Executive Licensing Panel - minutes

Centre 0077 (Regional Fertility Centre, Belfast)

Interim Inspection Report

Tuesday, 23 July 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Howard Ryan	Director of Strategy and Corporate Affairs Communications Manager Data Analyst
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Moya Berry	Licensing Manager Committee Officer

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:

- 9th 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 Regional Fertility Centre, Belfast has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services. Other licensed activities at the centre include storage of gametes and embryos.

1.2. The panel noted that, in the 12 months to 31 December 2018 the centre had provided 1133 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre.

1.3. The panel noted that, for IVF and ICSI, HFEA register data, for the year ending 28 February 2019, show the centre's success rates are in line with the national averages.

1.4. The panel noted that, in 2018, the centre reported 57 cycles of partner insemination, with four pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.5. The panel noted that, HFEA register data, for the year ending 28 February 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is likely to be statistically lower than the 10% multiple live birth rate target for this period.

1.6. The panel noted that an unannounced inspection took place on 19 February 2019.

1.7. The panel noted that at the time of inspection there were three major areas of non-compliance concerning witnessing, premises and facilities and suitable practices. There were also two 'other' area of non-compliance regarding the Quality Management System (QMS) and medicines management. Since the inspection, the Person Responsible (PR) has provided information and evidence that the recommendations on witnessing, the QMS and medicines management have been addressed. The PR has provided information and evidence that the recommendations concerning premises and facilities and suitable practices are being implemented but some planned actions still need to be completed.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment and storage licence, particularly noting the progress made by the centre in meeting the HFEA multiple birth rate target, the thorough and informative annual review of the centre's activities and QMS, alongside the positive comments made by patients in relation to their treatment at the centre.

2. Decision

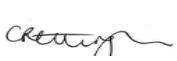
2.1. The panel expressed particular concern regarding the non-compliance relating to suitable practices, noting that an audit of patient comfort during procedures was due for submission, to the inspectorate, by 19 August 2019. Should the inspector not be satisfied with the content of this audit, the panel requested that a further report be submitted to them for consideration.

2.2. The panel was satisfied the centre was fit to have its treatment and storage licence continued, subject to the recommendations made in the report being implemented within the prescribed timescales.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

30 July 2019

Interim Licensing Report

Centre name: Regional Fertility Centre, Belfast
Centre number: 0077
Date licence issued: 1/4/2017
Licence expiry date: 31/03/2021
Additional conditions applied to this licence: None
Date of inspection: 19/02/2019
Inspectors: Andrew Leonard (Lead); Janet Kirkland Machattie
Date of Executive Licensing Panel: 23/7/2019

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. The current foci for an interim inspection are:

- **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 Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note: the progress made by the centre in meeting the HFEA multiple birth rate target, the thorough and informative annual review of the centre's activities and quality management system, and positive comments made by patients in relation to their treatment at the centre.

The ELP is asked to note that this report makes recommendations for improvement in relation to three major and two 'other' areas of non compliance or poor practice.

The Person Responsible (PR) has provided information and evidence that the following recommendations have already been addressed

Major areas of non compliance:

- The PR should take immediate action to ensure that the identity of partners providing sperm for use in treatment, is verified against photographic identification in the records.

'Other' areas of practice that require improvement:

- The PR should ensure that all audits, and actions to address non conformances found by audits, are documented, robust and likely to be effective.
- The PR should ensure that drugs for disposal are appropriately labelled.

The PR has provided information and evidence that the following recommendations are being implemented but some planned actions still need to be completed.

Major areas of non compliance:

- The PR should ensure that the centre's premises are risk assessed and appropriate actions are taken to control risk, so that the premises provide suitable areas in which to undertake and support licensed activities.
- The PR should ensure that patients are well cared for during egg collections.

Information about the centre

The Regional Fertility Centre, Belfast has held a Treatment and Storage licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 1133 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2018. In relation to activity levels this is a large centre.

Other licensed activities at the centre include storage of gametes and embryos.

