Executive Licensing Panel - minutes

Centre 0049 (Wales Fertility Institute, Cardiff) Interim

Friday, 17 June 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Joanne Anton Howard Ryan	Director of Strategy & Corporate Affairs Head of Regulatory Policy Technical Report Developer
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

1.1. The panel considered the papers, which included an inspection report and licensing minutes for the last three years.

1.2. The panel noted that Wales Fertility Institute, Cardiff has held a licence with the HFEA since July 1992. The centre provides a full range of fertility services.

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

1.4. The panel noted that the inspection took place on 12 April 2016.

1.5. The panel noted that in the 12 months to 31 January 2016, the centre provided 492 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

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

- the clinical pregnancy rate following ICSI in women aged under 38 years was lower than average at a statistically significant level.

1.7. The panel noted that for the year 2015, the centre reported 22 cycles of partner insemination with two clinical pregnancies. This is likely to be consistent with the national average.

1.8. Between November 2014 and October 2015, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 24%. This means that the centre's multiple live birth rate is not likely to be statistically higher than the 10% maximum multiple live birth rate target for this period.

1.9. The panel noted that at the time of the interim inspection on 12 April 2016, four major and one other area of non-compliance were identified. The panel noted that since the inspection the Person Responsible (PR) has fully implemented recommendations to address two of the major areas of non-compliance and has committed to fully implementing the outstanding recommendations.

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

2. Decision

2.1. The panel had regard to its decision tree.

2.2. The panel noted the centre's success rates and multiple birth rates and encouraged the PR to continue to monitor the centre's performance in order to improve the quality of service provided to patients.

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

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

30 June 2016

Interim Licensing Report

Centre name: Wales Fertility Institute - Cardiff
Centre number: 0049
Date licence issued: 1 October 2014
Licence expiry date: 30 September 2018
Additional conditions applied to this licence: None
Date of inspection: 12 April 2016
Inspectors: Polly Todd (lead), Louise Winstone, Sara Parlett (observer)
Date of Executive Licensing Panel: 17 June 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 inspection team recommends the continuation of the centre's licence.

The ELP is asked to note at the time of the inspection there were recommendations for improvement in relation to four major and one 'other' area of non compliance or poor practice.

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

'Major' areas of non compliance:

- The PR should ensure that CE marked devices are used where possible.
- The PR should ensure that there is written effective consent for the storage of all cryopreserved gametes.

The PR has given commitment to implement the following recommendations:

'Major' areas of non compliance:

- The PR should ensure that all records where patients have been treated with donated gametes or embryos (who are not married or in a civil partnerships) are audited to ensure the correct legal parenthood consents are in place.
- The PR should ensure that medicines management practices are compliant with regulatory standards and practice guidance.

'Other' areas of practice that require improvement:

- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.

Information about the centre

Wales Fertility Institute-Cardiff is located within University Hospital, Wales and has held a Treatment and Storage licence with the HFEA since July 1992.

The centre provides a full range of fertility services. Other licensed activities of the centre include storage of gametes and embryos.

In November 2014 the ELP granted a variation of licence to change licence holder.

The centre provided 492 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2016. In relation to activity levels this is a small 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 period November 2014 to October 2015 show the centre's success rates are in line with national averages with the following exception:

- the clinical pregnancy rate following ICSI in women aged under 38 years is lower than average at a statistically significant level. See 'on-going monitoring of centre success rates' section for further details.

For the year 2015 the centre reported 22 cycles of partner insemination with two clinical pregnancies. National data has yet to be analysed but this is likely to be consistent with the national average.

Multiple births[2]

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

Between November 2014 and October 2015 the centre's multiple pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 24%. This means that the centre's multiple live birth rates are not likely to be statistically higher than the 10% multiple live birth rate target. See 'on-going monitoring of centre success rates' section for further details.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification error does not occur. The inspection team was not able to observe any laboratory activities during the inspection but discussed witnessing with staff

[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%.

and reviewed witnessing records in patient notes. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

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

On inspection, the 'bring-forward' system was discussed with staff and the accuracy of storage logs and consent records were reviewed. These activities indicate that the centre's 'bring forward' system is effective, however on the day of inspection five sets of sperm samples were being stored beyond the period for which consent was in place. Centre staff were aware of this and explained that three samples, due to be allowed to perish were waiting for final 'sign off' by the PR to allow this to happen. The remaining two samples are particularly complex cases that the centre is making every effort to address. The centre's processes for storing gametes and embryos in line with the consent of the gamete providers are therefore partially compliant with HFEA requirements. See recommendation 2.

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 and staff in the laboratory were able to carry out their activities without distraction.

