Executive Licensing Panel - minutes

Centre 0198 (St Jude's Women's Hospital)

Renewal Inspection Report

Friday, 14 July 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Anjeli Kara Jessica Watkin	Director of Strategy & Corporate Affairs Regulatory Policy Manager Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

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 St Jude's Women's Hospital is a privately-owned clinic in Wolverhampton and provides a full range of fertility services except embryo testing. The centre has a satellite agreement with St Jude's Hospital Newcastle-under-Lyme, which is staffed by the same team.

1.3. The panel noted that the centre has been licensed by the HFEA since 2002.

1.4. The panel noted that, in the 12 months to 31 December 2015, the centre provided 116 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small sized centre.

1.5. The panel noted that the centre's current licence was granted on 18 September 2015 by an Appeals Committee of the HFEA for a period of two years (rather than the more usual four) with additional conditions. The PR has complied with the requirements of these conditions.

1.6. The panel noted that HFEA held register data, for the period March 2016 to February 2017, showed that the centre's IVF and ICSI success rates are in line with national averages.

1.7. The panel noted that between March 2016 and February 2017, the centre's multiple pregnancy rate (MPR) for all IVF, ICSI and FET cycles for all age groups was 27%. The panel noted that although this rate is high, the difference between the centre's MPR and the national target is not statistically different due to the very low number of cycles from which this figure is derived. This means that the centre's multiple live birth rate is unlikely to be statistically different from the 10% multiple birth rate target. The panel noted that the Person Responsible (PR) was encouraged to review the centre's multiple birth minimisation strategy. However, no further recommendation was required.

1.8. An inspection was carried out at the centre on 3 and 4 May 2017.

1.9. The panel noted that at the time of the inspection there were four major and five 'other' areas of practice which required improvement. The panel noted that the major areas of non-compliance concerned screening of patients and donors, extended storage of gametes, the Quality Management System (QMS) and suitability of premises and facilities. The 'other' areas of non-compliance concerned infection control, multiple births, safeguarding, disclosure of information held of the HFEA Register for use in research and finance. The PR provided a commitment to implement all of the recommendations made in this report.

1.10. The panel noted that the inspection team considers that there is sufficient information available to recommend renewal of the centre's licence. The inspection team referred to the HFEA Guidance on licensing regarding length of licence and, in overall consideration of all information to hand, the inspection team considers that it is appropriate to recommend a four-year licence. The inspection team acknowledged that the PR has engaged positively with the HFEA since this licence was granted and significant improvements were noted at this inspection. The centre's inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

1.11. The panel noted that the inspection team had also considered the additional conditions placed upon the centre's current licence when it was granted in September 2015. The PR has complied with the terms of these conditions in full. No recommendations for improvement were required relating to these conditions at either this licence renewal inspection or the interim inspection conducted in February 2016. The inspection team considers that these additional conditions have served their purpose in ensuring that there are proper procedures in place to direct the consenting

process; that patients and donors are provided with proper information and, that staff are trained and assessed as competent to seek consent and are therefore, no longer required. The PR has provided a commitment to ensure that appropriate annual update training is provided and evidence of this is submitted to the HFEA by the end of January each year. The centre's inspector will monitor this.

1.12. The panel noted that the inspectorate 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 the report being implemented within the prescribed timescales.

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 endorsed the inspectorate's recommendation to renew 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. Given the number of non-compliances and the actions due in the autumn to address them, the Panel request an Executive update in late 2017 or early 2018, providing a progress report on the recommendations made in the report.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

25 July 2017

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: 3 and 4 May 2017

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: Gill Walsh (lead), Douglas Gray, Shanaz Pasha, Chris Hall and Danya Harris.

