Executive Licensing Panel - minutes

Centre 0008 (IVI Midland)

Interim Inspection Report

Tuesday, 11 December 2018

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Lisa Whiting Helen Crutcher	Director of Strategy and Corporate Affairs Research Manager Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Senior Governance Manager

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

1.1. The panel noted that IVI Midland is located in Tamworth and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services.

1.2. The panel noted that, following the renewal inspection in March 2017 the Executive Licensing Panel (ELP) 'had some concerns about the non-compliances, particularly those relating to donor screening, consent and reporting of treatment data to the HFEA'. The panel was reassured by the inspectorate that there was no ongoing risk to patient safety and as the centre was due to change ownership to the IVI UK group and have a change of Person Responsible (PR), it was envisaged that changes would be made to the centre's processes that would assist improvements.

1.3. The ELP, at its meeting on 2 June 2017, agreed to the inspectorate's recommendation of a four-year licence with no conditions, but requested that the inspectorate conduct an interim inspection within 12 months of the licence coming into force, to ensure the non-compliances identified at the renewal inspection had been fully addressed.

1.4. The panel noted that, in addition, there had been a concern raised by a patient about social egg freezing at this centre and how the success rates are presented to patients. The inspection team took the opportunity, during this inspection, to discuss the concerns raised, to review in detail the centre's egg freezing procedures and all patient information including likely success rates. The inspection team was satisfied that the centre has revised all patient information to incorporate the egg freezing report that was published by the HFEA in September 2018. It was acknowledged by the centre that the way they present their success rates could be made clearer and the PR made a commitment to revise this to ensure that the data presented is clearer and that patients are given appropriate information concerning the chances of success.

1.5. The panel noted that, in the 12 months to 30 June 2018, the centre had provided 645 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre.

1.6. The panel noted that in 2017, the centre reported 19 cycles of partner insemination with one pregnancy. This is comparable to the national average.

1.7. The panel noted that, HFEA register data, for the period April 2017 to March 2018, show the centre's success rates for IVF and ICSI are in line with national averages.

1.8. The panel noted that the inspection took place on 27 September 2018.

1.9. The panel noted that at the time of inspection there were two critical areas of non-compliance identified concerning consent to storage of cryopreserved materials and medicines management. Three major areas of non-compliance were also identified concerning infection control, process validation and equipment, alongside one 'other' area regarding disclosure of information, held on the HFEA register, for use in research. Since the inspection, the PR has provided assurance that the critical non-compliance regarding medicines management has been fully implemented, alongside the recommendations relating to infection control, equipment and the disclosure of information, held on the HFEA register, for use in research. The PR has given a commitment to fully implement the recommendations relating to consent to storage of cryopreserved materials and process validation. Where required and by the dates specified, the PR will provide an update or summary of audits conducted to ensure the corrective actions taken are effective.

1.10. The panel noted that the inspectorate recommended the continuation of the centre's treatment and storage licence, but given the concerns raised in the interim report, proposed that a further inspection be conducted within the next 12 months.

2. Decision

2.1. The panel noted the PR's positive engagement with the inspection process.

2.2. The panel was satisfied the centre was fit to have its treatment and storage licence continued, agreeing with the inspectorate's recommendation that a further inspection should be conducted within the 12 months, given the concerns raised in the report.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

14 December 2018

Interim Licensing Report

Centre name: IVI Midland
Centre number: 0008
Date licence issued: 01/08/2017
Licence expiry date: 31/07/2021
Additional conditions applied to this licence: None
Date of inspection: 27/09/2018
Inspectors: Julie Katsaros, Polly Todd and Louise Winstone
Date of Executive Licensing Panel: 07/12/2018

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 targeted interim inspection and provides information on the centre's performance and level of compliance since the renewal inspection in March 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 an 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 Licensing Panel

The inspection team recommends continuation of the centre's licence, but given the concerns raised in this report, the inspection team recommends a further inspection be conducted within the next 12 months.

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

Since the inspection visit the PR has provided assurance that the following recommendations have been fully implemented:

Critical areas of non compliance:

- **The PR must ensure compliance with medicines management regulations and best practice guidance.**

Major areas of non compliance:

- The PR should ensure compliance with infection prevention and control practices in accordance with statutory and best practice guidance.
- The PR should ensure that all critical equipment is subject to monitoring.

'Other' areas of non-compliance:

- The PR should ensure that the consent to disclosure information supplied to the HFEA accurately reflects that given and recorded on disclosure consent forms.

