Executive Licensing Panel - minutes

Centre 0287 (Ayrshire Fertility Unit, Crosshouse Hospital)

Renewal Inspection Report

Friday, 14 July 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Hannah Verdin (Chair) Anna Coundley Anjeli Kara	Head of Regulatory Policy Information Access and Policy Manager Regulatory Policy Manager
Members of the Executive	Bernice Ash	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 considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that the Ayrshire Fertility Unit provides basic partner treatment services, intrauterine insemination (IUI) with partner sperm, to National Health Service patients.

1.3. The panel noted that the centre has been licensed by the HFEA since 2007.

1.4. The panel noted that in 2016, the centre reported 31 cycles of partner insemination with four pregnancies.

1.5. The panel noted that an inspection was carried out at the centre on 10 May 2017.

1.6. The panel noted that at the time of the inspection there were four major and one 'other' areas of non-compliance that required improvement. The Person Responsible (PR) had given a commitment to fully implement the major non-compliance recommendations concerning infection control, the Quality Management System (QMS), equipment and materials and staffing. The PR had provided evidence that the 'other' area of non-compliance concerning safety and suitability of premises and facilities had been fully implemented.

1.7. The panel noted that some improvement is required for the centre to reflect suitable practices. The PR had been encouraged to use QMS, to its best effect to monitor and improve the service provided.

1.8. The panel noted that the inspector will continue to monitor the centre's performance and the implementation of the report's recommendations within the prescribed timescales.

1.9. The panel noted that the inspectorate recommends the renewal of the centre's treatment (insemination using partner sperm) licence for a period of four years without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel expressed particular concern with regards to the major non-compliance surrounding infection control, noting this area for improvement had also been identified at the centre's last inspection. The panel encouraged the PR to use QMS to monitor and improve the service provided.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (insemination using partner sperm) licence for a period of four years without additional conditions subject to the recommendations made in the report being implemented within the prescribed timescales.

3. Chair's signature

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

Signature

Name

Hannah Verdin

Date

4 August 2017

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 10 May 2017

Purpose of inspection: Renewal of a licence to carry out 'Treatment' only.

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Janet Kirkland MacHattie (lead), Andrew Leonard

Executive Licensing Panel: 28 July 2017

Centre name	Ayrshire Fertility Unit, Crosshouse Hospital
Centre number	0287
Licence number	L/0287/3/a
Centre address	Crosshouse, Kilmarnock, Ayrshire, KA2 0BE
Person Responsible	Dr Santanu Acharya
Licence Holder	Dr David Rae
Date licence issued	1 November 2013
Licence expiry date	31 October 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Ayrshire Fertility Unit has held a licence with the HFEA since 2007. The centre provides basic partner treatment services, i.e. intrauterine insemination (IUI) with partner sperm, to National Health Service (NHS) patients.

Outcomes*
In 2016, the centre reported 31 cycles of partner insemination with four pregnancies.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement which resulted in recommendations being made in relation to four major and one 'other' area of non-compliance.

Since the inspection, the PR has provided evidence that the following recommendation has been implemented:

'Other' area of non-compliance

- The PR should ensure that staff are aware of local procedures in the event of a fire on the premises.

The PR has provided a commitment to implement the following recommendations:

Major areas of non compliance:

- The PR should ensure that the taps and flooring in the procedure room are appropriate for the environment and that clinical waste is secured prior to collection.
- The PR should ensure the quality management system (QMS) is updated, that standard operating procedures (SOPs) are updated and that audits are completed in all relevant areas.
- The PR should ensure that CE marked medical devices are used wherever possible and that all critical equipment is validated.
- The PR should ensure staff are available in sufficient number, and competent in the tasks they perform.

Recommendation to the Executive Licensing Panel

The centre has four major of areas of concern.

Some improvement is required in order for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales

The inspection team recommends the renewal of the centre's treatment licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and the patient to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

The centre does not recruit donors or provide treatment with donor gametes therefore this area of practice is not applicable to this inspection.

What the centre could do better
Nothing identified at this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos

Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable, notwithstanding the non compliance related to infection control di

The centre has procedures in place that are partially compliant with requirements to ensure that risks

The centre is compliant with HFEA requirements to process gametes in an environment of appropriat

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigat
important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that a

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing,

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre provides IUI treatment only; this area of practice is not applicable to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements

Procurement of gametes (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes in treatment, based on the patie
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 000
The centre does not distribute or receive gametes or embryos; this area of practice is not applicable t

Receipt of gametes and embryos (Guidance note15)
The centre does not receive gametes or embryos; this area of practice is not applicable to this inspec

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import and export gametes or embryos; this area of practice is not applicable to

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are

- to identify and locate gametes during any step from procurement to use for human application
- to identify the recipient of particular gametes;
- to identify any person who has carried out any activity in relation to particular gametes; and
- to identify and locate all relevant data relating to products and materials coming into contact w

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is partially compliant with HFEA requirements. The establishment and us

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have transport and satellite activities; this area is not applicable to this inspectio

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. All of

The centre is partially compliant with HFEA requirements to validate critical equipment. The centre ha

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This e

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The
incidents is important to ensure that centres share the lessons learned from incidents and continuous

What the centre could do better

Safety and suitability of premises and facilities
Staff were not able to describe the local procedures to be followed in the event of a fire on their prem

Infection control
The procedure room has hand operated taps, the taps should be operated either by a person's elbow
hospital setting by Health Protection Scotland, page 20; recommendation 1).

The procedure room floor had cracks in the surface material and the central joint was missing sealan
Note 00-10: Part A – Flooring, page 3; recommendation 1).

