Executive Licensing Panel - minutes

Centre 0287 (Ayrshire Fertility Unit, Crosshouse Hospital)

Interim Inspection Report

Tuesday, 14 January 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dan Howard Anna Coundley	Director of Strategy and Corporate Affairs Chief Information Officer Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

- 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 Ayrshire Fertility Unit, Crosshouse Hospital has held a treatment (insemination using partner sperm) licence with the HFEA since 2007. The centre provides basic partner treatment services to National Health Service (NHS) patients.

1.2. The panel noted that, in the 12 months to 31 December 2018, the centre had provided 80 cycles of partner insemination treatment. In relation to activity levels this is a very small sized centre.

1.3. The panel noted that, as a result of the 80 cycles of partner insemination, fourteen pregnancies were reported. This represents a clinical pregnancy rate of 18%, which is comparable to the national average.

1.4. The panel noted that as the centre provides insemination treatments only, it is not subject to the requirements of General Direction 0003 regarding multiple births. However, insemination treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. Thus, it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a multiple births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

1.5. The panel noted that the short notice inspection took place on 31 July 2019.

1.6. The panel noted that, at the time of inspection, there were four major areas of non-compliance concerning staff, the Quality Management System (QMS), CE marking and confidentiality. There was also one 'other' non-compliance regarding record keeping. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations surrounding CE marking, confidentiality and record keeping, and has committed, where required, to audit the effectiveness of those actions within the required timescales.

1.7. The panel noted that, given the inspection team's concerns regarding the staffing levels at the centre, a management review meeting was held on 17 October 2019, in accordance with the HFEA's Compliance and Enforcement Policy, to consider the level of risk to patients undergoing treatment at the centre. This review noted that the centre currently modifies treatment activity to fit the staffing resources available and therefore there is currently no direct risk to patients attending the centre for treatment. However, if service continuity is not assured, and no contingency plan is put in place, despite attempts to do so by the PR, there is a hypothetical risk that activities at the centre could be suspended if there is a further reduction in staff numbers.

1.8. The panel noted that the management review concluded that the PR should engage further with senior management and the Health Board to seek the appropriate resources to address the staffing concerns and ensure that a suitable contingency plan is put in place to ensure safe staffing levels and to enable the continuation of the service for the benefit of patients accessing treatments in the future.

1.9. The panel noted that the management review also assessed whether the recommended level of non-compliance or poor practice should be elevated to critical. The management review considered that findings at the previous inspection, in relation to staffing, were not the same at this interim inspection. As there was not an immediate risk to patients, the recommendation would remain as a major area of non-compliance or poor practice.

1.10. The panel noted that the inspectorate recommended the continuation of the centre's treatment (insemination using partner sperm) licence, particularly noting the many positive comments made by patients in relation to their experiences in the centre's own feedback.

2. Decision

2.1. The panel noted that no patients had provided feedback on their experience of the centre, in the last 12 months, through the 'Choose a Fertility Clinic' facility available on the HFEA website; the panel suggested that the centre actively encourages patients to use this mechanism to provide feedback.

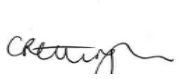
2.2. The panel expressed serious concern about the level of staff and leadership at the centre, identifying that, since the last renewal inspection in 2017, the centre's activity levels have more than doubled, but the number of staff working at the centre has remained the same. The panel requested the inspector to monitor activity levels at the centre, in relation to concerns over staffing levels.

