Executive Licensing Panel - minutes

Centre 0198 (St Jude's Women's Hospital) Interim Inspection Report

Friday, 2 December 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Jessica Watkin Anna Rajakumar	Director of Strategy & Corporate Affairs Policy Manager Scientific Policy Manager
Members of the Executive	Dee Knoyle	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 noted that St Jude's Women's Hospital is located in Wolverhampton. The centre has held a licence with the HFEA since 2002 and provides a full range of fertility services.

1.2. The panel noted that in May 2014 the centre's application for a licence was refused by the HFEA Licence Committee. The PR exercised his statutory right to make representations regarding this decision which were heard in September and October 2014. In November 2014 the Committee considering the representations refused the application for a licence. This decision was overturned on appeal by the PR in 2015 and a licence was granted was granted on 18 September 2015 for a period of two years with additional conditions.

1.3. The panel noted that the inspection took place on 10 February 2016.

1.4. The panel noted that in the 12 months to 31 December 2015, the centre provided 104 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

1.5. The panel noted that HFEA-held register data for the period October 2014 to September 2015, for IVF and ICSI, showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2015 the centre reported 13 cycles of partner insemination with three pregnancies. This is likely to be consistent with the national average.

1.7. Between October 2014 and September 2015, the centre's multiple clinical pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 29%. Although this is high, the difference between the centre's multiple clinical pregnancy rate and the national target is not statistically different, due to the very low number of cycles from which this figure was derived. This means that the centre's multiple live birth rate is unlikely to be statistically different to the 10% maximum multiple live birth rate target for this period. The panel noted that the Person Responsible (PR) is encouraged to review the multiple birth minimisation strategy. No further recommendation is required in this area.

1.8. The panel noted that at the time of the interim inspection on 10 February 2016, two critical, two major and six other areas of non-compliance were identified. In particular, the panel noted the critical areas of non-compliance relating to consent to legal parenthood and ensuring that the premises and facilities at the centre are suitable and the major areas of non-compliance relating to medicines management and the provision of data to the HFEA. The panel noted that since the inspection the PR has implemented the recommendations made by the inspectorate and addressed all of the non-compliances.

1.9. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence.

2. Decision

2.1. The panel noted that the centre has complied with the requirements of the additional conditions placed on the licence within the prescribed timescales.

2.2. The panel was satisfied that the centre was fit to have its treatment and storage licence continued.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

16 December 2016

Interim Licensing Report

Centre name: St Jude's Women's Hospital
Centre number: 0198
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.

Date of inspection: 10 February 2016
Inspectors: Mrs Gill Walsh and Dr Douglas Gray
Date of Executive Licensing Panel: 2 December 2016

Purpose of the report

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

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

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. For 2015-2017 the focus of an interim inspection is:

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

- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

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

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

Summary for the Executive Licencing Panel

The inspection team now has sufficient information to recommend the continuation of the centre's licence.

The ELP is asked to note that the centre has complied with the requirements of the additional conditions placed on this licence within the timescales required as follows:

- On 11 December 2015 the PR provided copies of revised patient and donor information relating to egg donation, egg sharing and receiving treatment with donor eggs in accordance with the requirements of points (a) and (b) of the conditions applied to this licence. A copy of the centre's policy and standard operating procedure for taking consent was also provided.
- On 1 February 2016 the PR provided written confirmation that, in accordance with point (d) of the additional conditions imposed on this licence, all staff (listed) had been provided with professional development training in taking consent entitled 'Consent – getting it right' which was delivered by an external advisor to the centre on 11 January 2016.

