Licence Committee - minutes

Centre 0185 (CARE Manchester) - Interim Inspection Report

Thursday, 14 July 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Committee members	Andy Greenfield (Chair) Ruth Wilde Anita Bharucha Margaret Gilmore	
Members of the Executive	Ian Brown Trent Fisher	Head of Corporate Governance Secretary
Legal Adviser	Sarah Ellson	Fieldfisher LLP
Observers	None	

Declarations of interest

- members of the committee declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

The following papers were considered by the committee:

- interim inspection report
- previous licensing minutes from the last three years
- executive update (tabled)

1. Consideration of application

1.1. The committee noted that CARE Manchester (centre 0185) has held a licence with the HFEA since April 1999 and that the centre provides a full range of fertility services, including embryo testing.

1.1. The committee noted that the centre's licence is due to expire on 30 September 2018.

1.2. The committee noted that in the 12 months to 31 January 2016, the centre provided 1827 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre. It also noted that for the period 1 November 2014 to 31 October 2015, HFEA-held register data for IVF and ICSI showed the centre's success rates were in line with national averages.

1.3. The committee noted that, in 2014, the centre reported 27 cycles of partner insemination with two clinical pregnancies. This represents a clinical pregnancy rate which is likely to be consistent with the national average. Between 1 November 2014 to 31 October 2015, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 11%. This means that the centre's multiple pregnancy rate is not statistically different from the 10% maximum multiple live birth rate target for this period.

1.4. The committee noted that at the time of the interim inspection on 1 March 2016, two critical, two major and one other area of non-compliance were identified:

- Critical
  - The PR should ensure that gametes and embryos are stored in accordance with the gamete provider's consent and where relevant, the permitted statutory storage period.
  - The PR should ensure that effective consent to legal parenthood is obtained.
- Major
  - The PR should review whether there are barriers to the implementation of learning from HFEA guidance, their own incidents and/or guidance from other sources.
  - The PR should ensure that CE-marked medical devices are used wherever possible.
- Other
  - The PR should ensure that audits conducted assess the centre's compliance with regulatory requirements, approved protocols and quality indicators, and that standard operating procedures (SOPs) are developed to cover all activities.

1.5. The committee noted that at inspection issues of legal parenthood consent had been identified and that the centre's legal parenthood audit, carried out in 2014, identified four couples with anomalies on their legal parenthood consent forms and, at the time, the previous PR provided assurances to the HFEA of the robustness of the audit and that all four cases identified where resolved.

1.6. The inspection, carried out on 1 March 2016, found that two of the cases identified had not been resolved and contained anomalies in relation to legal parenthood consent. A further sample was taken from the same time period and a further two cases were identified to have anomalies relating to legal parenthood consent. The previous PR was not available on the day of the inspection, therefore further discussions regarding the original audit methodology and findings were not possible.

1.7. The summary for the Committee explained that, as a consequence of the nature and severity of the areas of concern identified during the inspection on 1 March 2016, a management review

meeting was held on 8 March 2016 in accordance with the HFEA's Compliance and Enforcement policy. This resulted in the decision to schedule a second inspection visit which was undertaken on 16 March 2016. The previous PR informed the inspectorate that since the original inspection the centre had performed an additional audit into legal parenthood consent and that a total of 17 cases containing anomalies had been identified and legal advice was being sought for those affected.

1.8. Following the second inspection, a further management review was held on 14 April 2016 to evaluate the findings of both inspections. The management review resulted in the matter being referred to a Licence Committee.

1.9. The committee had regard to the fact that that since the inspection the centre has appointed a new Person Responsible (PR) (approved on 20 May 2016). It also noted a new Licence Holder (LH) was agreed on 21 March 2016.

1.10. The committee noted that since the inspection the newly appointed PR has provided assurance that recommendations for two critical and one major areas of non-compliance have been implemented and has committed to implementing all of the remaining recommendations within the prescribed timescales.

