**
Inspectors: **Sara Parlett (Lead), Debra Bloor and Ian Peacock (observer)**
Date of Executive Licensing Panel: **28/11/2012**

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLCs).

This is a report of an interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2012-14 the focus of an interim inspection is:

- **Quality of service:** the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience:** it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence. In particular we note the progress made by the centre in meeting the HFEA multiple birth rate targets and the positive comments made by patients in relation to their experiences.

The Executive Licensing Panel is asked to note that there are recommendations for improvement in relation to two major areas of non-compliance and three 'other' areas of non-compliance. Since the inspection, the PR has given a commitment to fully implement all of the following recommendations:

Major areas of non compliance:

- The PR should ensure that the data provided to the HFEA regarding patient consent to the disclosure of identifying information to researchers is accurate.
- The PR must ensure that an appropriate level of revalidation is performed after the re-commissioning of all critical equipment.

'Other' areas of practice that require improvement:

- The PR should risk assess whether not labelling all containers at egg collection could lead to misidentification.
- The PR should review the centre's third party agreements (TPAs) against all CoP requirements and take corrective actions to ensure their compliance.
- The PR should provide appropriately redacted donor pen portraits and good will messages to potential recipients before treatment.

Information about the centre

CARE Sheffield is part of the CARE fertility group and has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services.

The centre provided 697 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2012. In relation to activity levels this is a medium sized centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are very important indicators of centres' ability to provide high quality patient care and to meet the requirements of the law.

Outcomes[1]

HFEA held register data for the year ending April 2012 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exception:

- Clinical pregnancy rates following frozen embryo transfer (FET) in patients aged 16-39 are above average at a statistically significant level.

In 2011, the centre reported 17 cycles of partner intrauterine insemination with one pregnancy. This equates to a six per cent clinical pregnancy rate and is consistent with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

In 2010/11 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 25%. This represented performance that was not likely to be statistically different from the 20% live birth rate target.

For the time period April 2011 to March 2012 the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%. This also represents performance that is not likely to be statistically different from the 15% live birth rate target.

[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.
[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

The progress in reducing the clinical multiple pregnancy rates from 2010/11 to 2011/12 suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: egg collection; thawing of embryos and embryo transfer.

All of the procedures observed were witnessed in accordance with HFEA requirements using an electronic witnessing/manual system.

The inspection team was able to review records that were present in patient notes and on the electronic witness system database and concluded that records of both manual and electronic witnessing are maintained.

CoP Guidance requires manual witnessing to be performed at the point of mixing sperm and eggs or injecting sperm into eggs even when an electronic system is in use. However, it was observed during the patient notes audit that these steps are witnessed only using the electronic system. A risk assessment performed by the centre concluded that there is no increased risk of error with this approach and further, that using manual witnessing for this step alone would undermine the validity of electronic witnessing at all other transfer steps.

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 16 patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in all except five cases in the records reviewed. In all five instances where errors were found, the patients or partners had consented to disclosure but the EDI entry recorded that they had not consented.

Discordant consent was also noted in one of these five cases, where the patient had both consented to disclosure to all research and then consented only to non-contact research.

See recommendation one.

Consent: To the storage of cryopreserved material

A review of the centre's records of consent to storage of gametes and embryos showed that gametes and embryos currently in store are being stored in accordance with the consent of the gamete providers and are within the consented storage period.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: patients were seen promptly on arrival; telephone calls were responded to quickly, the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Patient experience

During the inspection visit we spoke to seven patients who provided feedback on their experiences and observed interactions between centre staff and patients. A further nine patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive with six of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions, with one exception (see below).

At the time of the inspection the centre did not share pen portraits or goodwill messages written by donors with the potential recipients of donor gametes. CoP Guidance states that parents and patients who are seeking treatment with donated gametes should have access to this information. However, the CARE group considered that the risk of accidentally releasing identifiable information was too great and imposed a universal restriction on the sharing of this information. On inspection, the PR confirmed that it had been decided to lift this restriction and policies were currently being drafted to guide the redaction of potentially identifying information. See recommendation five.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

From the information submitted by the centre in their self assessment questionnaire (SAQ) and from observations during the visit to the centre, the inspection team identified the following non-compliances:

- Revalidation of re-commissioned equipment was not appropriately performed for one piece of critical equipment.

  See recommendation two.