2.3. The panel was satisfied the centre was fit to have its treatment (insemination using partner sperm) licence continued, subject to recommendations being implemented within the prescribed timescales. Given their particular concern regarding staffing and the quantity of non-compliances identified at the interim inspection, the panel requested that the renewal inspection occur, as soon as possible, within the next 12 months.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

20 January 2020

Interim Licensing Report

Centre name: Ayrshire Fertility Unit, Crosshouse Hospital
Centre number: 0287
Date licence issued: 1 November 2017
Licence expiry date: 31 October 2021
Additional conditions applied to this licence: None
Date of inspection: 31 July 2019
Inspectors: Julie Katsaros and Mhairi West
Date of Executive Licensing Panel: 14 January 2020

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 a short notice 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

Given the inspection team's concerns regarding the staffing levels at the centre a management review meeting was held on 17 October 2019 in accordance with the HFEA's Compliance and Enforcement Policy, to consider the level of risk to patients undergoing treatment at the centre. The management review noted that the centre currently modifies treatment activity to fit the staffing resources available and therefore there is currently no direct risk to patients attending the centre for treatment. However, if service continuity is not assured, and no contingency plan is put in place, despite attempts to do so by the Person Responsible (PR), there is a hypothetical risk that activities at the centre could be suspended if there is a further reduction in staff numbers. The management review concluded that the PR should engage further with senior management and the Health Board to seek the appropriate resources to address his concerns and ensure that a suitable contingency plan is put in place to ensure safe staffing levels and to enable the continuation of the service for the benefit of patients accessing treatments in the future.

The management review also assessed whether the recommended level of non-compliance or poor practice should be elevated to critical. The management review considered that the findings at the previous inspection in relation to staffing were not the same at this inspection and as there was not an immediate risk to patients the recommendation would remain as a major area of non-compliance or poor practice.

The inspection team recommends the continuation of the centre's licence. In particular we note the many positive comments made by patients in relation to their experiences in the centre's own feedback.

The ELP is asked to note that this report makes 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 evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non-compliance:

- The PR should ensure that CE marked medical devices are used where possible.
- The PR should ensure that all areas where confidential information is held are always secure.

'Other' areas of practice that require improvement:

- The PR should ensure that a record is maintained of how, and by whom, patients and donors have been reliably identified.

Information about the centre

Ayrshire Fertility Unit, Crosshouse Hospital has held a licence with the HFEA since 2007. The centre provides basic partner treatment services to National Health Service (NHS) patients.

The centre provided 80 cycles of treatment in the 12 months to 31 December 2018. In relation to activity levels this is a very 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]

In 2018, the centre reported 80 cycles of partner insemination with 14 pregnancies. This represents a clinical pregnancy rate of 18%, which is in line with the national average.

Multiple births[2]

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

The centre provides insemination treatments only and is therefore not subject to the requirements of General Direction 0003 regarding multiple births. However, insemination treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth. Thus, it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a multiple births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

Witnessing

The inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and to review witnessing in patient records. These activities indicated that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The centre does not have a licence to provide storage services therefore requirements related to consent to storage of cryopreserved material were not relevant at this inspection.

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 did not appear suitable for the activities being carried out as detailed below (recommendation 1).

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[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

The centre places significant reliance on one specialist nurse to provide treatments and manage the Quality Management System (QMS). The PR is aware that this specialist nurse intends to retire in the next 12 to 18 months and is concerned that despite his best efforts, succession planning contingencies have not been implemented by the Health Board.

The inspection team spoke to senior trust management at the inspection, who were aware of the PR's representations to senior management regarding staffing levels. The inspection team expressed concern that the centre had no contingency plan in place for the loss of the specialist nurse. The team were also informed that the waiting times for patients' initial consultations had increased since the last inspection.

On the day of inspection the specialist nurse was the only member of staff on duty. The inspection team were concerned that if the specialist nurse required clinical input during patient appointments there would not be the necessary support available and patients' treatments could be compromised.

Staffing levels and the reliance on staff to come into work on their days off or during planned annual leave to cover the service at short notice were discussed with the PR following the inspection. He explained that on occasion staff had come in at short notice to cover the service, so that treatments undertaken by patients at the centre were not affected. Although the specialist nurse was the only member of staff working in that area on the day of the inspection, there were other staff working in close proximity in other departments and specialist doctors were available to call upon if required. However, it was unclear to the inspection team whether those personnel were aware that they could be called upon in these situations and whether or not they would meet the requirements pertaining to staffing in terms of the HF&E Act (1990) as amended and standard licence conditions.