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

Critical areas of non compliance:
The PR must ensure that there is effective consent in place for all stored gametes and embryos

Major areas of non compliance:

- The PR should ensure critical procurement and processing procedures are validated.

Where required and by the dates specified, the PR will provide an update or summary of audits conducted to ensure the corrective actions taken are effective.

Information about the centre

IVI Midland is located in Tamworth and has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services.

The centre provided 645 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2018. In relation to activity levels this is a medium sized centre.

Following the renewal inspection in March 2017 the ELP *'had some concerns about the non-compliances, particularly those relating to donor screening, consent and reporting of treatment data to the HFEA'*. The panel was reassured by the inspectorate that there was no ongoing risk to patient safety and as the centre was due to change ownership to the IVI UK group and have a change of Person Responsible (PR), it was envisaged that changes would be made to the centre's processes that would assist improvements.

The panel agreed to the inspectorate's recommendation of a four-year licence with no conditions but requested that the inspectorate conduct an interim inspection within 12 months of the licence coming into force to ensure that the non-compliances identified at the renewal inspection had been fully addressed.

In addition, there has been a concern raised by a patient about social egg freezing at this centre and how the success rates are presented to patients. The inspection team took the opportunity during this inspection to discuss the concerns raised, to review in detail the centre's egg freezing procedures and all patient information including likely success rates. The inspection team was satisfied that the centre has revised all patient information to incorporate the egg freezing report that was recently published by the HFEA. It was acknowledged by the centre that the way they present their success rates could be made clearer and the PR made a commitment that this was to be revised to ensure that the data presented is clearer and that patients are given appropriate information concerning the chances of success.

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 April 2017 to March 2018 show the centre's success rates are in line with national averages.

In 2017, the centre reported 19 cycles of partner insemination with one pregnancy. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

[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 multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 10% MLBR target is calculated as equivalent to a MCPR of 13%.

Between April 2017 and March 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 9%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure 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 did discuss witnessing with staff and review witnessing in patient records. 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 stored gametes and embryos, storage logs, and consent records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are not effective because:

- Three patient sperm samples and eggs from two patients are being stored beyond the statutory storage period, without a valid Medical Practitioner's Statement (MPS);
- A MPS is in place for another patient's cryopreserved eggs, to confirm the patient's eligibility to extend the storage period, but the patient has not completed an extended storage consent form and therefore the storage of this sample is non-compliant with the Human Fertilisation and Embryology Authority (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ('the 2009 Regulations') ;
- Five donor sperm samples are being stored beyond the period to which the sperm donor had given their consent;
- The storage consent for one embryo had expired.

The centre has a significant history of non-compliance with storage consents. At the inspections in 2009, 2011 and 2013, storage consent issues were identified. At the interim inspection in 2015, whilst there were no samples being stored outside of their consented period, the inspection team raised concerns about the centre's processes for reviewing stored samples for which the consent period was coming to an end. At the renewal inspection in 2017, three stored samples were found to be non-compliant with storage regulations.

The inspection team was extremely concerned that the centre has failed to implement procedures to ensure ongoing compliance with statutory and regulatory storage requirements and requested immediate actions from the PR, prior to this report being completed, to which the PR has responded.

See recommendation 1.

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.

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 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: witnessing, consent to storage and medicines management.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements with the exceptions noted in this report (see 'Consent to the storage of cryopreserved materials' above, and 'Medicines management' section below).

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

- The use of CE marked medical devices.
- The use of the most recently issued HFEA consent form versions.
- The centre's audit of legal parenthood.

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

Medicines management

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

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

- Consistently throughout the controlled drug register only one patient identifier was documented.
- The time of administration of the controlled drug is not recorded in numerous cases.
- The administration of the controlled drug is not witnessed in numerous cases.
- On receipt of controlled drugs into stock, the requisition number is not recorded.
- There are several deletions and amendments in the controlled drugs register which are not in line with regulatory requirements or the centre's own standard operating procedure (SOP).

- The carry-over of controlled drugs from one page to another is not recorded or witnessed.
- The controlled drugs audit lacked robustness in that it did not identify the issues noted in this report.

See recommendation 2.

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.

