Executive Licensing Panel - minutes

Centre 0295 (Bristol Centre for Reproduction)

Renewal Inspection Report

Wednesday, 26 September 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dan Howard Erin Barton	Director of Strategy & Corporate Affairs Chief Information Officer Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance Manager

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:

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

1. Consideration of application

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

1.2. The panel noted that the Bristol Centre for Reproductive Medicine (BCRM) is located at Southmead Hospital, Bristol and has held a treatment and storage licence since 2007, following the amalgamation of two other HFEA licensed centres located in Bristol. Other licensed activities at the centre include the storage of gametes and embryos.

1.3. The panel noted that the centre was owned by North Bristol NHS Trust (NBHT). NBHT gave up the NHS contract in 2017, and BCRM then became independent of the Trust. It treats NHS and self-funded patients. The centre is part of the 'Any Qualified Provider' framework run by the local Clinical Commissioning Group (CCG). Under the framework, NHS-funded patients are given a choice of six centres, with BCRM being one of those. This transitional process has been complex and taken some time, resulting in reduced staff numbers and treatment cycles performed, and slightly reduced premises size. BCRM is a limited company with the Licence Holder(LH) and the Person Responsible (PR) acting as Directors of the company.

1.4. The panel noted that, in the 12 months to May 2018, the centre provided 949 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a medium sized centre.

1.5. The panel noted that, between March 2017 and February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.6. The panel noted that, for IVF and ICSI, HFEA held register data, for the period of 12 months to February 2018, show the centre's success rates are in line with national averages, with the exception of the clinical pregnancy rate following ICSI in patients aged less than 38 years, which is above average at a statistically significant level.

1.7. The panel noted that, in 2017, the centre reported 170 cycles of partner insemination with 25 pregnancies. This represents a clinical pregnancy rate of 15%, which is in line with the national average.

1.8. An inspection was carried out at the centre on the 18th and 19th July 2018.

1.9. The panel noted that at the time of the inspection, there were two major areas of non-compliance concerning the storage of gametes and embryos and medicines management. There were also four 'other' areas of non-compliance regarding the screening of donors, record keeping, the Quality Management System (QMS) and disclosure of information. Since the inspection, the Person Responsible (PR) has fully implemented the recommendation concerning the screening of donors and has given a commitment to fully implementing the recommendations concerning the storage of gametes and embryos, medicines management, record keeping, the QMS and disclosure of information.

1.10. The panel noted that the success rates are consistent with the national average and their multiple clinical pregnancy and live birth rates meet the target. The inspection team noted the significant changes that have occurred at the centre over the last few years and congratulates the centre on managing this change effectively and with no apparent impact on patient experience or pregnancy rates.

1.11. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients. The inspector will continue to

monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

1.12. The panel noted the PR has requested a change to the centre's address as part of the renewal application. The premises remain in the same location, but as they now independent of the Trust, reference to this entity should be removed. The centre's address would be:

Southmead Hospital
Bristol
BS10 5NB

1.13. The panel noted the inspectorate recommendation to renew the centre's treatment and storage only licence for a period of four years without additional conditions, subject to the recommendations in the report being implemented within the prescribed timescales.

1.14. The panel also noted the inspectorate's recommendation to issue the licence for the updated address.

2. Decision

2.1. 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.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel congratulated the centre on its success in lowering the multiple birth rate.

2.5. The panel noted that the major non-compliance, regarding medicines management, had also been identified at the centre's last inspection in June 2016 and was concerned that it had been a major non-compliance again at this inspection.

2.6. The panel encouraged the PR to work closely with the inspectorate to ensure the non-compliances concerning the storage of gametes and embryos, medicines management, record keeping, the QMS and disclosure of information are fully implemented.

2.7. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage only licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented.

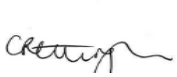
2.8. The panel endorsed the inspectorate's recommendation to change the centre's licence to the following address:

Southmead Hospital
Bristol
BS10 5NB

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

5 October 2018

Renewal 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: 18-19 July 2018

Purpose of inspection: Renewal of a licence to carry out Treatment 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: Mhairi West, Sara Parlett, Kathryn Mangold, Cathy Hodgson and Zakia Ezzouyar.

Date of Executive Licensing Panel: 28 September 2018

Centre name	Bristol Centre for Reproductive Medicine
Centre number	0295
Licence number	L/0295/3/a
Centre address	Department of Women's Health, North Bristol NHS Trust, Southmead Hospital, Bristol BS10 5NB.
Person Responsible	Mr Valentine Akande
Licence Holder	Paul Wilson
Date licence issued	19 December 2014
Licence expiry date	18 December 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Bristol Centre for Reproductive Medicine (BCRM) is located at Southmead Hospital, Bristol and has held a HFEA licence since 2007 following the amalgamation of two other HFEA licensed centres located in Bristol. Other licensed activities at the centre include the storage of gametes and embryos.