1.11. The committee carefully considered the tabled update in and noted that on 12 July 2016 the newly appointed PR informed the HFEA that the centre had identified further anomalies in relation to legal parenthood, the extent of which was being verified.

1.12. The committee noted that the newly appointed PR had written to the HFEA expressing doubt over the robustness of the audit carried out by the centre on sperm donor treatments between January 2016 – June 2016. In the email the PR committed to ensuring that all issues of legal parenthood consent were identified and resolved by:

- Stopping the audit of the historic patients, so that the centre can first concentrate on the recent cycles (January-June 2016); repeating the recent audit in order to assess current practice.
- Completing the audit using a newly devised corporate audit tool, which includes a method for identifying and recording the birth mother and all other relevant details.
- Having the audit conducted by PRs from other CARE units, to provide some external assessment of current practice and to facilitate shared learning across the group.
- Then going back to re-audit the historical treatments in the same way.
- Dealing with any non-compliances in the same manner as others already identified, by informing the patients and offering legal advice and support and also informing the HFEA.

1.13. The committee noted that the Group Medical Governance Director of the CARE group had voluntarily agreed to cease the provision of treatment with donor sperm, or embryos created with donor sperm, at CARE Manchester immediately until such time that the HFEA is satisfied that the procedures for obtaining effective legal parenthood consent are robust.

1.14. The committee expressed great concern regarding the continuing issues of legal parenthood consent at centre 0185. The committee noted the importance of all centres obtaining correct legal parenthood consent from patients.

1.15. The committee looked to its legal adviser to provide clarity on what its powers are under the Act and what actions the committee could take.

1.16. The Legal Adviser referred the Committee to the Compliance and Enforcement policy and reminded the Committee that in taking action or making recommendations to the Licence Committee, the Authority's compliance department will take account of the attitude of the PR and the centre's compliance history, the risk to patients and the impact on people using the service, and that also, throughout the policy, the need to respond proportionately was emphasised.

"Proportionality" in such situations could be understood to be taking the least necessary enforcement action to adequately address the concerns raised in the particular case.

1.17. The Legal Adviser indicated that the Committee should use its decision tree for interim inspection/incident and would see that, if it considered that enforcement action might be necessary it could, as the Licence Committee, consult the decision tree for variation, revocation or suspension of licence.

1.18. The Legal Adviser reminded the Committee that the Centre has not applied for any variation of its licence so any decision to add a condition would have to comply with a number of legal requirements. In such situations, as set out in the decision tree, the Act requires the Committee to be satisfied that one or more of the grounds for revocation of the licence exist, albeit the Committee could then decide that it would be more proportionate to add a condition or conditions. The Executive had referred to s18(2)(i) of the Act, which refers to a material change of circumstances; a number of grounds were clearly not relevant but one possible ground concerns circumstances in which a PR has failed to discharge their duties under s17. However, in this case, the Committee would have regard to the fact that the PR is new in post.

1.19. If the Committee thought one or more of the grounds set out in s18(2) was met, it would have grounds to revoke the centre's licence, but it could opt for a lesser enforcement action by imposing conditions on the licence. Any conditions would need to clearly set out what was required of the clinic.

1.20. If the Committee chose not to take these more formal steps it was open to them to make clear recommendations and their reasons could highlight any reliance placed on the voluntary restrictions offered by the clinic. Both a breach of conditions and a failure to comply with the voluntarily offered restrictions would both likely be viewed as serious matters which would trigger potential escalation of enforcement action.

1.21. The committee noted that the PR has been actively engaging with the HFEA with regards to the issue of legal parenthood consent.

2. Decision

2.1. The committee had regard to the advice of its legal adviser. It decided to continue the centre's treatment (including embryo testing) and storage licence. It decided not to impose conditions on the centre's licence at this time. As the PR has provided immediate and full engagement and appeared to be being proactive with the HFEA, the committee did not consider that she has failed to discharge her duties under s17.