- At egg collection, not all containers used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code. Embryologists check that the class II cabinet is clear of containers at the start of each egg collection and this check is recorded on the laboratory worksheet. It was not clear if a similar check is performed for the hot block in theatre.

  See recommendation three.

- The SAQ responses identified that the centre has not fully evaluated the ability of all third parties to meet the required standards nor does the content of all TPAs comply with SLCs. One TPA with a laboratory providing diagnostic services was reviewed on inspection. Both the TPA and the accompanying information demonstrating the laboratories CPA accreditation status had expired. The inspector concluded that the centre has not been proactive either in reviewing TPAs or in ensuring that third parties meet the requirements of relevant SLCs. The PR acknowledged that this has been an issue of concern at other CARE centres and provided draft copies of a new TPA template being developed for use across the CARE group.

  See recommendation four.

Compliance with recommendations made at the time of the last inspection

Following the interim inspection in August 2010 recommendations for improvement were made in relation to three areas of major non-compliance and two 'other' areas of non-compliance.

The PR provided information and evidence that all but one of the recommendations were fully implemented within the prescribed timescales.

The following recommendation has not been implemented:

- The PR must assure the accuracy of data provided via EDI regarding consent to the disclosure of identifying information to researchers.

  See recommendation one.

On-going monitoring of centre success rates

The centre has not been issued with any performance alerts in 2012.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out.

This centre has a good record of data submission and of compliance with related regulatory requirements. The quality of data currently supplied to the HFEA contains a low level of error and the centre works proactively with the HFEA to correct errors and provide missing data. Nevertheless, a small number of form submissions are outstanding at the time of writing and intention to treat (ITT) forms are not always submitted within the timeframes required.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
None			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. In five cases the patient's consent to disclosure to researchers had been incorrectly reported to the HFEA. General Direction 0005. **This was identified as an area for improvement at the time of the last inspection.**	The errors identified during the inspection should be corrected immediately. The centre should review its related systems and processes and where appropriate address the cause(s) of the discrepancies going forward. Three months and six months after the inspection the PR should audit a random sample of twenty sets of patient records to ensure that consent to disclosure to researchers taken from patients has been correctly transferred for entry on to the HFEA register. The records audited should have had this consent completed within the previous	Corrections have been made. Discussed with Administration staff that correct information entered onto CIS. Check to be introduced. Unit Management has set up audit to be performed on 20 sets of notes in DEC 12 and March 12 to assess the effectivness of the measures above and it will be submitted by the dates below Going forward:- Following the previous inspection auditing was set up to be	The inspection team acknowledges the PR's response and will continue to monitor progress in implementing the recommendation.

Discordant consent was also noted in one of these five cases, where the patient had both consented to disclosure to all research and but then consented only to non-contact research.	three months. The audits should be submitted to the inspector by 12 January 2013 and 12 April 2013. The centre should ensure that consent obtained from patients does not conflict with other consenting decisions they have made.	performed twice a year during the internal patient tracer audit on 5 patient notes. The EDI audit will be expanded to include the responses recorded on CIS for research Nursing staff to check patient has understood the options and completed correctly once COD received before filling.	
2. Revalidation of re-commissioned equipment was not appropriately performed for one piece of critical equipment. SLC T25.	The PR must ensure that an appropriate level of revalidation is performed after the re-commissioning of all critical equipment. Documented evidence of the test results must be retained. This should be implemented immediately. The centre's standard operating procedure for revalidation following repair and re-commissioning of equipment should be reviewed, revised and submitted to the inspector by 12 December 2012.	Revalidation discussed at local embryology meeting 11th Sept and at the Laboratory Managers meeting 20th September. After discussion the following policies were updated immediately to include re-commissioning of equipment. QMS 6.4.1- Up dated to include re-commissioning and re validation. SH Lab 107- New, repaired and re-commissioned equipment form- outlining testing for initial validation and re validation signing off before use.	The inspection team acknowledges the PR's response and will continue to monitor progress in implementing the recommendation.