The centre's licence was renewed from 1 April 2017 for four years after a renewal inspection which identified three major and five 'other' areas of non-compliance. The current licence was varied in May 2018 to reflect a change of PR to Dr Ishola Agbaje.

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]

HFEA held register data for the year ending 28 February 2019 show the centre's success rates for IVF, ICSI, frozen embryo transfers (FET) and donor inseminations (DI), in terms of clinical pregnancy rates, are in line with national averages.

For the year 2018, the centre reported 57 cycles of partner insemination with four clinical pregnancies. This represents a clinical pregnancy rate of 7%, which is comparable to the national average.

Multiple births[2]

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

HFEA held register data for the year ending 28 February 2019 shows the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is likely to be significantly lower than the 10% multiple live birth rate target for this period.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed: two egg collections; two sperm preparations. All of the procedures observed were witnessed using an electronic witnessing system, with manual witnessing where necessary, in accordance with HFEA requirements with one exception: There is no check of the identity of partners providing sperm for use in treatment, against photographic identification in the records, to categorically confirm a sperm provider's identity. These

[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%.

activities indicated that witnessing procedures are partially compliant with HFEA requirements (recommendation 1).

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 staff and the storage records were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

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; staff in the laboratory were able to carry out their activities without distraction and were 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 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: medicines management; patient feedback; storage consent and dewar contents; legal parenthood; witnessing; traceability; consent to treatment.

The centre's procedures for auditing and acting on the findings of audits are broadly compliant with requirements because: Audits were generally of good quality but occasionally were not robust, e.g. the medicines management audit did not include review of entries in the CD register against drugs usage documented in the patient records; the weekly infection control observational audit was not documented; and the monthly legal parenthood consent audit did not review if counselling was offered and taken up before consent was signed, or if there was a record of consent withdrawal and appropriate actions being taken by centre staff in response. Proposed actions in response to non conformances in the audits of traceability and consent were considered by the inspection team unlikely to be effective (recommendation 4).

It is noted that a fully compliant legal parenthood audit is performed annually, in addition to the monthly audit discussed above, and that the annual review of centre activity and the QMS was, notably, of high quality.

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:

- leadership
- patient support
- information provision
- surrogacy
- imports of gametes and embryos from outside the EU/EEA
- the use of the Single European Code
- the use of CE marked medical devices
- HFEA Clinic Focus articles regarding screening requirements

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 broadly compliant with guidance because: Drugs for disposal were present in the controlled drugs cupboard but were not marked 'for disposal' (recommendation 5).

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 compliant with guidance, notwithstanding concerns discussed below related to premises which impact on infection control.

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 used in egg and sperm procurement and egg culture was reviewed in the course of the inspection. 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. Only four patients have provided feedback in the 12 months to 31 December 2018, giving an average 3 star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.

The HFEA website also gives the ability for patients to comment on the cost of treatment. All four patients confirmed that they had paid what they expected to.

Because of the lack of feedback, the centre's own most recent patient survey was reviewed. It comprised an analysis of 37 responses to a questionnaire provided to approximately 100 patients over a month of treatment. Feedback was generally good and more than ten patients provided written comments complimenting the centre. Some negative comments were made; these were discussed with staff and it was apparent to the inspection team that the comments had been considered and actions taken where possible to improve the patient pathway, with the exception of the issue discussed below in recommendation 3.

No patients were available to speak to inspectors during this inspection visit.

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;
- has staff who are supportive and professional;
- 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 or observations during the visit to the centre, indicate that:
a) The centre's premises are partially compliant with HFEA requirements to have suitable premises and facilities (recommendation 2) because:

- The centre was being renovated in some non-clinical areas at the time of the inspection and several risks were identified:
    1. Some fire exits were not clear.
    2. Some non clinical areas were dusty and cluttered.

3. A patient corridor contained trolleys with cardboard boxes containing floor tiles and adhesive. These latter boxes were marked as flammable.
4. The renovation project had not been risk assessed.