The ELP is also asked to note that at the time of the inspection there were recommendations for improvement in relation to two critical and two major areas of non-compliance and six 'other' areas of practice that require improvement as follows:

'Critical' areas of non-compliance:

- **The PR should ensure that proper consent to legal parenthood is obtained in all case where such consent is required.**
- **The PR should take immediate action to ensure that the premises and facilities at the centre are suitable. To note, following the inspection the PR has already taken corrective action with regard to the most significant areas of concern. The PR should ensure that laboratory consumables and liquids are stored appropriately in conditions that do not pose a risk to patients or staff and that COSHH requirements are adhered to.**

'Major' areas of non-compliance:

- The PR should ensure that a controlled drugs accountable officer (CDAO) is appointed or that evidence be provided that application for exemption has been made to the Care Quality Commission (CQC). The PR should also conduct a review of the process by which medicines are stored and additional medicines are dispensed to patients.
- The PR should ensure that all treatment data is reported to the HFEA as required by directions and that when required, corrections are made within the required timeframes.

'Other' areas of practice that require improvement:

- The PR should review the centre's website and written patient information to ensure it is accurate and consistent.
- The PR should ensure that the centre's procedures for laundering clinical linen reflect suitable infection control practices.

- The PR should ensure that products are CE marked for their designated use.
- The PR should ensure that appropriate SOPs are in place for the management of clinical and non-clinical emergencies.
- The PR should provide an update regarding the areas identified in the centre's self assessment questionnaire (SAQ).
- The PR should ensure fees payable to the HFEA are made in a timely manner.

Since the inspection the PR has now provided confirmation or evidence that all of the recommendations have been implemented.

Information about the centre

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.

The centre provided 104 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 with additional conditions as described earlier.

At its meeting on 12 May 2014 the centre's application for a licence was refused by the HFEA Licence Committee. The PR exercised his statutory right to make representations regarding this decision which were heard in September and October 2014. In November 2014 the Committee considering the representations refused the application for a licence. This decision was overturned on appeal by the PR in 2015 and a licence was granted as described above.

The centre's licence was varied in October 2016 to reflect a change of Licence Holder.

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

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.

Details of Inspection findings

Quality of Service

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

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period October 2014 – September 2015 show the centre's success rates are in line with national averages.

In 2015 the centre reported 13 cycles of partner insemination with three pregnancies. This is likely to be consistent with the national average.

Multiple births[2]

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

Between October 2014 and September 2015, the centre's multiple clinical pregnancy rate (MPR) for all IVF, ICSI and FET cycles for all age groups was 29%. 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 multiple birth minimisation strategy however no further recommendation is required.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and review witnessing records in patient notes. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

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

On inspection, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed, the 'bring-forward' system was discussed with the senior embryologist. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

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[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%.

Staffing

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

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; the senior embryologist described that he is able to carry out laboratory activities without distraction and staff are available to carry out witnessing activities when required.

Quality Management System (QMS)

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

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: controlled drugs, witnessing, consent to storage and consent to legal parenthood. The centre's procedures for auditing and acting on the findings of audits are compliant with requirements. However, the centre's most recent self-assessment questionnaire (SAQ) indicates that the centre's consent procedures and, from inspection, control of infection procedures have not been audited. Quality indicators have not been established for the provision of information (see section 'Compliance with HFEA standard licence conditions and recommendation 8). It was also noted that the centre does not have a SOP to direct action in the event of a clinical or non-clinical emergency (recommendation 8).

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

- the centre's audits of witnessing, consent to storage, consent to legal parenthood and controlled drugs
- the use of CE marked medical devices
- the content of the centre's website
- the use of the most recently issued HFEA consent form versions
- HFEA Clinic Focus articles regarding: screening requirements, equipment failures and Zika virus

The centre has been effective in ensuring compliance with guidance issued by the HFEA, with one exception noted in the 'equipment and materials' section of this report.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way. Centre staff described that patients are provided with routine treatment medicines via a home delivery pharmacy. On occasion additional medicines will be provided to the patient directly, for which the PR is responsible.

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

- the medicines fridge contained a small number of part used blister packs of tablets that could not clearly be identified;
- a log of the minimum and maximum daily operating temperature of the medicines fridge is maintained and was within range, however on the day of inspection the min/ max temperature readings on the fridge thermometer appeared to be significantly out of range and it could not be determined whether this was a fault with the thermometer or the fridge itself, this could pose a risk that the medicines contained within the fridge were compromised;
- the centre does not have a Controlled Drugs Accountable Officer (CDAO) registered with the Care Quality Commission (CQC) or evidence of exemption from this requirement.