		The validation documentation is presently under full review including introducing a new change control record. All reviewed documents will be submitted before the deadline 12th Dec	

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
3. At egg collection not all containers (dishes, vials, ampoules, tubes etc) used during the procurement of eggs are labelled with the patient's/donor's full name and a further identifier or a uniquely identifying donor code (including labelling in the form of electronic tags). Embryologists check that the class II cabinet is clear of containers at the start of each	The PR should risk assess whether not labelling all containers at egg collection could lead to misidentification and take corrective action where appropriate. The risk assessment and details of any action taken should be submitted to the inspector by 12 December 2012.	Risk assessment completed- An audit of the processes in place needs to be completed to validate the risk assessment process and will be submitted before 12th Dec An additional theatre check has been introduced to sign for a clear area at start of day and inbetween cases. This new check and the embryology clear station check will be auditted to update the risk	The inspection team acknowledges the PR's response and will continue to monitor progress in implementing the recommendation.

egg collection and this check is recorded on the laboratory worksheet. It was not clear if a similar check is performed for the hot block in theatre. SLC T101.		assessment before above deadline	
4. The centre has not fully evaluated the ability of all third parties to meet the required standards nor does the content of all TPAs comply with SLCs. SLCs T111 – T117.	The PR should review the centre's TPAs against all CoP requirements (notably SLCs T111 – T117) and take corrective actions to ensure their compliance. Confirmation of completion of this action should be provided to the inspector by 12 March 2013.	A New template for TPA's has been introduced following CARE Nottinghams inspection comments. Completion by all companies will be checked by Debbie Mansfield and reported to the PR and inspection team by 31.12.12	The inspection team acknowledges the PR's response and will continue to monitor progress in implementing the recommendation.
5. Donor pen portraits and good will messages are not currently provided to persons seeking treatment with donor gametes. On inspection, the PR confirmed that it had been decided to lift this restriction and policies were currently being drafted to guide the redaction of potentially identifying information.	The PR should ensure that the centre's new policy for providing pen portraits and good will messages is fully implemented by 12 December 2012.	Egg Donation meeting Aug 12 had identified issues with providing pen portraits guidance was given by PR. Clinical Meeting due in Nov all staff to be made aware of addition to nursing checklist for recipients that Pen portrait offered and whether given. Pen Portraits to become an agenda item for egg donation meeting to feedback issues.	The inspection team acknowledges the PR's response and will continue to monitor progress in implementing the recommendation.

CoP Guidance 20.1a.		Audit on information offered and given for Dec deadline	

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

28 November 2012

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 2

Centre 0061 – (CARE Sheffield) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Jasper Squire, Computer Programmer Paula Robinson, Head of Business Planning	Joanne McAlpine

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has been licensed since 1992.

2. The Panel noted that the centre offers a full range of fertility services and provided 697 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2012, and that in relation to activity levels this is a medium sized centre.

3. The Panel noted that at the time of the inspection the Inspectorate identified two major and three other areas of non-compliance.

4. The Panel noted that since the inspection visit the Person Responsible (PR) has given a commitment to implementing all of the above areas of non-compliance that were identified at the time of the inspection.

5. The Panel noted that the data held on the HFEA register for the year ending April 2012 shows that the centre's clinical pregnancy rates are in line with national averages with the exception that clinical pregnancy rates following frozen embryo transfer (FET) in patients aged 16-39 are above average.

6. The Panel noted that for the time period April 2010 to March 2011 the centre's multiple clinical pregnancy rate for IVF, ICSI and FET cycles for all age groups was 25%, and that this represented performance that was not likely to be statistically different from the 20% live birth rate target.

7. The Panel noted that for the time period April 2011 to March 2012 the centre's multiple clinical pregnancy rate for IVF, ICSI and FET cycles for all age groups was 18%, which represents performance that is not likely to be statistically different from the 15% live birth rate target.

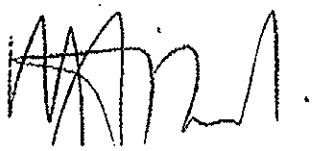
8. The Panel noted that the Inspectorate identified five cases where the patient's consent to disclosure to researchers had been incorrectly reported to the HFEA. The Panel noted the PR's response, which was to conduct an audit on 20 sets of notes in December 2012 and March 2013 to assess the effectiveness of the measures taken and a detailed plan going forward.

9. The Panel noted and endorsed the Inspectorate's recommendation to continue to monitor progress in implementing the corrected errors on the consent to disclosure forms to the HFEA and urged the PR to comply with this recommendation within the indicated timescales.

Decision

10. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence with no additional conditions.

11. The Panel noted the planned audits taking place on 6 January and 12 April 2013 regarding the consent to disclosure for research data, and urged the PR to keep the Inspectorate informed of the outcome.

Signed: 

Date: 10/12/2012

Juliet Tizzard (Chair)