Infection control

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

During the inspection, we reviewed infection control practices and found them to be partially compliant with guidance because:

- The centre could not provide assurance that the protocol used to wash staff uniforms is appropriate to prevent the potential spread of infections.
- Cleaning schedules in the phlebotomy room, scan room two and the patient's toilets were not fully completed.
- A privacy curtain had not been changed in line with the centre's own protocols.
- Sharps bins were not labelled in line with regulatory requirements.
- The sharps bin in the phlebotomy room was filled above the indicated maximum fill line.
- Temporary closures on sharps bins were not being used.
- A holdall containing an emergency oxygen cylinder was very dusty. The inspection team was concerned that the equipment contained within the holdall had not been checked.

See recommendation 3.

Equipment and Materials

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

The CE mark status of the following medical devices was reviewed in the course of the inspection: sperm pots, Repromed and vitrolife pipettes.
We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Ten patients have provided feedback in

the last 12 months. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting staff at the clinic.

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre, however, the centre also obtains their own feedback from patients via an online patient satisfaction survey, the findings of which were sent to the inspector for review after the inspection. Feedback was generally positive.

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

- Treats patients with privacy and dignity.
- Gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions.
- Has staff that treats patients with empathy and understanding.

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is compliant with HFEA requirements with the following exception: a fridge containing anaesthetic drugs is not subject to temperature monitoring (see recommendation 5).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to six major and five 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales. However, during this inspection it became apparent that the following recommendations had not been implemented fully:

- 'The PR should ensure critical procurement and processing procedures are validated'. Following the inspection in 2017, the PR was asked to complete a validation programme, following which a sample of documents were requested and reviewed by the centre's inspector. However, the validation programme was not complete because the process for sperm freezing and thawing, and the preparation of culture dishes has not been validated. (see recommendation 4).
- 'The PR should ensure a valid medical practitioner's statement is available for all samples that have been stored beyond 10 years'. Non compliance with storage requirements has reoccurred at this inspection (see recommendation 1).

The Executive notes that shortly after the inspection in 2017, a new PR was appointed. However, the PR was aware of the findings of the previous inspection and agreed to take responsibility for the outstanding issues.

On-going monitoring of centre success rates

Since the last renewal inspection in March 2017 the centre has not received any performance related risk tool alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is partially compliant with requirements to submit information to the HFEA because:

- One discrepancy was found between 10 completed patient disclosures on the patient files and the related consent data submitted for inclusion on the register for the disclosure of information, for use in research (see recommendation 6).

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.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At that inspection in March 2017, legal parenthood consenting processes were found to be robust.

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

Areas of practice that require the attention of the Person Responsible

This 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 made.

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 non-compliance requires immediate action to be taken by the Person Responsible.

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

Area of practice and reference	Action required and timescale for action	PR response	Inspection team's response to the PR's statement
1. **Consent to storage of cryopreserved materials** On the day of the inspection the centre did not have effective consent for the storage, because: • Three patient sperm samples and eggs from two patients are being stored beyond the	The PR should ensure that there is valid consent for all cryopreserved gametes and embryos. The PR should complete a full audit of all samples in storage to establish if there are any further samples without valid consent.	An immediate audit undertaken on consents for storgae of gametes and embryos. Summary of the audit attached. Currently all non compliances addressed. Majority needed discard after ensuring reasonable attempts of contact. Some needed extension and patients consent and MPC in place. One of the completed	Since the inspection and prior to the release of this report the PR has conducted a review of practices and a full audit of all cryopreserved materials and has informed the centre's inspector of further storage consent anomalies. Following the audit of cryopreserved materials the

statutory storage period, without a valid MPS. • A MPS is in place for another patient's cryopreserved eggs, but the patient has not completed an extended storage consent form and therefore this sample is being stored outside of the consented storage period. • Five donor sperm samples are being stored beyond the statutory storage period and beyond the period to which the sperm donor had given their consent. • The storage consent for one embryo has expired. The centre has a significant history of non-compliance with storage consents, at the inspections in 2009, 2011 and 2013, and 2017. Human Fertilisation and Embryology (Statutory Storage Period for Gametes and Embryos)	A summary of this audit should be provided to the centre's inspector by 15 October 2018. In all cases where there has been a failure to comply with the 2009 Regulations, the PR should seek independent legal advice on how to proceed, including whether affected patients ought to be informed. Proposed actions in response to this advice should be forwarded to the centre's inspector prior to any action being taken. The PR should investigate how this non compliance has reoccurred, identifying the barriers to ensuring medical practitioner's statements and valid consents are in place, and should review processes accordingly. The PR should also ensure all relevant staff members understand the requirements of the Act as it relates to consent and the 2009 Regulations. The outcome of this	consent form from patient held in IT quarantine. Legal advice has been obtained from James Lawford Davies regarding the storage samples which did not meet the 2009 statutory storage regulations. Patient informed of this as per the advice. Further clarity awaited as there is a QC instructed by the HFEA on this. Action Plan: - Appropriate resources allocated to contact and chase patients - Bring forward system put back to 6 months rather than 4 months - colour coded system implemented on the data base to alert time frame - added to clinical meeting agenda with a monthly report to be presented at the monthly meetings - avoid email receipt of consents	PR has made good progress in her efforts to ensure compliance. The PR is seeking legal advice regarding the continued storage of samples which do not meet the requirements of the 2009 Statutory Storage Regulations. Continuing discussions outside of this report will take place. **Further update following PR response** The Executive acknowledges the PR's response and commitment to implementing this recommendation. However, the PR has still to provide Information as to why this issue has reoccurred and how she plans to ensure that all staff are fully conversant with statutory storage regulations.