The inspection team were not assured that, if the specialist nurse retired earlier than expected, or had a period of unplanned absence, any thought or planning had been given as to how patients currently in treatment or on the waiting list could be accommodated or managed. Since the last renewal inspection in 2017, the centre's activity levels have more than doubled yet the number of staff working at the centre has remained the same.

Staff in the laboratory were able to carry out their activities without distraction and confirmed that they 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: witnessing, infection control and consent to treatment.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements because (recommendation 2):

- The scope of the witnessing audit is not clear. The inspection team, however, were assured that witnessing processes are robust and did not see any evidence of non-compliance with the process.
- An audit of patient records included the completion of the Male Gamete Insemination (MGI) consent form. This was documented as 100% compliant but this did not marry with the findings on inspection where five patient records were reviewed and in each record section five, which refers to patients who are planning to store any sperm that is left over after treatment and consent decisions regarding the stored sperm, were found to have been completed inappropriately, as the centre do not have a licence to provide storage services and the inspection team were concerned that this is not made clear to patients when they complete the forms.
- An audit of legal parenthood and parental responsibility was documented as 100% compliant. However, this centre does not offer treatment with donor sperm and is therefore not relevant for this centre.

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:

- patient support
- information provision
- the use of CE marked medical devices
- the use of the most recently issued HFEA consent form versions

The centre has been partially effective in ensuring compliance with guidance issued by the HFEA because some non CE marked medical devices were in use (see 'equipment and materials' section below).

Medicines management

The centre does not keep, dispense or administer medicines therefore this area of practice is not applicable to this inspection.

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.

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 plasticware used in sample preparation was reviewed in the course of the inspection. We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices wherever possible because the following medical devices are not CE marked to the appropriate level: 10ml pipettes, 2ml pipettes and round bottom sample tubes.

Information provided by the centre post inspection regarding the plastic pipettes confirmed that they are "in vitro diagnostic medical devices", which is not appropriate for use in preparation of samples for Artificial Reproductive Therapy (ART) treatment (recommendation 3).

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. No patients have provided feedback in the last 12 months. 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.

There were no patients available on the day of inspection to speak with the inspection team about their experiences.

The centre's audit of patient feedback for 2018, was provided to the lead inspector on the day of the inspection. The audit included a review of 15 patient questionnaires received over a twelve-month period. Feedback was positive and patients complimented 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:

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;

Monitoring of the centre's performance

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

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is compliant with HFEA requirements with the exceptions noted elsewhere in this report and with regard to the following issues:

- The door to the nurse's office where patient records were stored was not secured when vacant, which could result in unauthorised personnel gaining access to this area (recommendation 4).

- The centre does not maintain documented records of how and by whom each patient has been reliably identified (recommendation 5).

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to four major and one 'other' area of non-compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

The HFEA risk tool is used to monitor the success rates of centres providing IVF and ICSI treatments. This centre is not subject to ongoing monitoring through the HFEA risk tool and has not therefore been issued with any performance alerts.

Provision of information to the HFEA

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

The centre provided its annual IUI treatment return for 2018 within the required timescale.

Legal parenthood

The centre does not provide treatment with donor gametes, therefore requirements related to legal parenthood consent were not relevant at this inspection.