(Recommendations 2 and 3).

Infection Control

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

During the inspection, the inspection team reviewed infection control practices and found them to be broadly compliant with guidance as described below and in the section 'Compliance with HFEA standard licence conditions'.

- the centre launders all clinical linen on site. The process by which the linen is laundered has not been validated against guidance on the decontamination and laundering of clinical linen;
- the centre has not conducted an audit of infection control practices.

It is however acknowledged the centre has not reported any incidence of infection (recommendations 6).

Equipment and Materials

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

The CE mark status of the medical devices in use was reviewed in the course of the inspection. The centre is compliant with HFEA requirements to use CE marked medical devices wherever possible with one exception, although the pots used for the collection of sperm to be used in treatment are CE marked, this is for in vitro diagnostic use only. A product CE marked for this specific use has however only recently become available (recommendation 7).

Patient experience

During the inspection, there were no patients available to speak with the inspectors about their experiences at the centre. Thirteen patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with eight of the individuals providing written feedback giving compliments about the care received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- has staff who are supportive and professional;
- maintains an effective system for responding to patient phone calls.

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

Information submitted by the centre in their SAQ, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is non-compliant in a number of areas as follows:

The centre's most recent SAQ submitted on 11 December 2015 indicates that the centre has not:

- established quality indicators for the provision of information;
- evaluated all third parties ability to meet required standards and;
- cannot provide documented evidence of the outcome of regular audits and evaluations of the progress and effectiveness of the multiple births minimisation strategy.

Due to other matters taking priority on the day of inspection, it was not possible to discuss whether the actions outstanding from the centre's SAQ had been completed and will therefore be followed up separately (recommendation 9).

It was noted that the centre's website contains information regarding permitted storage periods that does not accurately reflect current legislation in that it refers to that permitted prior to a change in the law in 2009. It was also noted the written information for egg donors, egg sharers and their recipients is inconsistent (recommendation 5).

Suitable premises and facilities:

A tour of the premises showed that whilst the areas accessed by patients appeared to be clean and orderly, some non-patient areas were generally cluttered and could pose a hazard. For example, decommissioned equipment and materials were being stored in various places around the centre, including in rooms used by patients. Some areas were not clean, and in particular the following points were noted:

- the room in which dry sterile consumables for use in theatre and the medicines fridge was housed is damp, smelt strongly of mould and the integrity of the walls was compromised as damp has lifted much of the paint and plaster from the wall onto the floor immediately behind the medicines fridge;
- medical records are stored in a room within an annex to the main building, although some of the records were stored in filing cabinets, these were not locked. Access to this building was uncontrolled on the day of inspection and there was no facility to lock the door leading to the area where records were stored;
- the call bell in one recovery bay was not working;

- a store cupboard in the male production room was not secure and contained redundant equipment, laboratory consumables and liquids which are subject to Control of Substances Hazardous to Health (COSHH) regulations;
- an outside area leading from a fire exit via the centre's laundry room was heavily littered with waste, empty clinical waste containers and containers filled with foul water which could make evacuation in an emergency hazardous. A small oxygen cylinder still with the regulator attached had been discarded and appeared to be corroded;
- fuel canisters used to supply the centre's emergency generator were propped against a wooden part of the building. The canisters appeared to be made of a plastic material and had been bleached by the sun and therefore the integrity of the casing could not be assured;
- a vault like cupboard off the laundry room which housed cleaning equipment, the emergency generator control and also the centre's fire alarm panel was cluttered and the integrity of the floor was poor and very uneven, it was considered that this was a significant risk to staff entering this area.

Such was the level of concern raised by these findings; the PR was required to take immediate corrective actions as described in the section 'Areas of practice that require the attention of the Person Responsible' (recommendation 2). The issues identified on inspection with regard to these areas are serious, however it is acknowledged that the PR has already taken action to rectify the issues that were of greatest concern and as such the inspectors consider the premises are now suitable.