- A store room in which the IT server is located, was cluttered with boxes, Christmas decorations and items which staff could not identify. The state of the room was a risk due to multiple slip/trip hazards and from boxes stored on high shelves, some of which seemed unstable.
- The centre's clinical waste is stored in a locked communal waste storage area outside the centre. The area around the locked store was in an unacceptable state, being badly maintained and littered on the ground with rubbish and what appeared to be bags of laundry. The inspection team considered it to be a risk to health and safety of staff and the general public, to whom it appeared accessible.
- There was sealed flooring in the clinical areas generally but in the procedure room it was cracked in some areas and the wood frame surrounding the entrance door was fragmented and splintered. These issues comprise infection control risks as they make it very difficult, without injury, to clean to the standard expected in a procedure room.
- Unsecured cylinders were noted in the exterior gas store (10 cylinders) and the procedure room (6 cylinders).

b) The inspection team considered that the centre's practices were partially compliant with HFEA requirements. This was because patient feedback regarding pain and discomfort during egg collection (from six of 37 respondents) has not been addressed. Indeed a patient having an egg collection during the inspection was in pain. Pain relief only is currently provided during egg collections in the centre, though egg collections under general anaesthesia are occasionally undertaken in the main hospital theatres. The PR and relevant staff have considered the situation and plan to introduce a pain-relief/sedation protocol for egg collections in the centre, but need an anaesthetist for this and have not yet been successful in resourcing this post (recommendation 3).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in September 2016, recommendations for improvement were made in relation to three major and five 'other' areas of non-compliances or poor practice. The PR provided information and evidence that the recommendations were implemented within the required timeframes.

On-going monitoring of centre success rates

Since the last renewal inspection in September 2016, the centre has received two risk tool alerts related to success rates and has responded to these appropriately.

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 generally compliant with requirements to submit information to the HFEA. Since the last renewal inspection in September 2016 however, the centre has received five alerts related to the submission of data for treatments with donated gametes. These have been responded to appropriately by centre staff. On inspection, the barriers to the timely

submission of donor treatment data were discussed and staff committed to monitor data submission and take action if further failures occur. The centre's inspector will continue to monitor this are of practice and considers a recommendation is not required at this time.

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 September 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

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 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
None identified.			

‘Major’ area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor, embryo or 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.

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Witnessing There is no check of the identity of partners providing sperm for use in treatment, against photographic identification in the records, to categorically confirm a sperm provider’s identity (SLC T71).	The PR should take immediate action to ensure that the identity of partners providing sperm for use in treatment, is verified against photographic identification in the records. The centre’s inspector should be advised of the measures taken to implement this recommendation when the PR responds to this report. Within three months of actions being taken, the centre should conduct an audit of witnessing and a summary report of the	The laboratory witnessing protocols and sign sheets have been amended to include a photographic verification of the patient identification against the patinet's electronic record at the time of sperm procurement for use in treatment. The embryology, medical and nursing staff have been advised of these changes. This additional check has been added with immediate effect. The option of introducing the use of a tablet to facilitate the process of checking the electronic record is being evaluated.	The inspector acknowledges the PR’s response and actions taken to address this non compliance. No further actions are required beyond completion of the follow up audit by 19 August 2019.