Regulations 2009, paragraph 3(3)(b). Schedule 3, 8(1) HF&E Act 1990 (as amended).	investigation, including the centre's intended actions and the timescales for their implementation should be submitted to the centre's inspector by 15 October 2018. Six months after the implementation of corrective actions, the PR should conduct an audit of storage practices, procedures and consents, to ensure that corrective actions taken have been effective in achieving and maintaining compliance. A summary report of the audit should be provided to the centre's inspector by 27 March 2019. The PR is reminded of guidance issued in CH(03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions to take should there be a possibility of legal challenge to the disposal of cryopreserved material.		The PR should submit this review to the centres Inspector by 15 January 2019 Further action required

2. Medicines management A review of the controlled drug register found the following non compliances: • Consistently throughout the register only one patient identifier was documented. • The time of administration of the controlled drug is not recorded in numerous cases. • The administration of the controlled drug is not witnessed in numerous cases. • On receipt of controlled drugs into stock, the requisition number is not recorded. • There are several deletions and amendments in the controlled drugs register which are not in line with regulatory requirements or the centre's own standard operating procedure (SOP).	The PR should ensure compliance with medicines management regulations and best practice guidance. The PR should commission a review of the centre's medicines management practices by a qualified pharmacist including. but not exclusively. the issues identified in this report. This review should also encompass any training and competency requirements identified. The PR should provide a copy of the review and a plan of action to the centre's inspector by 15 October 2018. Three months after the implementation of corrective actions, the PR should perform an audit to ensure that these corrective actions have been effective. A summary report of this audit should be provided to the centre's inspector by 27 January 2019.	Dicsussion held soon after the insepction with our CD accountable officer and anesthetists to inform of the concerns raised. All relevant staff trained again on completing the CD register. Independent external review undertaken by a senior pharmacist. Report attached. Recommendations incorporated into the Medicines management SOP and disseminated to the staff. A monthly internal audit will de done to ensure compliance and reported in the monthly clinical meeting. Audit summary report will be provided to the centre's PR by 27 January 2019.	Since the inspection and prior to the release of this report the PR has taken steps to implement this recommendation. The outcome of the independent medicines management has been received by the Executive and recommended further actions, which the PR has committed to implementing. **Further update following PR response** The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action beyond submission of the audit due by 27 January 2019.

• The carry-over of controlled drugs from one page to another is not recorded or witnessed. • The controlled drugs audit lacked robustness in that it did not identify the issues noted in this report. DH; Controlled Drugs (Supervision of management and use) Regulation 2013. NICE Guideline [46] April 2016 'Controlled drugs; safe use and management' (section 1.7.4). 'Controlled drugs in Perioperative Care' 2006 (section 4). Misuse of Drugs (safe custody) Regulations 2001. DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (sections 4.11.1.1; 4.11.1.2).			

‘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. Infection control On inspection the following issues were noted: • The centre could not provide assurance that the protocol used to wash staff uniforms is appropriate to prevent the potential spread of infections. • Cleaning schedules in the phlebotomy room, scan room two and the patient’s toilets were not fully completed. • A privacy curtain had not been changed in line with the centre’s own protocols.	The PR should ensure compliance with infection prevention and control practices in accordance with statutory and best practice guidance. The PR should review the cleaning schedules and infection control practices to ensure compliance with this recommendation by 27 December 2018. Three months after this review, the PR should conduct an audit of the centre’s cleaning and infection control practices to ensure that corrective	Inspection findings discussed with relevant staff and the Infection control lead. Non compliances adressed. Staff uniforms are being washed as per the latest Central Government Legislation – HTM 01-04. Cleaning schedules were not completed due to change of staff from the external company. This has been fedback to the company and our house keeper has taken charge of insepcting this on a regular basis to ensure compliance.	Since the inspection and prior to the release of this report the PR has taken steps to implement this recommendation. **Further update following PR response** The Executive acknowledges the PR’s response and commitment to implementing this recommendation and confirms receipt of the requested review No further action beyond submission of the audit due by 27 March 2019.