2.2. The committee noted that, with the centre voluntarily ceasing all treatments involving donor sperm, including embryos that have been created with donor sperm, there appeared to be no immediate risk to patients at the centre and the Committee decided that the voluntary steps meant that it was not necessary to consider more formal enforcement action.

2.3. The committee was clear that, as indicated by the PR, no treatment involving donor sperm, or embryos that have been created with donor sperm, is to resume until:

- the centre has provided the newly devised corporate audit tool to the executive so that it can decide whether it is satisfactory; and
- The executive has reviewed and is satisfied with the outcome of the new audit of January 2016 - June 2016 data; and
- A satisfactory procedure for obtaining legal parenthood consent has been formulated and reviewed by the executive.

2.4. Given the issues with legal parenthood and the related audits (which need to reviewed) the committee request that a progress report from the centre, regarding the issues of legal parenthood, be presented to the Licence Committee at its meeting on 8 September 2016.

2.5. The committee further requests that the centre comply with the recommendations set out in the interim inspection report within the required timeframes.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Andy Greenfield

Date

25 July 2016

Interim Licensing Report

Centre name: CARE Manchester
Centre number: 0185
Date licence issued: 1 October 2014
Licence expiry date: 30 September 2018
Additional conditions applied to this licence: None
Date of inspections: 1 March 2016 and 16 March 2016
Inspectors: Karen Conyers (lead), Gill Walsh
Date of Licence Committee: 14 July 2016

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 (SLC).

This is a report of an unannounced interim inspection (1 March 2016) and a second scheduled inspection (16 March 2016) 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 2015-2017 the focus of an interim inspection is:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

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.

Summary for the Licence Committee

The Executive recommends the continuation of the centre's licence subject to the recommendations made in this report being effectively implemented within the prescribed timescales. The Executive will continue to monitor the centre's performance. Failure to implement the recommendations relating to these critical areas of non-compliance may result in the submission of a further report to a licensing committee with the recommendation that regulatory action be taken in accordance with the HFEA's Compliance and Enforcement Policy.

As a consequence of the nature and severity of the areas of concern identified during the inspection on 1 March 2016, a management review meeting was held on 8 March 2016 in accordance with the HFEA's Compliance and Enforcement policy, to discuss the risk to patients, particularly relating to consent to legal parenthood, and to consider the recommendation for continuation of this centre's licence. It was concluded at that meeting that there was insufficient information to make a fully informed assessment of the quality of the centre's audit of legal parenthood consent, or to provide assurance that the centre's processes for obtaining consent to legal parenthood are robust. Consequently, it was agreed that a second inspection of the centre be scheduled, with notice, to ensure key personnel and records were available. This inspection was conducted on 16 March 2016 by the same inspection team that undertook the inspection on 1 March 2016.

Following the second inspection, a further management review was held on 14 April 2016 to evaluate the findings of both inspections. The management review concluded that the inspection team was assured from their inspection findings that the centre's current procedures for obtaining consent to legal parenthood are compliant and therefore there is no immediate risk to couples requiring treatment with donated gametes or embryos where legal parenthood consent applies. However, in consideration of the nature and severity of the non-compliances identified on inspection, it was agreed that this report should be considered by a Licence Committee of the HFEA rather than the Executive Licensing Panel (ELP).

The Executive considers that the PR has failed to discharge his duty under section 17 of the HF&E Act 1990 (as amended), because he provided assurance in October 2015 as to the robustness of the centre's 2014 audit of consent to legal parenthood, whereas there was no foundation to do so (see 'Legal Parenthood' section below). Further to this, anomalies identified in the 2014 audit were not acted upon in accordance with HFEA guidance.

The PR tendered his resignation as PR to the HFEA. An application to appoint a new PR was submitted by the centre's Licence Holder (LH) and was agreed by the ELP on 20 May 2016. The new PR has confirmed her commitment to implementing the recommendations in this report and her agreement with the PR responses contained in this report.