The centre was owned by North Bristol NHS Trust (NBHT). NBHT gave up the NHS contract in 2017, and BCRM then became independent of the Trust. It treats NHS and self-funded patients. The centre is part of the 'Any Qualified Provider' framework run by the local Clinical Commissioning Group (CCG). Under the framework, NHS-funded patients are given a choice of six centres, with BCRM being one of those. This transitional process has been complex and taken some time, resulting in reduced staff numbers and treatment cycles performed, and slightly reduced premises size. BCRM is a limited company with the Licence Holder and the Person Responsible (PR) acting as Directors of the company.

The centre provides a full range of fertility services. It provided 949 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2018. In relation to activity levels this is a medium-sized centre.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period of 12 months to February 2018 show the centre's success rates are in line with national averages, with the following exception:

- The clinical pregnancy rate following ICSI in patients aged less than 38 years is above the national average at a statistically significant level.

In 2017, the centre reported 170 cycles of partner insemination with 25 pregnancies. This represents a clinical pregnancy rate of 15%, which is in line with the national average.

Multiple births[2]

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

Between March 2017 and February 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. 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%.

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 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 the centre's 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 which have resulted in the following recommendations:

Since the inspection visit, the following recommendations have been fully implemented:

'Other' areas that requires improvement:

- The PR should ensure that oocyte donors are screened according to best practice guidelines.

The PR has given a commitment to fully implementing the following recommendations:

Major areas of non compliance:

- The PR should ensure that effective consent is in place for all gametes and embryos that are in storage.
- The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance and ensure that the audit of medicines management is effective.

'Other' areas that requires improvement:

- The PR should ensure that a clear record is kept of how, and by whom, a patient/donor has been reliably identified.
- The PR should ensure that quality indicators (QIs) for HFEA data submission are established and audited and update the centre's infection control standard operating procedure (SOP).
- The PR should review procedures and take appropriate corrective actions to ensure disclosure consent information supplied to the Authority accurately reflects that recorded on disclosure consent forms.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy and live birth rates meet the target. The inspection team notes the significant changes that have occurred at the centre over the last few years and congratulates the centre on managing this change effectively and with no apparent impact on patient experience or pregnancy rates.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The inspection team recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

The ELP is asked to note that the PR has requested a change to the centre's address as part of the renewal application. The premises remain in the same location, but now they are independent of the Trust, reference to this entity should be removed.

The inspection team recommends that ELP issues a renewed licence for the following address:

Southmead Hospital
Bristol
BS10 5NB.

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 compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better
Nothing identified at this inspection.

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)
It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and embryos. The centre's procedures for screening donors are broadly compliant with HFEA requirements.

Payments for donors (Guidance note 13; General 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)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to

access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better

Screening of donors (Guidance note 11)

The centre does not screen egg donors for gonorrhoea at the time of donation. Sperm donors are screened for gonorrhoea but the PR considers the risk of transmission with egg donors to be very low (CoP Guidance 11.23; see recommendation 3).

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 so that 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 process gametes and embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's 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 to be accredited 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 (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are partially compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
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; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for 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; General 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 / 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 note 15)
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 they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export 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;
- to 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 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; General Direction 0010)
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This is important to ensure that activities performed by 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 compliant with HFEA requirements. All of 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 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 (including serious adverse events and reactions) to the HFEA. The centre investigates all 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

Medicines Management (Guidance Note 25)
A review of the controlled drugs (CD) register showed that alterations were made by overwriting rather than using a method in line with the regulations; i.e. using a margin note or footnote, despite instructions displayed in the front of the register. The centre's monthly CD audit did not highlight these deficiencies in completion of the controlled drugs register as noted on inspection.

During observations in theatre, it was noted that the disposal of the waste portion of a controlled drug drawn up but not used was not witnessed in an effective manner, involving identification of the drug and visual witnessing of disposal by a second person.

Misuse of Drugs (safe custody) Regulations 2001; SLC T2: see recommendation 2.

QMS (Guidance Note 23)
The centre is in the process of developing its own infection control SOP since becoming independent from the NHS Trust. This has not yet been completed.

The centre has not established QIs relevant to the submission of data to the HFEA.

SLC T33b; see recommendation 5.

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.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have 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 to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
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 does not perform embryo testing therefore requirements relating to this are not relevant to this inspection.