• Sharps bins were not labelled in line with regulatory requirements. • The sharps bin in the phlebotomy room was filled above the indicated maximum fill line. • Temporary closures on sharps bins were not being used. • A holdall containing an emergency oxygen cylinder was very dusty. The inspection team was concerned that the equipment contained within the holdall had not been checked. SLC T2; T17. CoP 25.19; 25.20. DH Health and Social Care Act 2008: Code of practice on the prevention and control of infections and related guidance. DH Health Technical Memorandum 07-01 Safe	actions implemented have been effective in achieving and maintaining compliance. A summary report of this audit with corrective actions taken should be provided to the centre's inspector by 27 March 2019.	Staff educated about best practice on the use of sharps bin. Infection control policy being reviewed to incorporate further steps to ensure future compliance. An audit in 3 months is added to our audit cycle and the report will be sent to the centre's inspector by 27 march 2019.	

Management of Healthcare Waste (2013).			
4. Process validation The process of sperm freezing and thawing and the preparation of culture dishes have not been validated. The above processes were previously cited as a non-compliance at the renewal inspection in 2017. SLC T72.	The PR must ensure all critical processes used by the centre are validated. When responding to this report, the PR should advise the centre's inspector of the planned date by which validation of the processes identified in this report are expected to be completed. It is expected that validation will be completed by 27 December 2018 and the PR is to provide a copy of the validation reports to the centre's inspector. The PR is asked to explain why this non compliance was not implemented following the inspection in September 2017, when responding to this report.	Following on from the previous insepction in 2017, a number of critical steps have been validated, however not completed. Apologies for not having completed them within the stipulated time. Dedicated member of staff has been allocated adequate time to complete the pending process validation asap. The report will be sent to the centre's inspector by 27th december 2018.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.
5. Equipment	The PR should ensure that all critical equipment is subject to monitoring and that corrective actions are documented.	The fridge containing the anesthetic drugs has now been installed with a thermometer and incorporated into the central	Since the inspection and prior to the release of this report the PR has taken steps to ensure that

A fridge containing anaesthetic drugs is not subject to temperature monitoring. SLC T24.	The PR should inform the centre's inspector of actions taken when responding to this report. Within three months, the centre should carry out an audit of the temperature monitoring to ensure that the corrective actions implemented have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 27 January 2019.	Brittania monitoring system with the alert systems in place. A monthly report of this will be reviewed by our line manager to ensure proper functioning of the system. An audit will be undertaken and report provided to the centre's inspector by 27 January 2019.	the fridge will be subject to temperature monitoring. **Further update following PR response** No further action beyond submission of the audit due by 27 January 2019.

‘Other’ areas of practice that require improvement

Other 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
6. Disclosure of information, held on the HFEA Register, for use in research One discrepancy was found between 10 completed patient disclosures on the patient files and the related consent data submitted for inclusion on the register. This failing does not lead to a risk that the HFEA may release patient identifying information, to researchers, without consent but that the consent wishes of the patient may not be able to be followed. CH(10)05, GD 0005.	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register. 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 the patient’s disclosure consent forms by 27 December 2018. Three months after this review, the PR should carry out an audit of consents to disclosure to researchers to ensure that corrective actions have been effective in ensuring	The discrepancy has been amended. SOP has been reviewed and amended with additional steps to avoid this in future. An audit following this will be conducted and the summary sent to the Centre's inspector by 27 March 2019.	The Executive acknowledges the PR’s response and commitment to implementing this recommendation. No further action beyond submission of the audit due by 27 March 2019.

	compliance. A summary report of the audit should be provided to the centre's inspector by 27 March 2019. The PR should also correct the data discrepancy identified in this report and confirm to the centre's inspector that this has been done when responding to this report.		

Additional information from the Person Responsible
I would like to thank the inspectors and specially our Centre's inspector Polly Todd for taking me through this inspection. It has been very helpful to liaise with them, especially in the light of me being a PR for just over an year. I appreciate their help in guiding me through the actions required for the non conformities.