Compliance with recommendations made at the time of the last inspection

Following the licence renewal inspection in 2013, recommendations for improvement were made in relation to two critical, seven major areas non compliance and five 'other' areas of practice that required improvement.

The PR subsequently provided evidence that the critical areas of non compliance had been addressed and evidence or assurance was provided that the major areas of non compliance had also been addressed. Evidence of subsequent practice audit, and follow up monitoring, had not been possible to obtain whilst the centre's licence renewal application was being considered by the Appeals Committee. Where possible these areas of practice were reviewed during this inspection and were found to be compliant with requirements.

On-going monitoring of centre's performance

Since the licence renewal inspection in June 2013, the centre has not received any HFEA risk tool alerts relating to success rates, the centre has however received numerous alerts relating to the late payment of treatment fees due to the HFEA. The HFEA finance department report that there has been no real improvement in this regard (recommendation 10).

Provision of information to the HFEA

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

In January 2014 the General Medical Council (GMC) asked the HFEA to assist with a line of enquiry being made pursuant to their statutory functions in relation to the accuracy of treatment and outcome data provided by the PR to a Clinical Commissioning Group (CCG). The HFEA was asked that this data be compared with the treatment data provided to the HFEA register as required by Direction 0005. The HFEA was able to assist as permitted by Section 8E of the Human Fertilisation and Embryology Act (as amended) which gives power to the HFEA to provide assistance to another public authority for the purposes of assisting that authority in the exercise of its functions. The HFEA viewed the data provided by the GMC against that held on the HFEA register for the same period. A number of discrepancies were noted. The register team worked with the PR and some reconciliation of the data was achieved however a number of discrepancies remained. The PR felt that is this would be best addressed by a review of primary records held at the centre. In October 2014, an on site visit was conducted by members of the HFEA register team. Since that time the register team has continued to work with the PR in order to determine where errors or omissions from the register are apparent and to reconcile the data held. It is acknowledged that significant progress and improvement has been made with regard to data submission, there are however a small number of treatment data discrepancies still under investigation. At the time of the inspection the register team had queries outstanding relating to five patient records (recommendation 4).

Legal parenthood

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.

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 appeared to be comprehensive and described that it 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. The PR was advised to seek legal advice and to inform the HFEA of his intended course of action. At the time of the inspection the PR was still in the process of seeking legal advice and considering his course of action. Since the inspection the PR has provided confirmation that the anomaly identified by the centre's own audit has been addressed in that the couple were in fact in a civil partnership prior to treatment.

A sample of records where treatment was provided with donor sperm and legal parenthood may be required, drawn from a list of donor treatments submitted to the HFEA register; was requested on inspection. The centre has not provided any treatment with donor gametes or embryos for over a year. Five patient records were reviewed, two of which contained anomalies. One case had been identified by the centre's own audit and one other was

identified by the inspection team. In this instance the couple had received three cycles of treatment and the patient's record contained two sets of legal parenthood consent forms, the second of which were completed correctly. However, the consent forms which related to one cycle of treatment resulting in a live birth contained an anomaly. The PR was advised of this on inspection (recommendation 1). The centre's current procedures for ensuring counselling with regard to the implications of legal parenthood is offered and taking consent to legal parenthood were discussed with the PR and centre staff. The PR is responsible for obtaining consent in all cases where legal parenthood is required. The process described appears to be robust.

It was also noted that one patient had received three cycles of treatment according to the patient's record but that only two had been reported to the HFEA register. This has subsequently been corrected (recommendation 4).

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas of non-compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. Legal Parenthood Anomalies have been identified in the consent to legal parenthood forms for two couples. The PR has subsequently provided assurance that in one instance identified by the centre's own audit, the couple were civil partners prior to treatment. Although the audit of legal parenthood provided by the PR appeared robust, one further	The PR should ensure that proper consent to legal parenthood is obtained in all cases where such consent is required. The PR should provide a summary of the legal advice obtained and detail of his action with regard to the case identified on inspection when responding to this report. The PR should conduct a full	All staff have undergone training in taking consent to legal parenthood. We have again reviewed the audit on legal parenthood and can confirm the case identified during the inspection is a one off. I have contacted the same-sex couple in this isolated case. They have informed me that the child's birth certificate bears the name of the partner as second parent. They	The executive acknowledges the PR's response and action in regard to the legal parenthood consent anomaly noted and also the correction regarding responsibility for obtaining written consent to legal parenthood. The PR has now provided confirmation that the couple do not wish to proceed with any further action at this time.