Following the retirement of the centre's LH, the appointment of the CARE corporate body as LH was agreed by the ELP on 21 March 2016, and the CARE group's Medical Governance Director has been identified as the named contact person.

The Licence Committee is asked to note that since the inspections, the Executive considers that both the previous PR, new PR and new LH have engaged fully with the HFEA in addressing the areas of concern identified.

This inspection report makes five recommendations for improvement in relation to two critical, two major and one 'other' area of non-compliance or poor practice.

In responding to the report the PR has provided assurance that the following recommendations have been implemented.

Critical areas of non-compliance:

- **The PR should ensure that gametes and embryos are stored in accordance with the gamete provider's consent and where relevant, the permitted statutory storage period.**
- **The PR should ensure that effective consent to legal parenthood is obtained.**

Major area of non-compliance:

- The PR should review whether there are barriers to the implementation of learning from HFEA guidance, their own incidents and/or guidance from other sources.

The PR has also given a commitment to fully implement the following recommendations in the prescribed timescales.

Major area of non-compliance:

- The PR should ensure that CE marked medical devices are used wherever possible.

'Other' area of practice that requires improvement:

- The PR should ensure that audits conducted assess the centre's compliance with regulatory requirements, approved protocols and quality indicators, and that standard operating procedures (SOPs) are developed to cover all activities.

Information about the centre

CARE Manchester is located in Manchester and is part of the CARE Fertility group. The centre has held a licence with the HFEA since 1999. The current licence was varied to reflect a change of LH on 21 March 2016, a change in premises on 6 May 2016, and change of PR on 20 May 2016.

The centre provides a full range of fertility services including embryo testing. Other licensed activities of the centre included storage of gametes and embryos.

The centre provided 1827 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2016. In relation to activity levels this is a large centre.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 November 2014 to 31 October 2015 show the centre's success rates are in line with national averages

For the year 2014 the centre reported 27 cycles of partner insemination with two clinical pregnancies. This represents a clinical pregnancy rate of 7%, which is consistent with the national average. For 2015 the centre reported 17 cycles of partner insemination with two pregnancies. Data has not been analysed for this period, however this pregnancy rate is likely to be consistent with the national average.

Multiple births[2]

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

For the period from 1 November 2014 to 31 October 2015, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 11%: This means that the centre's multiple live birth rate is likely to meet the 10% multiple live 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. Some laboratory activities were observed in the course of the inspection (egg collection; sperm preparation) and the inspector was able to discuss witnessing with staff and to review witnessing documented in patient records. All the procedures observed were witnessed using an electronic witnessing system and manually, where required, in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On the day of inspection, the inspection team reviewed the centre's audit of stored gametes and embryos (see 'Quality Management System' section below) and the centre's 'bring-forward' system. Centre staff informed the inspection team of five samples in storage for which consent to storage had expired; one set of oocytes, one set of sperm and three sets of embryos (see recommendation 1). The inspection team noted that the centre staff had been in regular communication with the patients before the consents expired, advising

[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. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2] The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

them of the upcoming expiry of their storage consent, the requirements to extend storage and requesting action from them. Therefore, the inspection team does not consider that the 'bring forward' system has failed, although the date of expiry was incorrect for one of these samples (see 'Quality Management System' section below). Between the first and second inspection, all the patients had extended their consent to storage for their gametes or embryos. However, there remains an unresolved issue as to whether the clinic may lawfully continue to store samples in one case. The clinic has sought legal advice and there is ongoing dialogue between the HFEA and the centre about the matter separate to this report.

Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; 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.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following prescribed SOPs and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing, stored samples, controlled drugs and infection control.

The centre's QMS is broadly compliant with requirements because:

- The centre's audit of storage does not include a comparison of the consent expiry dates recorded in the database against that recorded in the patient's consent forms thereby reviewing the accuracy of the electronic records. The inspection team consider that there is a risk that an inaccuracy in the electronic records (which are the primary source of information for the 'bring forward' system) could lead to gametes or embryos being stored outside the terms of the gamete provider's consent, as has been determined to be the case for one sample in storage in the centre (see recommendation 5).
- The centre does not have a SOP to direct actions to be taken in the event of a clinical emergency, a non-clinical emergency or needle stick injuries (see recommendation 5).