Executive Licensing Panel: 14 July 2017

Centre name	St Jude's Women's Hospital
Centre number	0198
Licence number	L/0198/8/b
Centre address	263 Penn Road, Penn, Wolverhampton, West Midlands, WV4 5SF
Person Responsible	Mr Jude Harris Adeghe
Licence Holder	Ms Isoken Adeghe
Date licence issued	18 September 2015
Licence expiry date	17 September 2017
Additional conditions applied to this licence	a. By 4 pm on 11th December 2015 Centre 0198 shall formulate comprehensive written policies on all matters of the obtaining of consent from patients. b. By 4 pm on 11th December 2015 the Centre shall review and revise its patient information leaflet concerning egg sharing and egg donation. c. As soon as the above two conditions have been met, the documents and all of the Centre's policies and procedures

	shall be submitted to an independent external expert for review. d. By 4 pm on 31st January 2016 and thereafter by 4 pm on 31st of every successive January the Centre shall ensure that all clinical and nursing staff at the Centre have received training, which is consistent with the CPD standards of their respective professions, in the obtaining of consent from patients, the regulatory framework and HFEA guidance. Full records of the content of the training shall be kept on file.

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
St Jude's Women's Hospital is a privately-owned clinic located in Wolverhampton. The centre has held a licence with the HFEA since 2002 and provides a full range of fertility services except for embryo testing.

The centre provided 116 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2015. In relation to activity levels this is a small centre.

The centre's current licence was granted on 18 September 2015 by an Appeals Committee of the HFEA for a period of two years (rather than the more usual four) with additional conditions as described earlier. The PR has complied with the requirements of these conditions.

This is the first licence renewal inspection since that time, however the centre was last inspected for an announced (rather than unannounced) interim inspection in February 2016. The licence was varied in October 2016 to reflect a change of Licence Holder.

The centre registered as a new service with the Care Quality Commission (CQC) in February 2015 but has not been inspected by CQC in relation to this registration to date.

The centre has a satellite agreement with its sister clinic, St Jude's Hospital Newcastle-under-Lyme which is staffed by the same team.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period March 2016 to February 2017 show the centre's success rates are in line with national averages.

The low number of cycles for these groups means it has not been possible to analyse the clinical pregnancy rate compared to the national average using HFEA's risk tool.

In 2016, the centre reported eight cycles of partner insemination with one pregnancy, which is in line with the national average.

Multiple births[2]

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

Between March 2016 and February 2017, the centre's multiple pregnancy rate (MPR) for all IVF, ICSI and FET cycles for all age groups was 27%.

Although this MPR is high, the difference between the centre's MPR and the national target is not statistically different due to the very low number of cycles from which this figure is derived. This means that the centre's multiple live birth rate is unlikely to be statistically different to the 10% multiple live birth rate target. The PR is encouraged to review the centre's multiple birth minimisation strategy; however, no further recommendation is required.

[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 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 four major and five 'other' areas of non-compliance which have resulted in the following recommendations:

Major areas of non-compliance:

- The PR should ensure that patients and donors are screened within the timeframes specified by the Authority and consideration is made regarding guidance issued on Ebola virus.
- The PR should conduct an audit of all sperm samples which have been in store coming up to or more than 10 years, to determine whether effective consent to extended storage is accompanied by an appropriate medical practitioner's statement.
- The PR should ensure that where indicated, SOPs are in place, quality indicators established and audits are conducted and that audits are effective in identifying areas for improvement to improve the quality of the service provided.
- The PR should ensure that the lift is maintained.

'Other' areas that requires improvement:

- The PR should ensure that the viral / immunisation status of all clinical and laboratory personnel is known and that areas in the recovery area identified as a potential infection risk are addressed.
- The PR should ensure that, where a woman meets the criteria for eSET but more than one embryo is replaced, the indications for this are clearly documented in the patient's medical records.
- The PR should ensure suitable safeguarding training is provided for all staff, including himself as nominated safeguarding lead.
- The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.
- The PR should ensure fees are paid to the Authority within the timescale specified in Directions or in writing.

When responding to this report the PR has provided a commitment to implement all of the recommendations.