instance where anomalies are present in a couple's consent forms was identified on inspection. SLC T57	review of the centre's legal parenthood audit in order to establish whether the anomaly found in the sample reviewed by the inspection team is an isolated case. The findings of this review should be provided to the centre's inspector when responding to this report.	therefore do not believe that further court process or declaration is necessary. This not withstanding I am in the process of seeking appropriate legal advice. I have been away from base but returned recently. I anticipate that the process with be completed within two weeks. NOTE: In the report's commentary under the heading "Legal Parenthood" it is stated that "The PR is responsible for obtaining consent in all cases were legal parenthood is required". This statement is wrong. While the PR initiates discussion on the importance and implications of consent to legal parenthood, further information giving, verbal and written, and actual signing of consent to legal parenthhood is done by fertility nurses.	No further action is required.

2. Suitable premises and facilities: • the room in which sterile dry consumables and a medicines fridge was housed was damp and considered unsuitable. SLC T9 (b), T17 • on the day of inspection the temperature of the medicines fridge appeared to be out of range, it could not be determined whether the fridge or the thermometer was inaccurate. SLC T24 • the loft room in the annex to the main building were medical records are stored was not secure and access was not adequately controlled. SLC T43 and T45 • the area outside the fire escape via the laundry room was heavily littered with discarded equipment including an oxygen cylinder with regulator still attached,	On the day of inspection and subsequently in writing, the PR was asked to take immediate action to mitigate the risks identified as follows: • the medicines fridge and sterile consumables should be moved to a suitable, secure location within the centre; • the area outside of the laundry room should be cleared of waste and the discarded oxygen cylinder removed and returned to the supplier under safety guidance from the British Oxygen Corporation (BOC); • the fuel canisters should be removed to a place of safety; • the vault cupboard should be cleared so that access and egress from the area is not obstructed; • access to the annex should be properly controlled and medical records should be stored securely.	As already acknowledged in this report most of the issues highlighted in this section were promptly corrected (within 48 hours of the inspection). On other specific issues, the following actions have been taken: a) Training on compressed gases training for relevant staff is being arranged and evidence of training will be provided by the due date of 10/6/16 b) Liquids subject to COSHH found in a storage cupboard in the men's room have been removed and stored in the appropriate place	The executive acknowledges the PRs engagement by addressing the most pressing areas of concern swiftly following the inspection visit and providing photographic evidence of this. The PR has subsequently provided evidence of key staff having received formal training in the management of medical gases. No further action is required.

waste, and containers full of foul water. • the vault cupboard was cluttered and the integrity of the floor was poor and very uneven. SLC T9 (b) Health and Safety at Work Act 1974 • fuel canisters were not stored safely and appeared to have sun damage and were not stored securely Petroleum (consolidation) Regulations 2014. Such was the concern regarding the health and safety hazards this observations pose, the PR was required to take immediate actions as described 'Action required and timescale for action'. A store cupboard in the men's room contained laboratory stock and liquids which are subject to COSHH regulations. CoP guidance 25.17	Following the inspection the PR provided written confirmation and photographic evidence that the above actions had been completed. In addition, the medicines fridge and temperature monitoring thermometer has been replaced and evidence provided that the medical records store in the annex is now locked. In consideration of the actions already taken following the inspection, the premises are now suitable. The PR also provided a commitment that staff will receive training in the safe handling and storage of compressed gas as required by the Health and Safety at Work Act 1974. Guidance on this has been provided to the PR. The PR should provide evidence of compressed gas (including medical gases) safety training for staff to the centre's inspector by 10 June 2016.		

	The PR should ensure that laboratory consumables and liquids are stored appropriately in conditions that do not pose a risk to patients or staff and that COSHH requirements are adhered to. The PR should provide a summary of actions taken in this regard when responding to this report.		