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture, then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the centre's audits of witnessing, stored samples, management of medicines and infection control;

- the use of CE marked medical devices;
- the content of the centre's website;
- the use of the most recently issued HFEA consent form versions;
- the centre's audit of legal parenthood;
- The HFEA reports of adverse incidents from 2010-2012 and 2013 and the centre's actions in response to their own incidents;
- HFEA Clinic Focus articles regarding: screening requirements, equipment failures.

The inspection team consider that the centre is only partially effective in implementing learning from HFEA guidance and from their incidents (see recommendation 3). This is because:

- the centre has not been effective in implementing HFEA requirements regarding the audit of consent to legal parenthood (see 'Legal Parenthood' section below);
- the centre has not ensured compliance with guidance regarding the use of CE marked medical devices (see 'Equipment and Materials' section below) and;
- corrective action taken in response to breaches of confidentiality identified since the time of the last inspection have not been effective in preventing similar incidents.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be compliant with guidance.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be compliant with guidance. The centre has conducted a risk assessment of needle stick injuries but does not have a SOP directing the actions to be taken if such an injury occurs (see 'Quality Management System' section above).

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed in the course of the inspection: culture medium, plasticware and consumables. We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices wherever possible, because the following medical devices are not CE marked: culture medium, medium used for egg collection, 5ml tubes (see recommendation 4).

Patient experience

During the inspections, patients were not available to speak with the inspectors about their experiences at the centre. Twelve patients provided feedback directly to the HFEA in the time since the last inspection. Nine of these individuals provided additional written feedback which included both positive and negative experiences. This patient feedback was shared with the PR and centre management. Assurance was provided that there is an effective mechanism in place whereby the centre regularly seeks and acts upon patient feedback. Although no specific recommendation is considered necessary the centre's inspector will continue to monitor the centre's patient feedback in liaison with the PR and centre management.

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

- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions and;
- maintains an effective system for responding to patient phone calls.

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

Information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment and observations during the visits to the centre indicate that the centre is compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the licence renewal inspection in 2014, recommendations for improvement were made in relation to two major and four 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all the recommendations were fully implemented within the required timescales. However, one area of non-compliance was also found on this inspection: the use of non CE marked medical devices (see Equipment and Materials section above).

On-going monitoring of centre success rates

Since the last inspection in March 2014 the centre has not received any HFEA risk tool alerts related to their success rates.

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 information is held in the HFEA Register.

Historically the centre has experienced some issues regarding the submission of data to the HFEA register. The Register team is working with the centre's register contact to address these issues and does not consider that a formal recommendation is warranted at this stage.

Legal parenthood

Where a couple to be treated with donated gametes or embryos are not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided, or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient to obtain a court declaration to confirm legal parenthood.

In February 2014, the HFEA asked all centres to audit their records in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided a summary report of the audit to the HFEA within the required timeframe. The PR sought legal advice on the anomalies identified and informed the HFEA in March 2015 that he considered that these were all resolved and no further action was necessary.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded verbally and provided assurance of the robustness of the audit and staff competency.

At the inspection on 1 March 2016, the first since the 2014 request for legal parenthood consent audit, the centre's audit methodology and findings were reviewed. The centre's audit had identified four couples with anomalies on their legal parenthood consent forms and the PR had advised the HFEA that he considered all four cases had been resolved. The inspection team reviewed the records of these four couples and in two of the four the inspection team was satisfied that the issues identified were resolved. However, in the other two cases, a legal parenthood consent form was absent in one case and incomplete in the other. A further sample of records from the same time period was reviewed by the inspection team, including records for two couples who met the criteria for completing consents to legal parenthood. Both of these records were found to contain anomalies in the consent to legal parenthood forms. These findings were immediately fed back verbally to senior centre staff but the PR was not available on the day of the inspection, therefore further discussions regarding the original audit methodology and findings were not possible.