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			

‘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.Staff The inspection team considered that staffing levels in the clinic did not appear suitable for the activities being carried out. There were a number of issues identified during the course of the inspection documented in the main body of the report. SLC T12, T13, T15	The PR should ensure that any personnel working in the centre are available in sufficient number and be qualified and competent for the tasks they perform. The PR should assess how many cycles of treatment can be safely accommodated, document the review in a workforce-activity assessment, which should also include a review of the suitability of the personnel who he referred to as being available to support the centre’s staff and ensure	Following inspection the draft report was forwarded to higher management. Indeed the manager of the services was also present, albeit briefly, during feedback on the day of inspection. Since then a nursing staff has been recruited on bank shifts. She has extensive experience of working within a busy tertiary level Reproductive medicine unit. She is now given some hours to be orientated and working within AFU but also work in other areas. She would be good candidate for succession planning of the	The executive acknowledges the PR’s response. The executive awaits the workforce-activity assessment along with the PR’s review of the suitability of staff available to support the centre’s staff. The executive awaits further detail regarding the centre’s contingency plan in the event that any of the existing staff leave or have a period of unplanned absence. Further action required.

	that the workload is maintained within these limits. A copy of this assessment should be submitted to the centre's inspector by 31 January 2020. The PR should provide the centre's inspector with a contingency plan in the event that any of the existing staff leave or have a period of unplanned absence. A copy of this plan should be submitted to the centre's inspector by 31 January 2020. The PR should engage further with senior management and the Health Board to seek resources to address the centre's staffing needs and ensure that a suitable contingency plan is put in place. Part of the contingency plan should make sure that sufficient staff and resources are available to ensure provision of a compliant service and to undertake activities which are necessary	current QM and nursing staff who bears majority of the workload. Obviously the job needs to be formally advertised since a few more candidates has shown interest. This is a positive step towards succession planning. However, any recruitment of nursing staff can only take place once the current staff has tendered resignation which means the current level of staffing is unaltered. In terms of support the unit has very cohesive and well-knit team. PR could be contacted out of hours and even on leave or when abroad. The doctors and nurses always support each other if someone is unwell or on leave. There has not been any serious event demonstrated due to staff shortages yet. The higher management has been informed for a number of years now and this issue has been put on the Risk register of the organisation. During summer months when there is	

	for the centre to maintain compliance. If the service to patients were to be suspended the contingency plan should also cover how patients currently in treatment or on a waiting list are managed so that their treatment is not compromised. In the event of a further reduction in staff, the levels of activity must be controlled at a level that can be supported by the staffing available. If the centre is not able to offer a compliant service the PR should suspend the service immediately and should take appropriate corrective actions to regain compliancy. If the PR does suspend treatments then the centre's inspector should be notified immediately. The PR should provide a summary report of what actions he is going to take to address staffing needs and the timescale for engaging with senior management and the hospital's Health Board to implement a suitable contingency plan and forward	a possibility that two member of staff could be away on leave at the same time, no treatment is initiated. However, there has not been the necessity of suspending treatment in the past.	

	to the centre's inspector 30 April 2020.		
2. QMS system The following issues were noted: • The scope of the witnessing audit is not clear. The inspection team, however, were assured that witnessing processes are robust and did not see any evidence of non-compliance with the process • An audit of patient records included the completion of the Male Gamete Insemination (MGI) consent form. This was documented as 100% compliant but this did not marry with the findings on inspection where five patient records were reviewed and in each record section five, which refers to patients who are planning to store any sperm that is left over after treatment and consent decisions	The PR should ensure the centre's QMS is effective in supporting learning and continual improvement of the centre's services and provides assurance of compliance of the range of activities carried out in the course of providing treatment services, against regulatory requirements, the centre's SOPs and quality indicators. The PR should review the centre's QMS including, but not exclusively, the issues identified at this inspection. The PR should provide a summary report of the review with timescales for implementation to the centre's inspector by 31 January 2020. Three months after the review, the PR should audit the QMS to ensure that corrective actions implemented have been effective in achieving and maintaining compliance.	There have been further discussions around these QMS issues and all areas addressed to satisfactorily. Clinical governance team who carries out the independent rolling audit has been intimated about more rigorous and detailed report to be submitted and forward onto us the audit tool. MGI consent form that asks if they 'consent for storage' was filled in since the staff thought the man after producing the sample leaves the room and semen is 'stored' in the Lab for processing and finally transferred to the room for insemination within the next couple of hours. However, this misinterpretation has now been resolved. AFU only deals with partner's fresh sperms so no need to fill in this area which is not applicable.	The executive acknowledges the PR's response. Whilst reviewing the centre's QMS the PR is asked to confirm that the staff responsible for overseeing the audit tool, referred to by the PR, ensure that the audits contain the relevant scope and that those personnel are trained and competent and understand the scope of audits relevant to this centre. Further action required.