Quality Management System (QMS)

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

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: witnessing; infection control; consent to disclosure completion; medicines management; consent to treatment and storage.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

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

- the use of CE marked medical devices;

- the use of the most recently issued versions of HFEA consent forms;
- the HFEA reports of adverse incidents from 2014 – 2015;
- HFEA Clinic Focus articles regarding screening requirements.

The centre has been effective in ensuring compliance with guidance issued by the HFEA with one exception; non-compliance in the use of CE marked medical devices. This was also a non-compliance in the 2014 renewal inspection. See 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 found to be partially compliant with guidance because:

- the sealed emergency drug pack on the emergency trolley had expired January 2016, staff described that this had been reported to the hospital pharmacy and were awaiting replacement;
- an intravenous fluid giving set on the emergency trolley had expired;
- there was no record of when, or by whom, the emergency trolley had been checked;
- examination of the controlled drugs register noted that:
    - alterations to errors were not made in accordance with practice guidance requirements in that the original entry could not be determined;
    - some entries were illegible;
    - the 'carryover' of controlled drugs from one register page to the next had not been witnessed and signed by a second person in all cases;
    - in a number of instances, the strength and volume of the drug was not recorded at the top of each register page.

See recommendation 4.

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.

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: media; media supplements; flush solution; vitrification kits; sperm preparation kits; culture dishes; tubes; catheters and pipettes.

The centre is partially compliant with HFEA requirements to use CE marked medical devices wherever possible because the following medical devices are not CE marked: 10ml round bottom tubes; 5ml tubes and sperm pots. See recommendation 3.

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. Six patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was somewhat negative, with five of the individuals providing written feedback describing some complaint about the care received (there were no common themes identified). The centre demonstrated a positive response to patient feedback and on inspection, the inspection team reviewed patient feedback provided directly to the centre which was extremely positive about the care received. On the basis of discussion with staff and a review of the centre's own patient feedback, the inspection team consider that the centre actively seeks and is responsive to patient feedback and therefore no recommendation is required in this regard.

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;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;

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 the information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, the inspection team identified no further areas of practice that could be improved.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2014, recommendations for improvement were made in relation to five major areas of non-compliance.

The PR subsequently provided information and evidence that these recommendations were fully implemented.

However, because discrepancies were found between patient/partner disclosure consent decisions recorded in patient files and the related consent data submitted for inclusion on the register at the previous two inspections, (April 2013 and April 2014), the inspection team conducted an audit of patient/partner consent to disclosure decisions recorded in the patient notes to compare with the information held by the HFEA

It is important to ensure that the HFEA holds an accurate record of patients' consent decisions, so that it only releases the patient's identifying information, to researchers, accordingly. Information can be used by researchers to improve the knowledge about the health of patients undergoing assisted reproductive techniques (ART) and those born following ART treatment. Of the ten records reviewed, on inspection, one discrepancy was found between completed patient/partner disclosure consents on 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 followed. The patient record in question has been made known to the centre for correction.
Six of the records audited were not reported to the HFEA. However the inspection team acknowledges that the centre has been unable to submit data to the HFEA since December 2015 due to technical difficulties, and is working with the executive to rectify this issue. The inspection team therefore find the clinic is broadly compliant with requirements for the submission of information to the HFEA. See recommendation 5.

On-going monitoring of centre success rates

For IVF and ICSI, HFEA held register data show the centre's success rates are in line with national averages with the following exceptions, for which the centre has received two risk tool alerts relating to performance since the last inspection.

- Pregnancy rate per cycle – fresh stimulated ICSI patient under 38 years old (risk tool alert issued in November 2014);
- Pregnancy rate per cycle – fresh stimulated IVF patients under 38 years old and multiple pregnancy rates per pregnancy for all treatment cycles (risk tool alert issued in January 2016).

The PR has responded appropriately to these alerts on both occasions.

On receipt of the risk tool alert relating to multiple pregnancy rates, the PR responded promptly providing assurance that the centre's multiple birth minimisation strategy had already been significantly revised. Multiple pregnancy rates will continue to be monitored closely.

The inspection team notes that for the period November 2014 – October 2015, the success rates for ICSI in women < 38 yrs are below national average. The PR should ensure that the quality management system (QMS) is used to best effect to monitor and improve the centre's success rates so as to improve the quality of service offered to patients. During discussions at the time of the inspection, the PR provided a commitment to keep success rates in this group of patients under review. The centre's success rates will continue to be a focus of on-going monitoring by the centre's inspector.

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.
There has been an on-going issue with the centre's electronic data interface (EDI) system, which the executive is aware of. As a result the centre have not been able to submit data since December 2015 and there has subsequently been a high number of late and missing

records on the validation reports. The centre continues to work with the executive to rectify the issue and have themselves reported this on the organisation's risk register.