Such was the inspection team's concern that a second inspection visit was undertaken on 16 March 2016. The PR informed the inspection team that subsequent to the inspection on the 1 March 2016, centre staff had audited the records of consent to legal parenthood for all patients who had had treatment with donor sperm, donated embryos or cryopreserved embryos created with donor sperm, from 6 April 2009 to date. The methodology used and findings of this audit were provided on inspection. The audit appeared to be robust and identified a total of 17 cases (including the four cases identified in the centre's 2014 audit

and the two cases identified by the inspection team on 1 March 2016) with anomalies in the consents to legal parenthood. The PR advised the inspection team that legal advice was being sought regarding all cases where anomalies were identified (see recommendation 2).

The inspection team also reviewed the centre's current procedures for obtaining consent to legal parenthood. The PR and lead nurse described the process for obtaining consent to legal parenthood and confirmed that additional training in this area of practice had been provided to all relevant staff in 2015 and 2016 and that their competence had been assessed. Evidence of this was shown to the inspection team.

To provide further assurance of the effectiveness of the centre's current procedures, the inspection team reviewed 11 sets of records where treatment with donor sperm had been provided between July 2014 and December 2015, in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood and the offer of counselling were seen to be in place prior to treatment in all cases except two, which had already been identified by the centre's audit in March 2016. The inspection team was able to gain sufficient assurance that the centre's current processes for obtaining consent to legal parenthood are satisfactory.

Since these inspections, the centre has fully engaged with the HFEA and has committed to act in accordance with HFEA guidance in support of couples affected by anomalies in consent to legal parenthood.

Following the inspections, the PRs and LH have kept the HFEA updated on the actions taken in response to the findings of the audit, the specifics of the issues identified for each of the 17 couples, the contact or attempts at contact that have been made, and the further actions planned. On the basis of this information, the Executive is assured that the centre has taken actions and is offering appropriate support and guidance to the couples affected. Progress with these actions will be followed up by the centre's inspector.

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 areas 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	Executive review
Consent to storage 1. On the day of the inspection the centre did not have written effective consent to storage for two sets of stored gametes (one set of oocytes and one set of sperm) and three sets of stored embryos. At the time of the second inspection, consent to storage was in place for all	The PR should ensure that gametes and embryos are stored in accordance with the gamete provider's consent and, where relevant, the permitted statutory storage period. The centre should continue to engage with the HFEA regarding this matter and ensure that there is ongoing communication on this case. The PR is reminded of	We acknowledge that this is a serious matter and are in communication with HFEA to resolve the query as to whether we can legally continue to store the cryopreserved eggs of one patient even though the egg providers consent to extended storage and medical practitioner's statement were completed after the end of the	The Executive acknowledges the PR's response and her commitment to continue to engage with the HFEA regarding this case. This will be followed up separately to this report. The PR has provided a copy of the root cause analysis and the actions taken and those that are planned.

samples however, there remains in one case, an unresolved issue as to whether the clinic may lawfully continue to store the samples. The clinic has sought legal advice and there is ongoing dialogue between the HFEA and the centre about the matter. Schedule 3, 8(1) HF&E Act 1990, as amended.	HFEA guidance in relation to the timely disposal of cryopreserved material if there is the potential for legal challenge (see Chair's letter CH(03)03).	10 year statutory storage period. We will continue to do everything we can to assist in the resolution of this issue. We have undertaken a root cause analysis and are in the process of drafting a report of the findings. The investigation showed that the mistake arose because the consented storage period entered into the CARE electronic storage record was 11 years rather than 10. An audit of all other material stored beyond 10 years is being completed. An additional audit of 10% of all stored material to ensure the accuracy of the electronic record will be undertaken as advised below. We are also exploring a system change that will reduce the risk of an incorrect storage period being selected and highlight the need for a medical practitioner's statement as the 10 year statutory storage period approaches.	An audit of the accuracy of the consent period recorded in the centre's bring forward system database is to be provided in response to another recommendation in this report. No further action is required.