	findings of the audit should be provided to the HFEA by 19 August 2019.	The biannual witnssing audit will be carried out at the end of July 19 to evaluate compliance and the findings provided to the HFEA by 19th August 2019.	
2. Premises and facilities As detailed in the main body of the report, the centre's premises were in places cluttered, untidy, in a poor state of repair, and potentially unsafe due to slip / trip, fire and infection control hazards. In part this is related to the centre undergoing renovation in some non clinical areas, but this project has not been risk assessed. Unsecured cylinders were also noted in the exterior gas store and procedure room (SLC T17).	The PR should ensure that the centre's premises, including the exterior waste storage area, are presentable and provide suitable areas in which to support and undertake licensed activities. The renovation project, if still on-going, should be risk assessed and appropriate actions taken to control risks at acceptable levels. The actions taken to implement this recommendation should be advised to the centre's inspector in the response to this report The risk assessment of the renovation project if still on-going (along with risk control measures and timelines for implementation), should be	All renovation work in the non-clinical areas that was taking place at the time of the inspection is now complete. In future, all renovation projects will be risk assessed whether in clinical or non-clinical areas. The annual fire risk assessment is currently being undertaken and all appropriate actions taken to mitigate identified risks. Since the inspection, the exterior waste storage area has been tidied up and a risk assessment is being undertaken in conjuction with the trust Patient Client Support Services (PCSS) who are responsible for this area & the Health and Safety department. This will be completed by the 19th of June and provided to the HFEA.	The inspector acknowledges the PR's responses and actions taken to address this recommendation. The inspector accepts that the renovation work was completed by the time the centre received the report and also acknowledges the PR's assurance that in future all renovation work will be risk assessed before it starts. The inspector notes that gas cylinders are now secured, the storeroom has been tidied and decluttered, and that repairs in the procedure room have now been completed. The inspector notes the ongoing work within the exterior waste storage area and looks forward to receiving

	commenced on receipt of this report. A timeline for implementation of the risk assessment should be provided with the PR's response to the report, with the target that the risk assessment is completed, and all risk control measures and corrective actions are implemented, by 19 August 2019 and the centre's inspector is so advised.	All cylinders used by the Embryology lab (Co2) are secured within that area although it is also used by other areas of the hospital and this will form part of the risk assessment. All cyclinders in the procedure room have now been fixed securely to the wall from the 29th April 2019. In terms of the procedure room, the trust estates department have been contacted to inspect and repair both the flooring and door frame so that the necessary remedial work can be undertaken. All required works will be completed by the 19th June 2019. Under discussion with trust senior management, although the store room has been tidied and decluttered. It has been agreed that alternative space within the hospital will be identified as a priority.	the risk assessment of this area by 19 August 2019. **Further actions are required.**
3. Suitable practices	The PR should take immediate action to ensure	A meeting has been held with the trust's Anaesthetic Clinical	The inspector acknowledges the PR's response and actions

The inspection team was concerned that patient feedback regarding pain and discomfort during egg collection (from six of 37 respondents) has not been addressed. Indeed a patient having an egg collection during the inspection was in pain. The PR and relevant staff have considered the situation and plan to introduce a pain-relief/sedation protocol but need an anaesthetist for this and have not yet been successful in resourcing this post (SLC T2).	that patients are well cared for during egg collections and that they are less likely than at present to experience pain and discomfort. The PR should ensure that appropriate training is provided to relevant staff to undertake any new pain relief/sedation protocol introduced, along with the required level of life support training. The centre's inspector should be advised of the measures taken to implement this recommendation when the PR responds to this report. Within three months of actions being taken, the centre should conduct an audit of patient comfort during procedures, to determine the effectiveness of actions taken. A summary report of the findings of the audit should be provided to the HFEA by 19 August 2019.	Director and senior anaesthetist to review the current methods of pain management protocols as a means to introduce immeadiate improvements in the provision of pain relief whilst working towrads the provision of an anaesthetic sedation service. This is currently being planned, costed and a business case being undertaken. As part of this exercise, the anaesthetic team are also currently advising on the required life support training for our operator sedator clinicians and nursing staff. In cases where patients are either too nervous to have sedation only or if they have had a previous high pain score provision is currently made for deep sedation/anaesthesia to be provided for their egg collection in the adjacent theatre. This pathway is already established for such patients. An audit of the patients pain scores will be undertaken and	taken to address this non compliance. The inspector notes the training provided and the existing provision for deep sedation/anaesthesia in nervous and/or pain susceptible patients. The PR should keep the centre's inspector updated regarding progress in this area including what actions have been taken as a result of the meeting of the PR with the trust's Anaesthetic Clinical Director and Senior Anaesthetist, and the timelines for the introduction of the planned anaesthetic sedation service. The inspector looks forward to receiving the audit of patient comfort during procedures by 19 August 2019. **Further actions are required.**

		the findings provided to the HFEA by the 19th August.	