Recommendation to the Executive Licensing Panel

At this inspection, four major areas of concern were identified. The centre has a quality management system (QMS) and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

The inspection team considers that there is sufficient information available to recommend renewal of the centre's licence. The inspection team referred to the HFEA Guidance on licensing regarding length of licence. In overall consideration of all information to hand, the inspection team considers that it is appropriate to recommend a four-year licence. In so doing, the inspection team acknowledges that the PR has engaged positively with the HFEA since this licence was granted and significant improvements were noted at this inspection. The centre's inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The inspection team also considered the additional conditions placed upon the centre's current licence when it was granted in September 2015. The PR has complied with the terms of these conditions in full. No recommendations for improvement were required relating to these conditions at either this licence renewal inspection or the interim inspection conducted in February 2016. The inspection team considers that these additional conditions have served their purpose in ensuring that there are proper procedures in place to direct the consenting process; that patients and donors are provided with proper information and, that staff are trained and assessed as competent to seek consent and are therefore, no longer required. The PR has provided a commitment to ensure that appropriate annual update training is provided and evidence of this is submitted to the HFEA by the end of January each year. The centre's inspector will monitor this.

In summary, the inspection team recommends the renewal of the centre's treatment and storage licence for a period of four years, without additional conditions in accordance with Schedule 16 (3) of the 1990 Act (as amended) which permits 'the grant of a licence to any person by way of renewal or a licence granted to that person, whether on the same or different terms'.

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)** The centre's procedures for screening donors are partially 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/or embryos. **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)

In two of three egg donor records reviewed, the donors were not screened at the time of donation but some months earlier (SLC T53(b); see recommendation 1).

Whilst staff could describe that they discuss travel history and any risk of Zika virus with potential donors, a similar discussion about Ebola does not take place (SLC T52h Clinic Focus guidance Feb and April 2017; recommendation 1).

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 partially 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 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/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or 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 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 broadly 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 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. However, the centre is broadly compliant with the requirement to document the rationale for placing more than one embryo into a woman where she meets the criteria for elective single embryo transfer (eSET).

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 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 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 gametes or embryos;
- to identify any person who has carried out any activity in relation to 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 partially 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 a satellite agreement with its sister clinic St Jude's Newcastle under Lyme. This satellite centre is run by the same staff to the same standard operating procedures. All processes undertaken form part of the primary centre's audit processes. The inspection team consider that the primary centre is compliant with requirements for the management of satellite centres.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All 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 has not reported any adverse incidents (including serious adverse events and reactions) to the HFEA since before the last licence renewal inspection. The centre's own incident log was reviewed and showed that there were no incidents recorded that should also have been reported to the HFEA. The centre investigates all 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

Safety and suitability of premises and facilities
The centre has a small lift which is not used for passengers but is used to transport liquid nitrogen to the upper floor where the laboratory is situated. The lift is somewhat antiquated and appeared to be in a poor state of repair. The lift is no longer covered by any servicing / maintenance agreement (SLC T17, CoP guidance 25.4(a); see recommendation 4).

Infection control
The PR could not provide evidence of pre-employment screening such as the hepatitis and immunity status for clinical or laboratory staff (SLC T2; recommendation 5).

It was noted that there were gaps between the wall and skirting boards in the second recovery area which could present an infection prevention and control risk (SLC T2; recommendation 5).

Multiple births (Guidance note 7; General Direction 0003)
In two instances seen, the rationale for placing two embryos into a woman who met the criteria for eSET was not documented in the patient's medical records (Direction 0003 (7) SLC T49; recommendation 6).

Quality management system
The centre has not established SOPs for the transport and distribution or recall of gametes or embryos.

The centre's SOP for:

- egg donation / egg share does not specify that the donor should be screened at the time of donation;
- the safeguarding SOP does not provide a guide to local safeguarding services or provide details of contacts for that location (CoP guidance 25.33).

(SLC T33(b)).

The centre has not established quality indicators for counselling (SLC T35).

The centre has not audited the following within the last two years:

- record keeping,
- counselling,
- donor recruitment and screening.

(SLC T36).

(See recommendation 3).

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 broadly 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
The PR is the nominated lead for safeguarding and there is an overarching policy in place, however this does not provide local guidance and contact information (see recommendation 3).