regarding the stored sperm, were found to have not been completed appropriately, as the centre do not have a licence to provide storage services and the inspection team were concerned that this is not made clear to patients when they complete the forms. • An audit of legal parenthood and parental responsibility was documented as 100% compliant, however, this centre does not offer treatment with donor sperm and is not therefore relevant for this centre. SLC T32 T36	A summary report of this review should be provided to the centre's inspector by 30 April 2020.	Legal Parenthood: This was again an area of misinterpretation of the Code of Practice. AFU only deals with partner's sperm and therefore Legal parenthood is not applicable. This has now been resolved.	
3. CE marking The following medical devices were not CE marked: 10ml pipettes, 2ml pipettes and round bottom sample tubes.	The PR should ensure that CE marked medical devices are used where possible. We would not recommend precipitous changes that might	Although it was commented that the same device has been used without any untoward incidence supplied by a reputed supplier for more than a decade but since	The executive acknowledges the PR's response and for confirming that this recommendation has been fully implemented.

Information provided by the centre post inspection regarding the plastic pipettes confirmed that they are “in vitro diagnostic medical devices”, which is not appropriate for use in preparation of samples for ART treatment. The inspection team acknowledges that the centre has committed to replacing the round bottom sample tubes with appropriate CE marked products. SLC T30	impact on the quality of treatment, however the PR should ensure that a plan is developed and implemented so that appropriately CE marked medical devices are used. This plan should be provided to the centre’s inspector by 31 January 2020 and should include the timescales by which products identified in this report will either be replaced with a suitably CE marked alternative or will obtain CE mark certification. It is expected that the centre will be fully compliant with this recommendation by 30 April 2020.	inspection the Labs has confirmed that all medical devices used during licensed treatment has CE markings. This issue has now been resolved.	No further action is required.
4.Confidentiality The inspection team noted during the course of the inspection that the door to the nurse’s office, where patient records were stored, was not secured when vacant, which could result in unauthorised personnel or patients gaining access to this area.	The PR should ensure that all areas where confidential information is held are always secure. The centre’s inspector should be informed of the action taken to implement this recommendation when responding to this report.	This has been discussed and now processes are in place to ensure that confidentiality is maintained at all times. Two sets of keys has been issued to the only two personnel working within AFU so that they always keep the door under lock and key when	The executive acknowledges the PR’s response and for confirming that this recommendation has been fully implemented. No further action is required.

The HF&E Act 1990 (as amended) section 33A, SLC T45.		leaving the room. This issue has now been resolved	

‘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
5.Record Keeping The centre does not maintain a documented record of how and by whom each patient has been reliably identified. SLC T46b	The PR should ensure that a record is maintained of how, and by whom, patients have been reliably identified. The PR should undertake a review of the centre’s processes for establishing the identity of patients. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre’s	Since inspection we have agreed to confirm identity of all couples attending for licensed treatment by way of passports or driving license. In this regard the SOP and checklist has been appropriately amended. This would be audited as part of our rolling audit system by clinical governance department. Please find attached for your perusal. This issue has now been resolved.	The executive acknowledges the PR’s response, actions taken and commitment to implementing this recommendation. The amended SOP and checklist were not attached with the PR’s initial response, however, the PR subsequently provided these documents to the executive for review.

	inspector when responding to this report. Within three months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 31 January 2020.		No further action required beyond submission of audit report due 31 January 2020.

Additional information from the Person Responsible