‘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.

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
4. QMS Audits were occasionally not robust, e.g. the medicines management audit did not include review of entries in the CD register against drugs usage in the patient records; the weekly infection control observational audit was not documented; and the monthly legal parenthood consent audit did not review if counselling was offered and taken up before consent was signed or if there was a record of consent withdrawal and appropriate actions by centre staff. In addition, proposed actions in response to non conformances in the audits of traceability and consent were considered by the inspection team unlikely to be effective (SLC T32, T36).	The PR should ensure that all audits, and actions to address non conformances found by audits, are documented, robust and likely to be effective. The centre's inspector should be informed of the actions taken to implement this recommendation by 19 August 2019.	The RCA and resulting CAPA resulting from the traceabilty audit have been amended. The physical segregation of active and inactive lot numbers for all other lab products has been improved making it clear when embryologists introduce a new lot into practice. Lot numbers will be added as a standing item to the embryology lab meeting agenda. This will reinforce with staff of the importance of recording each new lot in the IDEAS system. The RCA from the treatment consent audit has been completed. The CAPA involved disemination of the findings to all staff at our multidisciplinary clinical meeting as well as speaking to the individual	The inspector acknowledges the PR’s responses and actions taken across multiple areas to address this recommendation. No further actions are required.

		clinician concerned. A rolling monthly treatment consent audit is ongoing to ensure improvement and further non conformance will be addressed through individual retraining. A legal consent workshop is being organised by the PR for the Autumn which will further highlight the importance of this area to all staff. The monthly legal parenthood audit template has been reviewed to include the following: was an offer of counselling provided and taken up before consent was signed, is there a record of 'withdrawal of consent' and has the appropriate action been taken by the centre. This audit is being repeated retrospectively from January 2019 to include the above additions. The medicines management audit has been altered to include a cross reference check with the individual patients drug kardex to ensure	

		the record of CD administration tallies with dose recorded in the patients' drug kardex. Daily Cleaning schedules are carried out in the unit by nursing staff as directed on the work rota, and in compliance with Belfast trust "ward/dept equipment cleaning weekly schedule" Doc no 951 These are displayed on the notice board in each clinical area for daily completion. In addition a monthly cleaning audit is independently carried out by the Trusts cleaning services management, a report is provided for the nursing Sister detailing areas of failures and actions required, along with scores of which 90% or above should be obtained for a pass. This is reported at the quarterly governance meeting and provided for admin to put up on the waiting room monitor. It will now be added to the ISO system for all members in the unit to have access to.	

		In terms of our audit processess overall, our audit SOP (PT-MN-AuditCom Doc No. 731) has been amended to highlight that the person completing the audit proforma and NCRCA is responsible for ensuring the audit is robust enough to determine if the process of audit captures the necessary information in order to determine any failures in that system. This will then enable the auditor/management team to establish the necessary corrective and preventive actions. All information must be documented on the necessary form and signed off only when the manager is confident that the corrective/preventive actions have been effective.	
5. Medicines management Drugs for disposal were present in the controlled drugs cupboard but were not marked as for disposal (SLC T2).	The PR should ensure that drugs for disposal are appropriately labelled. The centre's inspector should be advised of the actions taken to implement this	A protocol has been developed for the management of controlled drugs for disposal. Intact vials of controlled drugs for disposal will be placed in a box labelled 'For disposal' within the CD cupboard for collection by pharmacy.	The inspector acknowledges the PR's responses and actions taken to address this recommendation. No further actions are required.

	recommendation with the PR's response to this report.	For part ampuoles of controlled drugs, advice has been sought from the hospital lead pharmacist. Controlled drug denaturing kits, have been sourced through the hospital pharmacy and several will be ordered to assess suitability for use and means of disposal. If they meet requirements they will be placed on regular monthly order for use in clinical areas.	The PR should keep the centre's inspector updated regarding the denaturing kit choice made and its implementation in the centre.

Additional information from the Person Responsible