Consent to legal parenthood 2. The centre's audit of legal parenthood dated 15 March 2016 identified a total of 17 couples with anomalies in their consent to legal parenthood forms. CE(14)01and CE(14)02. SLC T36.	The PR should ensure that proper consent to legal parenthood is obtained. The centre should seek legal advice regarding the legal parenthood consenting anomalies identified by the centre's March 2016 audit. When responding to this report, the PR should provide a summary of the legal advice obtained and detail of the actions planned in response to this advice, including how the centre intends to communicate with and support all couples affected. The PR should conduct a root cause analysis into the circumstances which led to the failings subsequently identified in the centre's legal parenthood audit conducted in 2016, a copy of which should be provided to the centre's inspector by 16 June 2016. An audit of treatments between 6 April 2009 and March 2016 where consent to legal parenthood is required has been provided and	A CARE wide programme of parenthood consent training is being implemented and procedures for audit will also being reviewed. CARE has had expert legal advice on all of the anomalies in parenthood consent forms identified in the course of the audit. The advice, which was provided verbally, and recommended actions for communication are summarised in an appended document. All but two of the couples that our legal advisers confirmed had anomalies that may impact on the status of the non birth partner as legal parent have been contacted in writing. We are still in the process of establishing the contact details for two patient couples but all other affected couples have had letters explaining the anomalies in their forms and the potential impact on parenthood;	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. The PR has provided a detailed report of the actions taken and those planned in order to communicate with and support all couples affected. The PR has also provided a copy of the root cause analysis and investigations that have been conducted to establish the circumstances leading to the failings relating to the consent to legal parenthood and the reasons why the 2014 audit failed to identify these errors in consent. The Executive considers that the analysis has been comprehensive, provides evidence of a thorough investigation of the issue, and has resulted in learning both locally and at a corporate level. The action plan includes review the consent pathway, processes to check consent,

	is therefore not requested again. The PR should conduct a further audit of all treatments provided where legal parenthood consent is required, since the date of the audit in March 2016 to 1 June 2016, and provide a copy of the findings of the audit to the centre's inspector by 16 June 2016.	offering counselling; giving a full apology, and; giving a commitment to provide full support, including financial support, to resolve any issues arising as a result of the anomalies. At 20 May 2016, of the 17 cases with anomalies in parenthood consent forms, two patient couples have confirmed they were married or in a civil partnership at the time of treatment; legal advice provided to CARE with respect to two cases was that the anomalies in the forms are such that the status of the second parent could not be challenged; four patient couples are actively seeking legal advice funded by CARE. The terms of reference for the root cause analysis have been drafted and an expert external to CARE Manchester identified to conduct the review. A report of the RCA findings will be provided within the prescribed	further staff training and ongoing audits of practice. The PR has also provided the requested audit of consent to legal parenthood for treatments since the March 2016 audit. The Executive notes that no anomalies were identified in the centre's repeat audit providing further assurance of the centres current processes. No further action is required with respect to the recommendations in this report. Progress with the planned actions following the findings of the March 2016 audit will be followed up by the centre's inspector.

		timeframe. An audit of parenthood consents completed since March 2016 will be conducted and a full report provided within the prescribed timeframe.	

