Executive Licensing Panel – minutes

Centre 0033 (Manchester Fertility) Interim Inspection Report

Friday, 12 February 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Panel members	Paula Robinson (Chair) Hannah Verdin Trisram Dawahoo	Head of Business Planning Head of Regulatory Policy Digital Communications 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 Manchester Fertility, centre 0033, has held a licence with the HFEA since 1990. The centre provides a full range of fertility services

1.2. The panel noted that the centre's licence is due to expire on 30 April 2018.

1.3. The panel noted that the inspection took place on 11 November 2015.

1.4. The panel noted that in the 12 months to 31 August 2015, the centre provided 1302 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

1.5. The panel noted that for the year ending July 2015, HFEA-held register data for IVF and ICSI, showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2014, the centre reported 40 cycles of partner insemination with two pregnancies. This was in line with national averages.

1.7. Between August 2014 and July 2015 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 12%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% maximum multiple live birth rate target.

1.8. The panel noted that at the time of the interim inspection on 11 November 2015, two critical, three major and one other area of non-compliance were identified. The panel noted in particular, the critical areas of non-compliance relating to medicines management and legal parenthood. The panel noted that since the inspection the Person Responsible (PR) had addressed the critical areas of non-compliance quickly and constructively and had implemented most of the recommendations. The panel noted that the Person Responsible (PR) has committed to fully implementing the outstanding recommendations.

1.9. The panel noted that the inspectorate recommends the continuation of the centre's treatment and storage licence, without additional conditions, subject to the PR fully implementing the outstanding recommendations made in this report. The inspectorate also recommended an additional inspection in 2016, at the discretion of the executive.

2. Decision

2.1. The panel had regard to its decision tree. In light of the actions taken to date, it was satisfied that the centre was fit to have its treatment and storage licence continued without additional conditions, subject to the PR fully implementing the recommendations made in this inspection report.

2.2. The panel discussed the non-compliances found and agreed that the PR should remain mindful that serious issues could arise without proper consent to legal parenthood in place. In particular, the panel reminded the PR that HFEA consent forms should be used, in line with HFEA Directions 0007.

2.3. The panel endorsed the inspectorate's recommendation that, in order to fully assess the continued effectiveness of the corrective actions taken, an additional inspection should be conducted in 2016, at the discretion of the inspectorate. This would be earlier than the next routine inspection due in late 2017. This inspection would focus on medicines management and legal parenthood (the two critical non-compliances found), where an in-depth audit would be conducted to provide assurance that the centre's processes were effective.

3. Chair's signature

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

Signature

Name

Paula Robinson

Date

19 February 2016

Interim Licensing Report

Centre name: Manchester Fertility
Centre number: 0033
Date licence issued: 1 May 2014
Licence expiry date: 30 April 2018
Additional conditions applied to this licence: None
Date of inspection: 11 November 2015
Inspectors: Sara Parlett (Lead), Janet Kirkland, Polly Todd
Date of Executive Licensing Panel: 12 February 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 Licensing Panel

The ELP is asked to note that there are recommendations for improvement in relation to two critical, three major and one 'other' area of non compliance or poor practice.

In responding to the report the PR has provided assurance that the following recommendations have been implemented:

Critical areas of non compliance:

- **The PR should ensure that a suitably trained and competent controlled drugs accountable officer (CDAO) is appointed.**

  The PR should review practices relating to the management of medicines, including controlled drugs, to ensure that accurate and complete records are maintained and that medicines are administered and disposed of in accordance with legislation and best practice guidance.

- **The PR should ensure that effective consent to legal parenthood is obtained.**

Major areas of non compliance:

- The PR should seek expert advice on the suitable content of their resuscitation trolley and ensure that all equipment is within its expiry date.

'Other' areas of practice that require improvement:

- The PR should ensure that all notices fixed to walls in clinical areas are 'wipe clean' to ensure compliance with infection control best practice guidance.

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

Since the inspection the PR has also given a commitment to fully implement the following recommendations within the prescribed timescales:

Major areas of non compliance:

- The PR should ensure that audits are effective in assessing compliance with regulatory requirements and centre practice.
- The PR should ensure consent to treatment and storage is recorded clearly so that a patient's wishes are unambiguous.