Legal Parenthood

When a couple to be treated with donated gametes are not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The centre's audit identified two anomalies; children had been born to two couples treated with donated gametes without the required legal parenthood consent forms having been completed. The PR has informed the HFEA of the actions taken to inform the couples involved and to address these consent anomalies, which the executive considers to be supportive and appropriate.

Assurance has previously been provided by the centre that their audit was comprehensive. Indeed, the centre's legal parenthood audit methodology was broader in scope than that required in that it included single patients using donor sperm or donor embryos as well as couples not married or in a civil partnership. From there the centre determined where legal parenthood consent was required. The PR also provided assurance that he considers the current procedures for obtaining consent to legal parenthood are robust.

To provide further assurance of the effectiveness of the centre's procedures, five patient records detailed on the centre's legal parenthood audit were cross referenced with the information held by the HFEA. Two of the five records where patients had used donor sperm and the treatment had resulted in a live birth, were not included on the centre's audit. In the first record the patient had been treated as a single person in 2010, resulting in a live birth. Whilst her single status should have precluded her from the legal parenthood audit, the centre had included other single patients but had omitted this patient. In the second record the patient couple had not been included in the centre's audit. The appropriate consents have been completed correctly in both records and therefore there is no issue with regard to legal parenthood however the absence of these patients from the centre's original audit according to the centre's audit criteria, casts some doubt on the robustness of the audit process. See recommendation 1.

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
None identified at this inspection			

‘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
1. Legal parenthood: Two out of five patient records cross referenced with information held by the HFEA were not included on the centre’s original legal parenthood audit: • in the first record the patient had been treated as a single person in 2010, resulting in a live birth. Whilst her single status should have precluded her from the legal parenthood audit, the centre had included other single patients but had omitted this patient. • in the second record the patient couple had not	The PR should ensure that all records where patients have been treated with donated gametes or embryos (who are not married or in a civil partnerships) are audited to ensure the correct legal parenthood consents are in place. The PR should investigate why/how these patients were omitted from the original audit. The PR should inform the centre’s inspector of the outcome of this investigation when responding to this report.	As per HFEA suggestion a full re-audit will be undertaken and provided to the Inspector by the 12 August 2016. The omission of these patients appears to be a case of human error. No further rationale has been identified. In the next re-audit results will be checked by two individuals to ensure accuracy.	The inspection team acknowledges the PR’s response, commitment to implement this recommendation. The inspection team will provide appropriate support to enable to PR to complete the actions for this recommendation within the specified timescales in view of the EDI difficulties currently being experienced. Further action required.

been included in the centre's audit. The appropriate consents have been completed correctly in both records but their absence from the centre's original audit casts doubt on its robustness. It is acknowledged that this recommendation is not based on an actual non-compliance, but the implications if the centre's audit was not complete, are sufficiently serious to require a recommendation. CoP Guidance Note 6; SLC T36.	If there are any concerns, the PR should undertake a full re-audit in its entirety to ensure that no other relevant patients have been omitted. A summary report of this audit should be provided to the centre's inspector by 12 August 2016.	In view of the Centre's lack of EDI to cross reference records, it would be helpful if the Inspector could provide HFEA held records of those patients identified as using donated gametes or embryos.	
2. Consent to the storage of cryopreserved material: On the day of the inspection five samples were being stored beyond the period for which consent was in place. Three samples, due to be allowed to perish, were waiting for final 'sign off' by the PR to allow this to happen. The remaining two	The PR should ensure that there is written effective consent for the storage of all cryopreserved gametes and embryos. The PR should provide the centre's inspector with an update on the number of patients for whom gametes remain in store without effective consent when	The PR is confident that the current processes utilised to manage the storage of gametes and embryos is robust. The patient has returned from deployment in the armed forces and has contacted the Unit and extended the storage consent.	The PR has provided assurance that there are now no samples being stored beyond the period for which consent was in place. The inspection team acknowledges the PR's response and actions undertaken to conclude this matter.

samples are particularly complex cases that the centre is making every effort to address. HF&E Act Schedule 3, 8(1).	responding to this report. The PR should provide a plan of action documenting the centre's intended actions to achieve compliance with this recommendation and the anticipated timescale for their implementation when responding to this report. The PR should review the centre's processes for the management of stored gametes and embryos. A summary report of this review, with corrective actions should be provided to the centre's inspector by 12 August 2016. Within three months of the implementation of the corrective actions the PR should conduct an audit of the processes for the management of stored gametes and embryos, to ensure these actions have been effective in achieving and maintaining compliance.	The Centre is compliant with the HFEA requirements. Audit will be provided to Inspector as requested.	No further action required beyond submission of an audit of the processes for the management of stored gametes and embryos by 12 August 2016.
3. Equipment and Materials:	The PR should ensure that CE marked devices are used		Since the inspection the PR has confirmed that the non CE