Staff have not received training in safeguarding (CoP guidance 25.35, Health and Social Care Act 2008; see recommendation 7).

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 undertake embryo testing therefore these guidance notes are not applicable to this inspection.

What the centre could do better
Not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to two patients who provided feedback on their experiences and commented they had compliments about the care they had received. There has been no feedback provided directly to the HFEA since the last inspection in February 2016. However, feedback provided directly to the centre via their patient questionnaire was reviewed with the inspection team, in each case the feedback was positive.

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 compliant with HFEA requirements. This is important to ensure that:

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

- egg and 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; 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 its effectiveness and, in some

cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The PR did not provide a summary of the audit findings. Due to ongoing licensing matters outlined earlier, a further request for this information was not made to the PR at that time. Subsequent to the granting of this licence, the PR was asked to provide an audit of legal parenthood consents in accordance with Chief Executive's letter CE(14)01 issued in February 2014. The centre provided a report and a copy of the audit within the agreed timeframe in November 2015. The audit had been conducted in accordance with the criteria laid down in CE(14)01. One couple was identified as having anomalies in their legal parenthood consent forms but were later found to have been in a civil partnership prior treatment. One other couple found to have a consent anomaly, having sought advice, decided that they did not wish to proceed with any declaration of parenthood through the courts. Because of these findings, the PR arranged for all relevant staff to have further training regarding consent to legal parenthood.

At this inspection, we reviewed the centre's audit of consent to legal parenthood for the period January to December 2016 and found that it had been performed in accordance with the method specified by HFEA. There were no anomalies identified. The centre has not provided any further treatment with donor sperm since that time therefore more recent patient records of consent to legal parenthood could not be reviewed at this inspection.

In summary, having reviewed documentation and audits, and discussed the process with the PR and centre staff, the inspection team considers the processes used to seek consent to legal parenthood at this centre to be 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 assisted reproduction therapies (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)
A review of patient and partner consent to disclosure identified two discrepancies between 17 completed patient/partner disclosure consent forms held in medical records and the related consent data submitted for inclusion on the register. These patients had provided consent to non-contact research however the HFEA register indicated that consent was withheld. Whilst this does not pose a risk of inadvertent disclose of information, this does not accurately reflect the consent provider's wishes (Direction 0005 (5), CH(10)05; see recommendation 8).

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
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

The centre's procedures for screening patients are partially 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 partially 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

Screening of patients (Guidance note 17)

In two of three records reviewed, blood samples taken for screening purposes were taken more than three months ahead of the patient's first donation (SLC T51(b); see recommendation 1).

Whilst staff described that they discuss with patients their travel history and any risk of Zika virus, the risk of infection with Ebola is not considered (SLC T50(d) Clinic Focus guidance Feb and April 2017; see recommendation 1).

Storage of gametes and embryos (Guidance note 17)
A review of two records for patients who had stored sperm beyond 10 years showed that whilst consent to extend storage was in place, there was no accompanying documented medical practitioner's statement (SLC T82(b)), Interpretation of mandatory requirements 17D (17); see recommendation 2).

A review of the centre's storage records showed that no embryos are currently in storage beyond 10 years.

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 does not use embryos for training staff and therefore this guidance note is not relevant to this inspection.

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 and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained (with one exception noted in relation to multiple embryo transfers (see recommendation 6). 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 HFEA 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.

A sample of 107 IVF and nine DI sample treatments recorded within the centre's laboratory records were compared with an extract from that submitted to the HFEA's register. Treatment data for all treatments in the sample had been submitted to the HFEA prior to the inspection date.

To review the quality of data submitted by the centre for inclusion on the Register a comparison was made between source records (patient and donor files) against Register entries. This review found very few minor errors and omissions therefore the inspection team do not consider a recommendation is warranted. Details of the errors identified have been provided to the PR for correction.

The inspectors wish to note that this is a significant improvement on that found on earlier inspections for which the centre team is to be commended.