‘Major’ area of non-compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
3. Medicines management: The medicines fridge contained part strips of tablets in blister packs which could not be adequately identified. The centre does not have a CDAO in post nor has application to the CQC for an exemption been made. SLC T2, Misuse of Drugs Regulations 2001, Controlled drugs (Supervision of management and use) Regulations 2013.	The PR should ensure that a CDAO is appointed or provide evidence that application for exemption has been made to the CQC by 10 May 2016. The PR should conduct a review of the process by which medicines are stored, and how additional medicines are dispensed to patients. The PR should provide a summary of that review with detail of any actions taken in response to the centre’s inspector by 10 May 2016.	a) The centre recently had Home Office Controlled Drugs Inspection visit. We met all the home office regulatory standards. b) I am put myself forward as the Accountable Office which I have been in the past. c) Our process for providing medications for patients include the following: *A prescription written for individual patients *Prescription is sent to Healthcare At Home, a large reputable company where trained pharmacists label the medications with patient's name, package and post the medications to the patient	The executive acknowledges the PRs response to this recommendation. The PR has subsequently provided evidence of communication with CQC regarding the centre’s suitability for exemption from the requirement to appoint a controlled drugs accountable officer on account of the size of the clinic. The PR has provided assurance regarding the appropriate dispensing and labelling of occasional ‘top up’ medicines provided to patients at the clinic. This will be

		through the clinic. *Our fertility nurses give the medications to the patients following injection teaching, and a treatment diary. *We also keep a low level of stock medications in case a patient runs out of medications. In such cases, medications are packaged, labelled with clear instructions on usage.	reviewed once again at the next inspection.
4. Provision of information to the HFEA. There are a number of treatment data issues and discrepancies which remain unresolved: One treatment record is not satisfactorily accounted for, outstanding corrections have not been completed and requests for duplicate records to be deleted have not been submitted by the centre. Directions 0005	The PR should ensure that all treatment data is reported to the HFEA as required by directions and that where required, corrections are made within the required timeframes. The PR should liaise directly with the HFEA register team to ensure that all outstanding record anomalies are resolved to the satisfaction of the executive by 10 May 2016.	Our EDI audit in the past 18months have shown very good outcomes. We have achieved 100% in return of patient treatment data to the HFEA mostly within the required time scale. Accuracy has also been over 95%. As I have stated previously, the problems that are being referred to are historical, pre-dating 2013. New staff in place have received training and an SoP for Data returns was written and submitted to the HFEA. In my email to Mrs Gill Walsh	The executive acknowledges the PRs response to this recommendation. The centre has not received any risk tool alerts related to data submission however this will be monitored by the HFEA register team. No further action required at this time.

		and Chris Hall dated 17/02/16 I provided clarifications on the outstanding data issues. If there are further issues, please provide specific details so these can be addressed.	

‘Other’ areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
5. **Provision of information to patients**. Information on the centre’s website regarding the length of time gametes and embryos may be stored does not reflect the current storage periods permitted. Written information for egg donors and recipients is inconsistent. SLC T58	The PR should review the centre’s website and written patient information to ensure it is accurate and consistent. The PR should confirm that the information on the centre’s website had been revised and provide a copy of the amended egg donor and recipient information to the centre’s inspector by 10 May 2016.	The PR has provided his response to this recommendation in the section 'additional information from the PR'.	The executive acknowledges the PRs response to this recommendation and confirmation that changes have been made to the centre’s website. Copies of the amended information for egg donors and recipients have been provided. No further action is required.
6. **Infection control**: The process for decontaminating and laundering clinical linen has not been validated to ensure any risk of cross infection is mitigated. The centre has not audited their infection and control practices as yet.	The PR should ensure that the centre’s procedures reflect suitable infection control practices. The PR should validate the process by which clinical linen is decontaminated and laundered in house to mitigate any risk of cross contamination with potentially infectious	The PR has provided his response to this recommendation in the section 'additional information from the PR'.	The executive acknowledges the PR’s response to this recommendation and receipt of the centre’s validated SOP for the decontamination and laundering of clinic linen. The centre’s infection control audit will be reviewed as part of the next inspection.