Recommendation to ELP

As a consequence of the nature and severity of the areas of concern identified during this inspection, a management review meeting was held on 21 December 2015 in accordance with paragraph 4.6 of the HFEA's compliance and enforcement policy to discuss the risk to patients, particularly relating to legal parenthood and to consider the recommendation for continuation of this centre's licence. In accordance with point 4.2 of the compliance and enforcement policy it was agreed that informal action is appropriate at this stage.

The inspection team notes the significant work that has already been undertaken, in particular with regard to the two critical non compliances.

The inspection team recommends the continuation of the centre's licence without additional conditions subject to the PR fully implementing the recommendations made in this inspection report. In order that the continued effectiveness of any corrective actions taken may be fully assessed, the inspection team also recommends that an additional inspection be conducted at the discretion of the Executive in 2016, which is earlier than the next routine inspection due in late 2017. This inspection will focus on medicines management and legal parenthood, where an in-depth audit will be conducted to provide assurance that the centre's processes are effective.

Information about the centre

Manchester Fertility has held a licence with the HFEA since 1990 and provides a full range of fertility services.

The centre provided 1302 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2015. In relation to activity levels this is a large centre.

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 year ending July 2015 show the centre's success rates are in line with national averages.

In 2014, the centre reported 40 cycles of partner insemination with two pregnancies. This is in line with national averages.

Multiple births[2]

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

Between August 2014 and July 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This means that the centre's multiple live birth rate is likely to be consistent with the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: egg collection, sperm preparation and thawing of eggs. All of the procedures observed were witnessed using an electronic witnessing system in accordance 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, the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed with

[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%.

staff. 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 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 implemented, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing; storage of gametes and embryos, traceability, medicines management and infection control.

It is noted that the centre's commissioned pharmacy medicines management audit and the infection control audit failed to identify non compliance with regulatory requirements, noted later in this report. On this basis it is concluded that the centre's procedures for auditing are partially compliant with requirements (recommendation 3).

The inspectors 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 centre's processes for obtaining consent to legal parenthood;
- the content of the centre's website;
- the use of the most recently issued HFEA consent form versions;
- HFEA clinic focus articles regarding equipment failures;
- guidance on the confidentiality of data accessible on software driven systems.

A recommendation has been made relating to obtaining consent to legal parenthood (recommendation 2). In consideration of this it can be concluded that some improvement is required for the centre to have a fully effective learning culture (recommendation 3).

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 not compliant with requirements because:

- the CDAO has left her post and has not been replaced;
- clinical staff have not received training in medicines management;
- the dose of controlled drugs administered to patients was not clearly recorded in some instances, in either the controlled drugs register or the patient notes;
- the disposal of any unused portion of a controlled drug is witnessed, but the actual amount disposed of was not recorded in some instances;
- recording 'carry over' of controlled drug stock from one page of the register to the next was not witnessed by a second person;
- the centre does not clearly record the date of the stock check of emergency drugs on the resuscitation trolley.

See recommendation 1.

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 broadly compliant with guidance because notices fixed to walls in clinical areas were not 'wipe clean' (recommendation 6). It was also noted that corrective actions following the centre's own infection control audit with regards to sharps bins being partially closed, had not been adhered to (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 all consumables and reagents was reviewed in the course of the inspection. The centre is compliant with HFEA requirements to use CE marked medical devices wherever possible.

However a non-compliance was noted in relation to a nasopharyngeal tube – a potentially critical item of equipment on the resuscitation trolley that was out of date. Centre staff explained that they were aware of this but had not yet decided whether to purchase a replacement or if it was no longer required (recommendation 4).

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Four patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive with all four giving compliments about the care received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

The centre's own patient satisfaction survey results were reviewed and were generally positive. They take corrective action based on any negative trends. The results of these surveys are carefully considered and demonstrate a learning culture at the centre.

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

From a review of patient records during the visit to the centre, the inspection team identified the following non-compliance:

- in one set of records, the consent decisions on the male consent to treatment and storage (MT) consent form were not clear in relation to use of sperm and embryos if he were to die or become mentally incapacitated. Alterations had been made by the man, but it was not clear what his final consent decision was. Sperm and embryos can only be used in accordance with the man's consent, so if his wishes are not recorded properly it can have serious consequences (recommendation 5).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2013, recommendations for improvement were made in relation to one critical, five major and three 'other' areas of non compliance. Evidence has been provided that all recommendations have been fully implemented.