What the centre could do better
Not applicable.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspector spoke to two patients who provided positive feedback on their experiences. The centre actively collects feedback on patient experience through an in-house survey and also through social media, and acts on any negative comments received. The centre's most recent patient survey responses were reviewed. Feedback was positive, with all of the individuals providing written feedback giving compliments about the care that they received. Patients are also referred to the HFEA online feedback at numerous points during their treatment although only six have responded. The centre is further encouraged to support feedback to the HFEA Choose a Fertility Clinic website.

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 [and sperm] 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 the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

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; General Direction 0001)

The centre's procedures for egg sharing arrangements are broadly 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. Complaints are rare and dealt with promptly, with most resolved after verbal contact with the patients.

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

Egg sharing arrangements (Guidance note 12; General Direction 0001)
Egg donors are not screened for gonorrhoea (see 'screening of donors' section of the report and recommendation 3).

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and donors are 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
Nothing identified at this inspection.

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

What the centre does well

Consent (Guidance note 5;6)
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.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is 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 couple to obtain a court declaration to establish legal parenthood.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At that inspection in June 2016, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are broadly 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
Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)

One discrepancy was found between 16 completed patient/partner/donor disclosure consents on patient files and the related consent data submitted for inclusion on the register. However this failing does not lead to a risk that the HFEA may release patient identifying information to researchers without consent (CH(10)05 and Gen Dir 0005 5; 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) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- 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 and 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, with one exception noted below. 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

Storage of gametes and embryos (Guidance note 17)

One set of donor sperm samples is in storage past the statutory storage period. Donor sperm was imported from America in 2007 and used successfully in DI treatment by a patient couple, who now have three children. The centre contacted the patient following its bring forward system process in 2017, in advance of the expiry of the statutory storage period. The centre determined that the patient couple does not meet the necessary legal requirements to extend storage and therefore the samples would need to be used prior to

the expiry date or allowed to perish. However, the patient informed the clinic that they would be challenging this decision formally. The PR has kept the samples in storage to allow the couple sufficient time to launch a legal challenge. The centre staff have been in contact with the patient and no legal process has yet been started. The centre has given a deadline of 15 August 2018 for action to be taken (SLC T79; HF&E Act 1990 (as amended), Schedule 3 (8)(1); HF&E (Statutory Storage Period for Embryos and Gametes) Regulations 2009; see recommendation 1.)

The inspection team notes that this is a one-off exceptional case and the centre's general management of its stored gametes and embryos is effective.

Use of embryos for training staff

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 and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are broadly 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; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better

Record keeping and document control (Guidance note 31)
For each patient/donor the centre does not maintain an explicit record of the confirmation of identification of the patient/donor, detailing how the identification was performed, and by whom (SLC T46b; see recommendation 4.)

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The clinic is not compliant with requirements to submit information to the HFEA as there are a number of treatments which have either yet to be reported, or reported late. The centre has engaged with the HFEA over the last year to address significant problems with electronic data submission to the HFEA register, involving lengthy and sporadic periods where submission cannot take place. This matter has not been resolved and the centre has committed to continue to report issues, and to submit data when possible.

The inspection team considers the centre's non-compliance to be beyond the control of the centre and makes no recommendations, except that the PR continues to engage with the HFEA to ensure all data is submitted as soon as possible.

The centre does not have QIs for HFEA data submission. (SLC T35; see 'QMS' section of the report and recommendation 5.)

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, recommendations for improvement were made in relation to one area of major non compliance and four 'other' areas of non compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. However, there has been a reoccurrence of the non compliance related to medicines management (recommendation 2).

On-going monitoring of centre success rates

From 2012 to 2015, and during a spike in 2017 the centre was receiving periodic alerts about their multiple birth rates, and the centre was asked to review their multiple births minimisation strategy. The PR responded to the requests and registry data confirms that the centre's multiple clinical pregnancy rates are now in line with national 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, General 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.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

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.

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and Reference	Action required and timescale for action	PR Response	Executive Review
1. Storage of gametes and embryos One set of donor sperm samples is in storage past the statutory storage period. The centre determined that the patient couple does not meet the necessary legal requirements to extend storage. However, the patient informed the clinic that they would be challenging this decision formally. The PR has kept the samples in storage to allow the couple sufficient time to launch a legal challenge. The centre staff have been in contact with the patient and no	The PR should ensure that effective consent is in place for all gametes and embryos that are in storage. The PR should provide an update on the status of this case at the time of responding to the report.	The Centre has written to the patients concerned, informing them that it is our intention to remove the samples from storage on Friday 31st August 2018	The Executive acknowledges the PR's response and commitment to implementing this recommendation. The PR should provide confirmation of disposal of the samples when it occurs.