SLC T2 CoP guidance 26.3	material. It is suggested that the PR approaches this in a similar way to process validation reviewing relevant literature and guidance that is readily available. A copy of the validation and SOP for laundering clinical linen should be provided to the centre's inspector by 10 May 2016.		No further action is required.
7. CE marked devices Pots used for collecting sperm for use in treatment are CE marked for in vitro diagnostic use only. SLC T30	The PR should source an alternative product which is appropriately CE marked for this use and should confirm when this is done. This product should be in use no later than 10 September 2016.	An alternative semen collection pot has been sourced and is already in use	The executive acknowledges the PRs response to this recommendation. No further action is required.
8. Quality management system The centre does not have SOPs to direct actions in the event of a clinical or non-clinical emergency. SLC T33(b)	The PR should ensure appropriate SOPs are in place to direct actions in the event of a clinical or non-clinical emergency. A copy of the SOPs should be provided to the centre's inspector by 10 July 2016.	SoPs for clinical and non-clinical events management are being written and copies will be forwarded to the HFEA by 10/7/16.	The executive acknowledges the PRs response to this recommendation and receipt of the SOPs. No further action is required.

9. Self-Assessment Questionnaire (SAQ) responses: The centre's current SAQ indicates that the following requirements are outstanding: • The centre has not audited their consent procedures within the last two years; SLC T36 • The centre has not established quality indicators for the provision of information; SLC T35 • The centre has not evaluated all third parties against required standards; SLC T112 • The centre cannot provide documented evidence of the outcome of regular audits and evaluations of the progress and effectiveness of the multiple births minimisation strategy Direction 0003	The PR should appraise the centre's inspector by 10 May 2016 as to whether the areas identified in the SAQ have been met and if so provide a copy of relevant documentation as evidence be provided or, where these requirements remain outstanding; provide the centre's inspector with an action plan with timescales for when these requirements will be met.	a) The SAQ actually stated the centre has audited the consent procedures within the last two years, contrary to what is stated in this report b) Again the SAQ stated the centre had established quality indicators (number 2 was ticked). The centre has established quality indicators for provision of information c) The centre has evaluated all third parties against required standards d) Audit of the multiple births minimisation strategy is on-going. A report will be forwarded to the inspector by 1st July 2016	The executive acknowledges the PRs response this recommendation and clarification / update provided. A copy of the consent audit has been provided and confirmation that quality indicators for the provision of information have been formulated and third party agreements reviewed. Audits of the centre's multiple birth minimisation strategy have been provided for the period January to June 2016. No further action is required.

10. Finance Treatment fees payable to the HFEA are consistently made late, taking an average of 60 days for payment. SLC T9 (d)	The PR should ensure fees payable to the HFEA are made in a timely manner. The PR should review the process by which fees are paid to the HFEA to determine where there are barriers to prompt payment being made and provide a summary of actions taken in response to this review, to the centre's inspector by 10 May 2016.	I suggest that the HFEA send invoices by e-mail to: s.grainger@stjudeclinic.com and cc: clinic@stjudeclinic.com We have also noticed from our end that there seems to be a long lag time between when cheques are sent out and when it actually registers as paid at the HFEA.	The executive acknowledges the PR's response to this recommendation. The finance department of the HFEA have been informed of the PRs response and suggestion. No further action is required at this time.

Additional information from the Person Responsible
I was unable to write my response for No.5 - Provision of Information to Patients & No.6 - Infection Control in the appropriate box. I am therefore providing my response here: No.5 - Provision of Information to Patients: PR Response - The centre's website manager has been instructed to make the required corrections and he will do so ny the deadline of 10/5/16. Corrections have been made in the written information for egg donors and recipients. Copies will be emailed the centre's inspectors by 10/5/16. No.6 - Infection control: PR Response - The centre's SoP for decontaminating & laundering on clinical linen will be forwarded by 10/5/16. Validation process will be outlined.