HFEA Executive Licensing Panel Meeting

30 May 2014

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

Minutes – Item 1

Centre 0185 – (CARE Manchester) – Renewal Treatment (including embryo testing) & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Rachel Hopkins – Head of HR (Chair)	Dee Knoyle
David Moysen – Head of IT	**Observing:**
Matthew Watts – Regulatory Policy Manager	Sam Hartley – Head of Governance and Licensing

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

The Panel 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 considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a treatment (including embryo testing) and storage centre which provides a full range of licensed treatments including embryo testing. The Panel noted that in relation to activity levels this is a large centre.

3. The Panel noted that the centre has been licensed by the HFEA since 1999 and is on a five-year licence due to expire on 30 September 2014.

4. The Panel noted that in the 12 months to 28 February 2014 the centre provided 2045 cycles of treatment (excluding partner intrauterine insemination).

5. The Panel noted that for IVF and ICSI, HFEA-held register data for the period 1 Mar 2013 to 28 Feb 2014 show the centre's success rates are in line with national averages.

6. The Panel noted that in 2013, the centre reported 38 cycles of partner insemination with 4 pregnancies. This is consistent with the national average.

7. Between 1 April 2011 and 30 September 2012, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 15%: this represented performance that was not statistically different from the 15% maximum multiple live birth rate target for this period.

8. Between 1 October 2012 and 30 September 2013, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was11%: this represented performance that was not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

9. The Panel noted that at the time of the inspection on 19 March 2014, the Inspectorate identified two major and four other areas of non-compliance. The Panel noted in particular the non-compliances in relation to witnessing standard operating procedure, CE marked products and submissions for consent to disclosure to research. The Panel noted that since the inspection, the Person Responsible (PR) has addressed all major and other areas of non-compliance with some outstanding actions to complete.

10. The Panel noted the Inspectorate recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions, subject to compliance with the recommendations made in this report being fully implemented within the prescribed timescales.

Decision

11. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

12. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and that he has discharged her duty under section 17 of the HF&E Act 1990 (as amended).

13. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

14. The Panel endorsed the Inspectorate's recommendation to renew the centre's Treatment (including embryo testing) and Storage licence for four years, without additional conditions.

Signed: Date: 12 June 2014
Rachel Hopkins (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 19 March 2014

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) and Storage

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Bhavna Mehta, Susan Jolliffe, Vicki Lamb, Cathy Hodgson and Neil McComb

Executive Licensing Panel: 30 May 2014

Centre name	CARE Manchester
Centre number	0185
Licence number	L/0185/9/b
Centre address	108 -112 , Daisy Bank Road, Victoria Park, Manchester, M14 5QH, UK
Person Responsible	Mr Glenn Atkinson
Licence Holder	Mrs Charmian Russell
Date licence issued	01/10/2009
Licence expiry date	30/09/2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
CARE Manchester has held a Treatment and Storage licence with the HFEA since 1999 and provides a full range of fertility services. The licence was varied at the time of the last renewal inspection to a Treatment (including embryo testing) and Storage Licence. The centre is applying to renew the Treatment (including embryo testing) and Storage licence. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The centre provided 2045 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2014. In relation to activity levels this is a large centre.

Other licensed activities of the centre included storage of gametes and embryos.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 01 Mar 2013 - 28 Feb 2014 show the centre's success rates are in line with national averages.

In 2013, the centre reported 38 cycles of partner insemination with 4 pregnancies. This is consistent with the national average.

Multiple births[2]

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

Between 1 April 2011 and 30 September 2012, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 15%: this represented performance that was not statistically different from the 15% multiple live birth rate target for this period.

Between 1 October 2012 and 30 September 2013, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was11%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target for this period.

[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. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

[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 MLBR target of 10% (from October 2012) is calculated as equivalent to a 13% MCPR.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including two major and four 'other' areas of non-compliance.

Since the inspection visit, all the recommendations as follows have been fully implemented:

Major areas of non-compliance:

- The PR should ensure that whenever possible only CE marked medical devices are used.
- The PR should ensure that gamete providers are informed that they can vary or withdraw the terms of their consent until the point that their embryos are used in training.

'Other' areas of non-compliance:

- The PR should ensure that the multiple births minimisation strategy document is amended to reflect the current HFEA 10% target.
- The PR should ensure that witnessing checks should record the time of witnessing.
- The PR should review the witnessing standard operating procedure (SOP) to ensure that it reflects current practice.
- The PR should liaise with the HFEA register team to ensure that action is taken to correct the incorrect submissions for consent to disclosure to researchers and that all licenced treatment activity is reported to the Authority within the required timeframe.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of non- compliance and all major and other areas of non-compliance have been addressed by the PR.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/ live birth rates meet the target. The PR is encouraged

to continue to use the Quality Management System (QMS) to best effect to monitor and improve their success rates so as to improve the quality of the service offered to patients.