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

Section 3: Monitoring of the centre's performance

Following the interim inspection in February 2016, recommendations for improvement were made in relation to two critical, two major and six 'other' areas of non-compliance.

The PR provided information and evidence that had all recommendations been fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

The centre has not received any risk based alerts relating to success rates.

The centre has received numerous alerts relating to the late payment of fees to the HFEA (SLC T9 (d); see recommendation 9).

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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None identified			

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. **Screening of patients and donors** In two of three medical records reviewed, the egg donor had not been screened within the timeframes specified by the Authority. (SLC T53(b); Code of Practice 11.23) In two of three medical records reviewed, the patient had not been screened within the timeframe specified by the Authority. (SLC T51(b)) Patient and donor screening procedures have not been	The PR should ensure that patients and donors are screened within the timeframes specified by the Authority and the risk of infection with Ebola is assessed. The PR should review the centre's processes for screening patients and donors and ensure they are compliant with regulatory requirements and take account of HFEA and other professional body guidance and provide a summary of that review to the centre's inspector by 5 August 2017.	This will be actioned within the specified timescale.	The executive acknowledges the PR's commitment to implement this recommendation. Further action is required.

revised to account for Ebola virus guidance. (Clinic focus February and April 2017)	An audit of patient and donor screening should be conducted six months after the review and implementation of any changes. A summary of the audit should be provided to the centre's inspector by 5 February 2018.		
2. **Extended storage of gametes** A review of two medical records for patients who had stored sperm beyond 10 years showed that whilst consent to extended storage was in place, there was no accompanying documented medical practitioner's statement. (SLC T82(b), Interpretation of mandatory requirements 17D (17))	In order to determine whether this finding was an isolated incident or indicative of a systemic failure, the PR should conduct an audit of all sperm samples which have been in store, either coming up to or more than 10 years, to determine whether consent to extended storage is accompanied by an appropriate medical practitioner's statement. A copy of the audit should be provided to the centre's inspector by 5 October 2017. When the outcome of the audit is known, any further actions necessary will be considered separately to this report.	This will be actioned within the specified timescale.	The executive acknowledges the PR's commitment to implement this recommendation. Further action is required.

3. **Quality management system** There is no SOP for; • the transport and distribution or recall of gametes or embryos. The centre's SOP for: • egg donation / egg share does not specify that the donor should be screened at the time of donation • the safeguarding SOP does not provide a guide to local safeguarding services or provide details of contacts for that location. CoP guidance 25.33, SLC T33(b) The centre has not established quality indicators for counselling. SLC T35	The PR should ensure that a suitable SOP is established for the transport and recall of gametes and embryos, a copy should be provided to the centre's inspector by 5 August 2017. The PR should: • revise the SOP for egg donation / egg share to ensure the timeframes for screening are reflected and; • should revise the SOP for safeguarding to ensure it reflects local contacts for safeguarding and actions to be taken in that location. A copy of these SOPs should be provided to the centre's inspector by 5 August 2017. The PR should ensure that quality indicators are established for the counselling service and that outstanding audits as listed are completed. A copy of the quality indicators and audits should be provided to the centre's inspector by 5 October 2017.	We already have an SOP for transport and distribution of gametes and embryos. A copy will be sent to you. This will be done within the timescale. We already have defined quality indicators for Counselling. This will be forwarded to you. An audit has not been done but we do so within the specified time.	

The centre has not audited the following within the last two years: • record keeping • counselling • donor recruitment and screening SLC T36		We plan to conduct audits on record keeping, counselling and donor recruitment and screening by 31/01/18.	
4. **Suitable premises and facilities** The centre has a small lift which is not used for passengers but is used to transport liquid nitrogen to the upper floor where the laboratory is situated. The lift is somewhat antiquated appeared to be in a poor state of repair and is no longer covered by any servicing / maintenance agreement. SLC T17 CoP guidance 25.4(b))	The PR should ensure that the lift is properly maintained and subject to regular preventative maintenance. The PR should arrange for the lift to be serviced and inform the centre's inspector of the date on which this is scheduled when responding to this report. Servicing should be completed no later than 5 August 2017. Evidence of this and of arrangements for ongoing preventative maintenance should be provided to the centre's inspector by 5 September 2017.	Arrangements are on-going to find a suitable lift engineer to carry out servicing / maintenance.	The executive acknowledges the PR's commitment to implement this recommendation. The PR should provide evidence of preventative maintenance by 5 September 2017. Further action is required.