The following medical devices used by the centre are not CE marked: 5ml tubes; 10ml tubes and sperm pots. The use of non CE marked products was a non-compliance at the last inspection. SLC T30.	where possible. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this, the PR should provide the centre's inspector with a list of all medical devices currently in use in the clinic where devices are not CE marked, the list should document either the anticipated time by which a CE mark is expected to be obtained or the action that will be taken to ensure compliance. The list should be submitted to the centre's inspector by 12 August 2016.		marked medical devices have been replaced and the appropriate CE marked products are now in use at the centre. No further action required.
4. Medicines management: The following issues were noted on inspection: • the sealed emergency drug pack on the emergency trolley had expired January 2016; • an intravenous fluid giving	The PR should ensure that medicines management practices are compliant with regulatory standards and practice guidance. The PR should ensure that the expired drugs are replaced and provide	The PR can confirm that the expired drugs have been replaced. Current box expiry	The inspection team acknowledges the PR's response and commitment to implement this recommendation. Further action required.

set on the emergency trolley had expired;
• there was no record of when, or by whom, the emergency trolley had been checked;
• examination of the controlled drugs register noted that:
  • alterations to errors were not made in accordance with practice guidance requirements in that the original entry could not be determined;
  • some entries were illegible;
  • the 'carryover' of controlled drugs had not been witnessed and signed by a second person in all cases;
  • in a number of instances, the strength and volume of the drug was not recorded at the top of each register page.
 	
DH (2007) 'Safer
	confirmation of this to the centre's inspector when responding to this report.
	
	The PR must ensure that the emergency equipment and drugs box is checked and appropriately maintained in line with regulatory requirements and that a record of these checks is maintained.
	
	The PR should review the process for recording keeping with regard to controlled drugs to ensure that all entries into the controlled drugs register are accurate, legible and in accordance with regulatory requirements.
	A summary report of this review, with a plan for corrective actions should be provided to the centre's inspector by 12 June 2016.
	
	Within three months of the implementation of the corrective actions the PR should conduct a audit of the controlled drugs register to
		31 October 2016
		
		A new checklist and protocol have been implemented to ensure compliance.
		
		The procedure for checking the trolley has been amended to ensure it is operationally easier to use.
		
		Once ratified the SOP and checklist will be sent to the Inspector as evidence by the date specified.
		
		Draft guidance for the CD book will be ratified by the Unit management team - these instructions will be laminated and attached to the	

Management of Controlled Drugs; a guide to good practice in secondary care (England) Section 4.7.1.3. Misuse of Drugs Regulations 2001, schedule 20 (c) and 27. SLC T2.	to ensure these actions have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 12 November 2016.	CD book. A circulation will be sent to all staff in relation to the ratified instructions and staff will be instructed to sign an acknowledgement of understanding of the requirements. The audit will be undertaken and submitted to the Inspector by the specified date.	

‘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 noncompliance, but which indicate a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
5. Consent to Disclosure to Researchers: Of 10 records reviewed, one discrepancy was found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. The patient record in question has been made known to the centre for correction. Six of the records audited have not been reported to the HFEA. Patient consent to disclosure decision discrepancies have been a non compliance at the previous two inspections. The inspection team acknowledge that the centre have been unable to submit	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 correct the submission that has been identified as being incorrect. The PR should review procedures for submitting consent to disclosure consent decisions and take appropriate corrective actions to ensure that the information submitted to the HFEA for inclusion on the register accurately reflects the consent provider’s wishes. It is expected that the corrective actions would be different to those previously	The PR has been informed that this issue has been clarified with the Inspector and ackowledged. The unreported records are as a direct result of the Centre's EDI system being unavailable. The PR understands that a resolution is being sought. The process implemented by the Centre will ensure that compliance for data	The inspection team acknowledges the PR’s response and commitment to implement this recommendation. The inspection team will continue to liaise with the PR and offer flexibility with these timescales, dependant upon a resolution date for the EDI difficulties. Further action required.

data to the HFEA since December 2015 due to technical difficulties and are working with the executive to rectify this issue. This non-compliance has not been escalated to a major on this occasion due to the EDI issues currently being addressed. SLC T9e, CH(10)05 and General Direction 0005.	implemented in response to this non-compliance on other inspections. A summary report of these actions should be provided to the centre's inspector by 12 August 2016. Within three months of the implementation of the corrective actions the PR should re-audit practice to ensure these actions have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 12 November 2016.	submission is improved. An audit will be submitted to the Inspector by the 12 August 2016 the timescale of submission for actions and audit will be dependent upon the resolution date of the EDI issues currently being experienced. The PR will keep the Inspector informed in relation to this.	

Additional information from the Person Responsible
This was the first unannounced inspection that the Centre has undergone. The PR and Centre staff felt that the format and content of the inspection was productive. The PR would like to thank the inspectors for their valued input into the improvements that can be made by the Centre.