The inspection team recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of four years without additional conditions.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are broadly compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better

Witnessing checks are completed and recorded, but in two cases the time of the witnessing was missing in the patient records. SLC T71 (Recommendation 4)

The SOP does not reflect current practice, or guidance, in that it states that manual witnessing is not required for mixing sperm and eggs; injecting sperm into eggs; and placing gametes or embryos into and removing them from cryopreservation. It was noted at inspection that the centre does manually witness at these steps. SLC T33 and CoP 18.38 (Recommendation 5)

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection

during treatment, processing and storage of gametes and embryos.

Payments for donors (Guidance note 13; Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Nothing identified at this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to processes gametes and embryos in an environment of appropriate air quality.

Laboratory accreditation(Guidance note 25)
The centre's third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements, keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos

are compliant with HFEA requirements. This is important to ensure that all gametes and embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Direction 0006)
The centre's procedures for imports and exports of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
- identify the donor and recipient of particular gametes or embryos,
- to identify any person who has carried out any activity in relation to particular gametes or embryos, and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; Direction 0010)
The centre has systems in place to manage transport and satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by the satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are broadly compliant with HFEA requirements. The equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.
The centre is compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

QMS
The multiple births minimisation strategy referred the 15% target rather than the current 10% target. At the time of the inspection, the centre was working to meet the 10% target. However, the documentation had not been amended (General Directions 0003). Some other documents in the QMS have recently been reviewed but the history of the document had not been updated. SLC T34 (See recommendation 3)

Equipment and materials
The following medical devices used by the centre are not CE marked: 5ml tubes and serological pipettes. SLC T30 (See recommendation 1). The review of the non-conformances log records that the tubes are used as a suitable CE marked product cannot be sourced. The centre has assessed the risks of the use of these non CE marked tubes as a low: the Executive acknowledges that the use of non CE marked 5ml tubes is low and accepts the centre's assurances that no suitable CE marked alternative is available.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)

The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number: T/1089/7).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements.
The centre has suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.
The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. This is important to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided.

Safeguarding
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better

Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

What the centre could do better

Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspector spoke to six patients who provided feedback on their experiences. A further 24 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with seven 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 patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind

- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and donors are broadly compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Information given to patients prior to consenting to the use of embryos created with their gametes in the training of staff did not adequately cover the requirements of the HF&E Act 1990 (as amended). HF&E Act, Schedule 3 S.3 (1) (b) and SLC T97.
(See recommendation 2)

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well
Consent (Guidance note 5)

The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research(Chair's Letter CH(10)05; Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007)
The centre's procedures for taking consent to disclosure to researchers are partially compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better

Seven discrepancies were found between completed patient/partner disclosure consents in patient files and the related consent data submitted for inclusion on the HFEA register. Chair's Letter CH(10)05; Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007 (See recommendation 6)

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are compliant/ with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

What the centre could do better

Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32 ; Directions 0005)
This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements. The HFEA register audit team found some minor problems with the timeliness and accuracy of the centre's submission of data to the Register which the centre has, since the date of inspection, corrected.

What the centre could do better

Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2012, no recommendations for improvement were made

On-going monitoring of centre success rates

The centre has not received any HFEA alerts in the last six months regarding their success rates.

Areas of practice requiring action

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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. 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
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 to a 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	Executive Review
1. The serological pipettes used by the centre are not CE marked. SLC T30	We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that you are providing to your patients. In consideration of this, the PR should provide the HFEA with an anticipated time by which CE marked serological pipettes, where available, are expected to be obtained and the action that will be taken to ensure compliance with requirements, including validation of any new devices to be used, within the next year (by 20 March 2015).	I do not believe that this is a major area of non-compliance. The use of such pipettes has been validated and therefore their use does not pose any risk to safety of patients, embryos or children. It does not constitute a mojor shortcoming from statutory requirements which is apparently agreed by the HFEA otherwise the first paragraph in the 'action required' column endorses continued use. There is no combination of 'other areas of non-compliance' relating to pipettes. It is anticipated that the CE	The PR's comments are noted. The categorisation of this non-compliance is in line with the HFEA's assessment framework. SLC T30 requires that wherever possible only CE marked medical devices must be used. It is noted that CE marked pipettes will be used from July 2014. No further action.