legal process has been started. The centre has given a deadline of 15 August 2018 for action to be taken. HF&E Act 1990 (as amended), Schedule 3 (8)(1). HF&E (Statutory Storage Period for Embryos and Gametes) Regulations 2009 and SLC T79.			
2. Medicines management Alterations in the CD register do not follow professional guidelines, or the procedure detailed on the front of the register. **This was a non compliance at the last inspection.** Disposal of excess unused controlled drugs was not witnessed in an effective manner, involving identification of the drug and visual witnessing of disposal by a second person. Misuse of Drugs (safe Custody) Regulations 2001.	The PR should ensure that medicines management practices are compliant with regulatory requirements and professional body guidance. The PR should review medicines management procedures, including any necessary staff training, and provide a summary of actions taken to ensure compliance in relation to observations made in this report, when responding to this report. This review should also include a consideration of why previous corrective action taken has not been effective. Within three months of the	The review has been supplied to the Centres inspector, as requested. The Audit report will be provided to the Centres inspector within the prescribed timeframe.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action beyond submission of a restructured audit of medicines management practice due by 19 November 2018.

	implementation of corrective actions, the centre should carry out an audit of medicines management procedures to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the audit should be supplied to the centre's inspector by 19 November 2018.		
The centre's CD audit did not pick up deficiencies in the completion of the CD Register. SLC T2.	The PR should ensure that audits of medicines management is structured such that the errors in register completion are detected, corrected and learning is implemented to prevent further incidence. Evidence of this should be submitted to centre's inspector by 19 November 2018.		

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.

An 'other' area of non compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. Screening of Donors Donors of oocytes are not screened for gonorrhoea in accordance with current professional guidance produced by the relevant professional bodies. Guidance Note 11.23. UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors, 2008 (Association of Biomedical Andrologists, Association of Clinical Embryologists, British Andrology Society, British Fertility Society & Royal College of Obstetricians and Gynaecologists).	The PR should ensure that oocyte donors are screened according to best practice guidelines. The PR should either commence screening oocyte donors for gonorrhoea or provide a risk assessment to support going against recommended best practice guidance by 19 October 2018.	Screening has now been introduced for all oocyte donors.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required.
4. Record Keeping	The PR should ensure that a		The Executive acknowledges

For each patient/donor the centre does not maintain an explicit record of the confirmation of identification of the patient/donor, detailing how the identification was performed, and by whom. SLC T46.	clear record is kept of how, and by whom, a patient/donor has been reliably identified. The PR should submit a revised process for this to the centre's inspector by 19 October 2018.	The revised process will be supplied to the centres inspector within the requested timescale.	the PR's response and commitment to implementing this recommendation. No further action beyond submission of a restructured audit of medicines management practice, which is due by 19 October 2018.
5. Quality Management System The centre has not established QIs relevant to submission of data to the HFEA. SLC T35. The infection control SOP is incomplete. SLC T33b.	The PR should ensure that QIs for HFEA data submission are established and audited. Evidence of this should be submitted to the centre's inspector by 19 October 2018. The PR should ensure that the infection control SOP is updated and submitted to the centre's inspector by 19 October 2018.	QIs have been established; the requested audit will follow within the requested timescale. The Infection Control SOP has been updated and will be sent to the centres inspector within the requested timescale	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action beyond submission of an audit of HFEA data submission QIs and an updated Infection Control SOP, which is due by 19 October 2018.
6. Disclosure of information One discrepancy was found between 16 completed patient/partner/donor disclosure consents on patient files and the related consent data submitted for inclusion on the register. However this failing does not lead to a risk	The PR should review procedures and take appropriate corrective actions to ensure disclosure consent information supplied to the Authority accurately reflects that recorded on disclosure consent forms. A copy of this review should be provided to the centre's inspector by 19		The Executive acknowledges the PR's response and commitment to implementing this recommendation. The review of procedures to ensure accurate consent information supplied to the Authority, and an audit of any corrective actions, should be

that the HFEA may release patient identifying information, to researchers, without consent. CH(10)05 and Gen Dir 0005.	October 2018. The PR should review and correct the form identified on inspection and confirm this in response to this report. An audit should subsequently be performed to ensure that the corrective actions have been effective, and a report submitted to the centre's inspector by 19 January 2019.		submitted to the centre's inspector by 19 October 2018.

Reponses from the Person Responsible to this inspection report

Regarding Point 6 above;
Unfortunately, we are unable to enter data into the field as required. However, we acknowedge the requirements and the appropriate information will be forwarded to our Inspector within the requested timescales.

The BCRM Senior Management Team would like to thank the inspection team for their professionalism, advice and constructive feedback during the inspection process.