On-going monitoring of centre success rates

No risk tool alerts related to success rates have been issued since August 2013.

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 compliant with requirements to submit information to the HFEA.

Legal parenthood

Where a couple to be treated with donated gametes or embryos are not married or in a civil partnership, both the woman and her partner must given 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 centre provided the report of the audit to the HFEA within the required timeframe and took appropriate action with respect to the issues identified by the audit.

Evidence has previously been provided by the centre that their audit was comprehensive. The PR also provided assurance that she considered that the current procedures for obtaining consent to legal parenthood were robust.

To provide assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of patient notes, where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood is required. The following concerns were noted:

- the centre supplements the HFEA consent forms with its own 'internal consent form' which includes a section on legal parenthood. The inspection team considers that this increases the risk of error and confusion both for patients and clinic staff and may be indicative of a lack of understanding of legal parenthood consent requirements at the centre;
- the centre uses stickers printed with the patient or partner's identifying information (including name and date of birth) to fix to the HFEA consent forms so couples do not have to complete these details by hand. In one set of notes, the printing of the labels was misaligned so that the date of birth of the partner was not included in full;
- in one set of notes patient stickers had been fixed to the PP consent form, but the partner had also completed the details by hand. The partner's written date of birth was different to the printed date of birth;
- in one set of notes, the partner had recorded the date the consent form was signed rather than their date of birth on one section of the consent form.

Eight cases were considered as part of a judgment made by Sir James Munby in September 2015, concerning who, in law, is or are the parents of a child born as a result of treatment. Each case raised the question of whether there were valid written consents in place, three of which arose out of treatment at this centre.

In two cases, the forms were either absent or had been completed after treatment; it appears that the centre's current procedures are sufficiently robust to prevent similar errors in future. However, in the third case, the HFEA consent forms had been completed by both the patient and her partner at the appropriate time, but the partner had entered her date of birth rather than the date the consent was signed in two sections of the form. A similar error was noted during the inspection team's audit of a recent treatment cycle (see above).

The inspection team acknowledges that staff are acutely aware of the implications of errors with legal parenthood consent. There is a process in place whereby three separate members of staff check the consent forms prior to treatment and audits of consent to legal parenthood are frequently performed. However, the inspection team has concerns that despite these measures, errors have still occurred. It is also acknowledged that these may be considered minor form errors but the recent judgment indicates that only a court can decide on parenthood in such circumstances. The outcome of these treatment cycles was not known at the time of inspection (recommendation 2).

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. **Medicines management** The centre does not have a CDAO ('Controlled Drugs (Supervision of management and use) Regulations 2013'). Clinical staff have not received training in medicines management (SLC T15). The dose of controlled drug administered to patients was not	The PR should ensure compliance with medicines management regulations and best practice guidance. The PR should ensure that a suitably trained and competent CDAO is appointed. The PR's plans should be summarised when responding to this report.	At inspection the Centre did have a CDOA. In accordance with The Controlled Drugs (Supervision of Management and Use) Regulations 2013 the previous CDOA no longer satisfied Conditions 1,2 and 3 in regulation 8(6) to (8). Immediately the PR was appointed as Accountable Officer as she did satisfy all	The inspection team notes the PR's clarification and acknowledges her actions in response to this recommendation. Evidence from CQC records was submitted demonstrating that the PR is now the registered CDAO. A summary report of the audit to determine the effectiveness of