	The list and timeline should be submitted to the HFEA by 19 June 2014. The PR should confirm to the centre's inspector by 20 March 2015 that the centre uses only CE marked medical devices, where ever possible.	marked pipettes will be in use by July. A list of products used has already been submitted.	
2. Prior to giving consent to the use of their embryos in training, gamete providers are not informed: that they can vary or withdraw the terms of their consent until the point their embryos are used in training. This puts the centre at risk of failing to provide proper information to patients giving consent, as required the HF&E Act 1990 (as amended). HF&E Act, Schedule 3 S.3 (1) (b) and SLC T97.	The PR should provide the HFEA with a summary report of changes made to patient information and/or evidence of how the relevant information will be provided verbally to patients, by 19 June 2014.	I enclose a copy of the patient information form related to training consent. Under the paragraph headed'can I change my mind?' it quite clearly states that patients can vary or withdraw consent up until the training takes place.	The PR's comments are noted. The patient information submitted with the renewal application form was incorrect. The patient information submitted with the response to this report has been reviewed and is compliant with requirements. No further action.

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	Executive Review
3. The centre's multiple births minimisation strategy referred to the 15% target rather than the 10% target. General Directions 0003.	The PR should ensure that the centre's multiple births minimisation strategy is updated to ensure it reflects the current multiple birth rate target. The PR should confirm to the lead inspector when the change has been made by the time.	This has been updated and the updated version is included in this response	No further action.
4. Witnessing checks are completed and recorded, but in two cases the time of the witnessing was missing in the patient records. SLC T71	The PR should take immediate action to ensure that witnessing is fully completed and recorded at all critical points of the clinical and laboratory process. The lead inspector should be advised of the measures taken to ensure that this happens by 19 June 2014.	Witnessing is undertaken electronically and manually. This occurs at the same time and the time of the witnessing is recorded electronically by the 'Matcher system'. There is therefore a record of the time of witnessing and this is placed in the patient notes. However all embryologists have been reminded that all entries into notes or patient recoreds particulkarly with regard to	The PR's comments are noted. The PR should ensure that all staff that are involved in carrying out the witnessing checks ensure that these are always recorded in the patient files. No further action.

		witnessing have to be timed.	
5. The witnessing SOP does not reflect current practice in that it states that manual witnessing is not required for mixing sperm and eggs; injecting sperm into eggs; and placing gametes or embryos into and removing them from cryopreservation. It was noted at inspect that the centre does manually witness at these steps. SLC T33 and CoP 18.38	The PR should review the SOP for witnessing and ensure that it accurately reflects CoP 18.38. Following review the SOP should be forwarded to the lead inspector. By 19 June 2014	I believe the SOP states that in the case of insemination etc an electronic witnessing is undertaken instead of or in addition to manual witnessing. CARE Manchester's policy of undertaking electronic witnessing and manual witnessing for theses steps is consistent with the SOP and SLC T33. I believe that the sole use of electronic witnessing for these steps is undertaken in another CARE clinic and hence the 'either or bit in the corporate SOP. The clinic inquestion has performed a risk assessment (enclosed) and this has previoulsy been accepted by the HFEA.	Following further discussion the PR agreed that the SOP does not reflect practice at his centre: it is emphasised that this discrepancy was the source of concern for the inspection team. It is acknowledged that that the centre meets the HFEA requirements to manually witness these steps but it remains the Executive's opinion that the centre's SOP should accurately reflect practice – for an SOP not to do this poses a risk that a member of staff may adopt practices different from those expected. The centre's SOP showing the manual witnessing steps should be forwarded to the centre's inspector by 19 June 2014.
6. Patient consent to	The centre has recently carried	The submissions which had	The PR's comments are noted

disclosure of information, held on the HFEA Register, for use in research, was not accurately recorded and reported to the HFEA. Directions Chair's Letter CH(10)05; Guidance supplementary to Chair's Letter CH(10)05 and Direction 0007	out an internal review of consents to the disclosure of register information which identified issues and developed an action plan for correction. The centre should: • conduct an audit for six months of submissions to confirm that changes made to systems and processes are having the desired effect; and • correct the submissions that have been identified as being incorrect. The centre should liaise with the HFEA Register team until this recommendation has been implemented.	been identified as incorrect have been corrected I have instigated an ongoing audit to monitor submissions and ensure that these are correct	and the PR is requested to liaise with the HFEA Register team until this recommendation has been implemented.

Reponses from the Person Responsible to this inspection report
The inspection report does not seem to reflect the feedback from the inspection team on the day of inspection. I do not believe that the non-compliances are 'major' in nature as they do not fit the HFEAs own definition. The second 'major area of non-compliance relates to an old patient information document being submitted initially. The information available to patients is within the new form submitted and is compliant. There was therefore no area of non-compliance at all! As the inspection report is a public document the inclusion of these non-compliances in the major category is likely to give an erroneous impression of CARE MAnchester's compliance with all HFEA recommendations and directives which has always been excellent and shown to be so on previous inspections.