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
5. **Infection control** The PR could not provide evidence of pre-employment screening nor of the hepatitis and immunity status for clinical or laboratory staff. There were gaps between the wall and skirting boards in a recovery area which could present a cleaning and infection prevention and control risk. SLC T2, T26 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014).	The PR should ensure that the health and viral / immunisation status of all clinical and laboratory personnel is known. The PR should assess the areas of concern identified in the recovery area and make arrangement for any necessary works to be completed. A plan to complete this work should be provided to the centre's inspector by 5 August 2017 and work should be completed no later than 5 October 2017, following which confirmation of completion should be provided to the centre's inspector.	The PR, Senior Embryologist and Senior Nurse have had viral screening in previous jobs but these are now out of date. New screening tests will be done. The necessary work on flooring in the recovery areas will be carried out as recommended.	The executive acknowledges the PR's commitment to implement this recommendation. Further action is required.
6. **Multiple births** The rationale for putting back more than one embryo into a woman who meet the criteria for eSET is not routinely	The PR should ensure that, where a woman meets the criteria for eSET but more than one embryo is replaced, the indications for this are	This recommendation is noted and will be carried out.	The executive acknowledges the PR's commitment to implement this recommendation.

documented in the patient's medical record. SLC T49, Direction 0003 (7)	clearly documented in the patient's medical record. Six months after the implementation of any changes the PR should conduct an audit of all patient records where the woman met the criteria for eSET but more than one embryo was replaced, to determine whether the rationale for this was documented. A summary of the audit findings should be provided to the centre's inspector by 5 January 2018.		Further action is required.
7. **Safeguarding** The PR is the nominated lead for safeguarding and there is an overarching policy in place, however neither he nor his staff have received training in safeguarding. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014CoP guidance 25.35	The PR should ensure suitable safeguarding training is provided for all staff, including himself as nominated safeguarding lead. Training should be provided by 5 September 2017 and confirmation provided to the centre's inspector with a list of attendees by 5 October 2017.	Traning is being arranged and should be completed within the indicated timescale.	The executive acknowledges the PR's commitment to implement this recommendation. Further action is required.

8. **Disclosure of information held of the HFEA Register for use in research** A review of patient and partner consent to disclosure records showed two discrepancies between 17 completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register in that the patient files records consent to non-contact research however the HFEA register indicates consent was withheld. Direction 0005, CH(10)05	The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the HFEA accurately reflects that given and recorded on disclosure consent forms. The PR should correct the submissions that have been identified as being incorrect and confirmation of this provided when responding to this report. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the centre's inspector by 5 January 2018.	This recommendation will be taken on board. I can confirm that the errors identified have been corrected. Follow up audit will be conducted in six months time as recommended	The executive acknowledges the PR's actions to implement this recommendation. A summary of the scheduled audit should be provided by 5 January 2018. Further action is required.
9. **Finance** The centre has been subject to numerous HFEA alerts due to late payment of fees.	The PR should ensure fees are paid to the HFEA within the timescale specified in Directions or in writing.	I will notify HFEA finance department to send future invoices to my PA via email - s.grainger@stjudeclinic.com	The executive acknowledges the PR's commitment to implement this recommendation.

The PR has suggested that changes are made as to how the centre is alerted to fees being due. It was agreed that the PR would inform the HFEA of the proposed changes via the clinic portal. SLC T9(d)	Changes to the mechanism by which the centre wants to be alerted to fees due should be communicated to the HFEA finance department via the clinic portal. The efficacy of this action will be subject to ongoing monitoring by the finance team of the HFEA.		Further action is required.

Reponses from the Person Responsible to this inspection report