‘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;
- which can comprise 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	Executive review
Quality management system 3. The centre had not fully implemented HFEA guidance in relation to the audit of consent to legal parenthood and the use of CE marked medical devices, and has not demonstrated effective learning from their own incidents. SLC T32.	The PR should conduct a review to determine where there are barriers to the implementation of learning from HFEA guidance, their own incidents, and/or guidance from other sources, and identify a course of action to ensure that effective learning can be demonstrated. The PR should provide a summary of this review, including detail of any actions taken in response to the findings, to the centre’s inspector by 16 June 2016.	A wider understanding of the clinic’s apparent weakness in learning from guidance, incidents and our own audits will fall within the remit of the RCA referenced above. A report will be provided within the prescribed timeframe. Overall CARE as an organisation has implemented a clinical governance structure where learning from any incident or complaint is communicated to the whole group.	The Executive acknowledges the PR’s response and her commitment to fully implement this recommendation. The PR has provided a summary of the requested review which includes actions that have been taken and those that are planned. No further action is required.

Equipment and materials 4. The following medical devices used by the centre are not CE marked: culture medium, medium used for egg collection, 5ml tubes. SLC T30. This was identified as an issue at the last inspection.	The PR should ensure that CE marked medical devices are used wherever possible. It is expected that by 16 September 2016, all medical devices used by the centre will be CE marked for their designated use.	We fully expect to be compliant with this requirement within the prescribed timeframe.	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. The PR has provided a copy of the CARE group review of the CE mark status of medical devices currently in use and has confirmed that CE marked medical devices will be in use by 16 September 2016. Further action is required.

► 'Other' areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non-compliance, but which indicate a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive review
Quality management system 5. The centre's audit of storage does not include a comparison of the consent expiry dates recorded in the database against those recorded in storage consent forms in patient records. It is noted that the HFEA's assessment framework recommends this non-compliance be classified as 'major'. Given that this was found in one incidence only, the inspection team do not consider there is a systemic failure and therefore this has been classified as an 'other' non-compliance. The centre does not have a SOP to direct actions to be	The PR should ensure that audits conducted assess the centre's compliance with regulatory requirements, approved protocols, quality indicators, and that SOPs are developed to cover all activities. The PR should undertake the audit specified and provide a report of the audit, together with copies of the SOPs identified, to the centre's inspector by 16 September 2016. The PR should review the centre's auditing methodology in relation to the specified audit and ensure that all audits evaluate compliance with the	There is a CARE quality group that continually reviews and improves our audit procedures and the requirement to audit compliance with regulatory requirements and approved protocols will be considered and reviewed by the group. A report will be submitted as requested. SOPs to direct action in cases of clinical emergency and in the case of a needle stick injury are included in our quality management system and copies have been provided as evidence of this. Guidance on actions to take in the event of a needle stick injury are also displayed in relevant clinical areas as	The Executive acknowledges the PR's response and her commitment to fully implement this recommendation. The specified SOPs have been provided and the review of the centre's auditing methodology is awaited by 16 September 2016. Further action is required.

taken in the event of a clinical emergency, a non-clinical emergency and needle stick injuries. SLC T36 and T33b.	regulatory requirements, the centre's approved protocols and quality indicators and that any corrective actions identified are fully implemented. A summary report of the review including corrective actions and the timescale for implementation of corrective actions should be provided to the centre's inspector by 16 September 2016.	observed by the inspection team in the course of the site visit. At the time of the inspection the clinic had an "Emergency File" documenting the actions to be taken in cases of non-clinical emergency. This file was available in hard copy only which may explain why the inspection team were not provided with access to the document. Post inspection we recognised that the document required updating to reflect staff changes and an amended copy of the original has been provided. We will undertake the specified audit of storage consents and report within the prescribed timeframe.	

Additional information from the Person Responsible
We seek feedback from all patients after consultation and treatment. In the time period since the last HFEA inspection (19/03/2014 to 16/05/2016), post consultation, 99% of patients (based on 214 responses) would recommend the clinic to friends and family. Post treatment, for the same time period, 96% of patients (based on 472 responses) would recommend the clinic to friends and family. Although we acknowledge that the feedback provided to the HFEA was mixed, CARE Manchester receives a significantly higher number of responses which is, as noted above, extremely positive. We are not complacent where patients report a poor experience and when we are made aware of a concern we act on it to inform improvements.