clearly recorded in some instances, in either the controlled drugs register or the patient notes (NMC 2010 'Standards for medicines management. Standard 8). The disposal of any unused portion of a controlled drug is witnessed, but the actual amount disposed of was not recorded in some instances (Regulation 27 of the Misuse of Drugs Regulations 2001 and NMC 2010 'Standards for medicines management. Standard 8). Recording 'carry over' of controlled drug stock from one page of the register to the next was not witnessed by a second person (DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'. Section 4.7.1.3). The centre does not clearly record the date of the stock check of emergency drugs on	The PR should conduct a review of the centre's medicine management procedures and this should include staff training requirements. The findings of the review including corrective actions and timescales for implementation of the corrective actions should be submitted to the centre's inspector by 11 February 2016. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 11 May 2016.	the conditions as a Senior Manager, an Officer or Employee and does not prescribe, supply, administer or dispose of controlled drugs. This was explained to Janet Kirkland at inspection. We were awaiting the enhanced DBS check through CAPITA Resourcing Ltd and then notification to the CQC was issued through statutory notification through the CQC notification web form. The consultant pharmacist was made aware of staff changes immediately. Our Consultant Pharmacist had signed competencies for relevant clinical staff, however a review of medicines management training has been booked for all clinical staff 3.2.15. This will include the Medicines Policy, use of PGDs, emergency drugs, safe handling and storage of medicines. Medicines management training will be included in induction training of	this corrective action to be submitted to the centre's inspector by 11 May 2016.

the resuscitation trolley (DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'). This has been graded as a critical non-compliance due to the cumulative nature of the concerns regarding medicines management noted on inspection.		all new clinical staff. Medicines policies and procedures were audited and reviewed by our Consultant Pharmacist in August 2015. Further review was carried out by MF Quality Manager following inspection. Following audit findings the nursing procedure has been updated to include recording the actual amount of medication disposed of. Also added to internal medicines audit tool. MF Consultant Pharmacist audited our Controlled Drugs Register in January 2016 and found it to be in order. The mistake relating to recording the dose of controlled drug administered is down to an ommission by the Consultant Anaesthetist on the day of inspection. This has been addressed with the individual. All staff have been made aware of the CD regulations and legal requirements for CD registers.	

		Another observation made by MF staff was that the controlled drugs register column was too narrow which contributed to the omission of the amount of drug disposed. The consultant pharmacist has sourced a larger register and this will be used as soon as available, although the current book is deemed to fulfil legal requirements. The transfer of records will be overseen by the consultant pharmacist. Emergency trolley checklist updated to include expiry dates of equipment and drugs. Checked on a daily basis.	
2. Legal parenthood Of five sets of notes reviewed, three errors were noted on the legal parenthood consent forms. It is acknowledged that these may be considered minor errors but the recent High Court	The PR should ensure that effective consent to legal parenthood is obtained. The PR should conduct a full root cause analysis and review of the centre's legal parenthood consenting	The PR was shocked that the inspection team found three sets of notes where there were errors on legal parenthood forms. Since the audit results from	The inspection team recognises that these findings were unexpected and distressing for the centre staff who had full confidence in their legal parenthood consent procedures. The inspection team acknowledges the thorough root

judgment appears to indicate that only a court can decide on parenthood in such circumstances. The outcome of these treatment cycles was not known at the time of inspection. The inspection team was concerned that this centre is very aware of the implications of errors with legal parenthood consent, has a process where three separate members of staff check the consent forms prior to treatment and that audits are frequently carried out and yet these errors still occurred.	procedures. The findings of the review including corrective actions and timescales for implementation of the corrective actions should be submitted at the time of responding to this report. The centre should seek its own legal advice regarding legal parenthood status in these cases, if there is a successful outcome to these treatments, and provide a summary of this advice and action plan at the time of responding to this report.	2014 three checks are completed by MF staff prior to the use of donor sperm. The findings of the inspection questioned our current practice of multiple checks. Root cause analysis carried out immediately after inspection by the PR and Quality Manager identified two main issues: 1. Even though multiple checks were carried out on the forms no individual could be held responsible and they were relying on other people checking. The audit team were concerned that when checking the forms there was no personal ownership of the staff involved in taking the consent although everyone at MF is aware of the importance of WP/PP for patients. 2. New format on stickers resulted in patient information being misaligned and part of the date of birth was missing.	cause analysis performed and the corrective action that has been implemented. The executive will work with the PR to consider if the centre's experiences can be shared with the sector for wider learning and improvement. The PR is requested to provide an update to the centre's inspector on the effectiveness of the implementation of this corrective action by 11 April 2016.

		Immediate control measures were put into place: 1. Before a patient could enter treatment a new form was devised which showed full traceability of the checking process with a final sign off by the PR or senior member of the laboratory team. A record of any errors found is entered onto a database to be used to identify the individuals involved so that further training can be given. The PR will decide if disciplinary action is required. 2. Stickers are no longer used and the form is completed by hand. All three cases identified by the inspection team unfortunately had unsuccessful treatment and have completed new consent forms. The PR is concerned that the WP/PP forms are legal documents and yet there is no requirement for a formal witness as in other legal	

		documents i.e. passport applications. We are considering having the forms checked and witnessed by someone with legal training. From our experience it is a very common mistake on the WP/PP form for patients to insert their date of birth instead of the date when the form is completed,which suggests the format of the form leads to automaticity on completion. The PR will update our inspector on any further measures we put in place to prevent a recurrence of errors on completion of the forms. The Quality manager and PR are undergoing a rigorous audit of legal parenthood consent for all patients having donor sperm treatment.	

‘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. QMS The centre’s own audit practices failed to identify significant areas of non compliance or poor practice as identified during this inspection and described in the body of the report (SLC T32).	The PR should conduct a review of the centre’s quality management and audit process to ensure that audits are performed against regulatory requirements and that the audits are effective. The outcome of the review and an action plan with timescales for the implementation of any changes should be provided to the centre’s inspector by 11 February 2016.	The PR and Quality Manager are currently conducting a full review of audit practices. Future audits will be recorded on MF Audit Form in accordance with ISO standards and be audited against the actual section of the HFEA Code of Practice. The outcome of the review will be provided to the Centre's inspector by 11th February 2016. Advice has been taken from MF Infection Control consultants. Notices on walls in clinical are to be 'wipe clean' is best practice but not	The inspection team acknowledges the PR’s response and commitment to fully implementing this recommendation. A summary report of the review to be provided to the centre’s inspector by 11 February 2016.

		complusory, however this has been added to our commissioned Infection Control audit and internal audit.	
4. **Emergency equipment** A potentially critical item of equipment on the resuscitation trolley was out of date. Centre staff explained that they were aware of this but had not yet decided whether to purchase a replacement or if it was no longer required (SLC T23).	The PR should seek expert advice on the suitable content of their resuscitation trolley and ensure that all contents are within their expiry date. A summary of this advice and evidence of action taken should be submitted at the time of responding to this report.	Advice taken from MF ALS Instructor and the resuscitation trolley content updated. Checklist also includes expiry dates of equipment and drugs. This list checked daily and will be audited by QM.	The inspection team acknowledges the PR's response. **No further action is required.**
5. **Consent** In one set of records, the consent decisions on the male consent to treatment and storage (MT) consent form were not clear in relation to use of sperm and embryos if the partner were to die or become mentally incapacitated. Sperm and embryos can only be used in accordance with the man's consent so if his wishes are	The PR should ensure consent to treatment and storage is recorded clearly so that a patient's wishes are unambiguous. It is expected that the full review to be conducted for recommendation 2 can be expanded to include this non compliance. The PR should inform the	The patient in question does not have any sperm/embryos in storage. There is a clear instruction in his patient record that if returning for treatment new MT form to be completed. The PR and Medical Director are undergoing a full review of consent and are seeking legal advice to our in-house consent form including the form which contains a section on legal	The inspection team acknowledges the PR's response and commitment to fully implement this recommendation. The PR will be providing a summary of the review currently underway to the centre's inspector by 11 April 2016.

not recorded properly it can have serious consequences (SLC T57).	HFEA if sperm/embryos remain in storage for this patient when responding to this inspection report. If material remains in storage the PR should confirm that clear consent will be sought.	parenthood. We expect this to be completed by the end of March 2016. The outcome of the review will be reported to our Inspector.	

‘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
6. **Infection control** Notices fixed to walls in clinical areas are not ‘wipe clean’ (The Health and Social Care Act 2008; Code of Practice on the prevention and control of infections and related guidance).	The PR should ensure that all notices fixed to walls in clinical areas are ‘wipe clean’ to ensure compliance with infection control best practice guidance. Confirmation that this has been addressed should be provided to the centre’s inspector by 11 February 2016.	Notices on walls on ward/procedure room now kept to a minimum. Laminating machine purchased for ward use and any notices on walls are laminated. This issue has been added to internal Infection Control audit and annual external audit.	The inspection team acknowledges the PR’s response. **No further action is required.**

Additional information from the Person Responsible