The skip for clinical waste situated outside the public entrance to the centre, was not locked (SLC T2

The centre staff could not identify the infection control lead; responsible for the governance and esca

Quality management system
The performance of the QMS has not been reviewed in the last two years (SLC T32, Interpretation of

The QMS process by which regulatory changes and other learning are acted upon are not robust, an

The quality manual and SOPs have not been reviewed and updated for two years or more and, beca

The centre has not established SOPs for;

- describing the process by which information is provided to patients prior to them providing cons
- clinical and non-clinical emergencies
- fire evacuation and safety procedures

(SLC T33b; recommendation 2).

Specifications for materials, notably the class of CE marking necessary, are not included in SOPs (S

No practice audits have been performed in the last two years. The inspection team was informed this

Equipment and materials
The sperm procurement pots were not CE marked at an appropriate level, i.e. they were CE marked

The new incubator/oven has not been validated (SLC T24; recommendation 3).

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

Staff (Guidance note 2)
The centre is partially compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Staff
The centre team has reduced in number from five staff to three over a period of two years. This has had an impact on service provision; with an increase in the waiting times for an appointment at the centre. Despite treatment activity at the centre being controlled at a low level to account for the staffing resources available, major non compliances have been noted in the QMS, there was no evidence that nursing staff competencies having been assessed in the last two years.

This suggests that the staffing resources available may not be sufficient to facilitate essential compliance activities (SLC T12; recommendation 4).

The inspection team was concerned that although staff had fire safety training; on further discussion staff were not able to describe the local procedures to be followed in the event of a fire on their premises (SLC T12; recommendation 4).

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child (WoC) who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements, with the exception noted in the QMS section regarding the WoC form.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better

Welfare of the child
The welfare of the child process is compliant with the exception noted in the QMS section regarding the WoC form (SLC T56; recommendation 2).

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9); Embryo testing and sex selection (Guidance note 10)
The centre does not undertake embryo testing therefore these guidance notes are not applicable to this inspection.

What the centre could do better
Not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection, the inspectors spoke to two patients who provided feedback on their experiences, and the centres most recent feedback from patients was seen, apart from waiting times at the centre being a concern to some patients, a high level of satisfaction with the service was otherwise noted.

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;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Patient feedback reflected concerns about the waiting times at the centre, see section on staffing above (recommendation 4).

Treating patients fairly

Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients are treated fairly and that all licensed activities are conducted in a non discriminatory way.

Counselling (Guidance note 3)

The provision of a counselling service is not mandatory for patients undergoing IUI, however the centre does offer the contact details for a counsellor if required.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)

The centre does not undertake these activities; this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)

The centre does not undertake surrogacy; this area of practice is not applicable to this inspection.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH (11)02)
The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better
Nothing identified at this inspection.

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
The centre does not treat patients with donated gametes; this area of practice is not applicable to this inspection.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre does not provide any patient identifying information to the HFEA register, this area of practice is not applicable to this inspection

What the centre could do better
Nothing noted on inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo
What the centre does well The centre does not create embryos; this area of practice is not applicable to this inspection.
What the centre could do better Nothing identified at this inspection.

Screening of patients **Storage of gametes and embryos**
What the centre does well **Screening of patients (Guidance note 17)** The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes. **Storage of gametes and embryos (Guidance note 17)** The centre does not store gametes or embryos; this area of practice is not applicable to this inspection.
What the centre could do better Nothing identified at inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre does not create or store embryos, this area of practice is not applicable to this inspection.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
Centres providing basic partner treatment services only are only required to submit an annual return to the HFEA providing details of the number of treatments provided and the outcomes of those treatments. This enables the HFEA to satisfy their statutory reporting responsibilities and to provide information to patients via the HFEA website about centres' success rates.

The centre has submitted an annual return for treatments performed in 2016.

What the centre could do better
Nothing noted on inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, recommendations for improvement were made in relation to one area of critical non compliance and two 'other' areas of non compliance.

The PR provided information and evidence that all the recommendations were being fully implemented within the prescribed timescales. However, due to financial constraints the plans to replace the taps and flooring in the procedure room, which were considered an infection control risk, were never implemented (recommendation 1).

On-going monitoring of centre success rates

The centre has not received any alerts relating to its success rates.

Areas of practice requiring action

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, General 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 area 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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. 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	Executive Review
No issues identified			

Major area of non compliance

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

- which poses an indirect risk to the safety of a patient, donor, embryo or to a 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
- 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	Executive Review
1. Infection control The procedure room has hand operated taps (SLC T17, Standard Infection Control Precautions: Hand Hygiene Hand washing in the hospital setting by Health Protection Scotland, page 20). The procedure room floor has cracks in the surface material and sealant missing in a joint (SLC T17 and Health Building Note 00-10, Part A – Flooring) **This non-compliance was seen at the last inspection and had been escalated accordingly.**	The PR should ensure that the procedure room taps and flooring are suitable for the activities undertaken in the room, and that clinical waste is disposed of safely. The PR should complete a risk assessment for these infection control risks. The findings and a corrective action plan including implementation dates should be provided to the centre's inspector by 10 November 2017.	Apologies for not being able to implement the recommendations by HFEA during their previous inspection. There are multiple reasons including the very minimal activities due to long-term leave, end of the financial year, possible move of the AFU to another premises (this has now been scrapped). I have initiated talks with the Estates dept and have put in place timed action plan with completion hopefully by the end of the year.	The executive acknowledges the PR's response and the commitment to fully implementing this recommendation. Further action required

The skip for clinical waste was not locked (SLC T2).			
2. QMS The performance of the QMS has not been reviewed in the last two years (SLC T32, Interpretation of mandatory requirements 23A, CoP Guidance 23.13). The quality manual and SOPs have not been updated for two years (SLC T33b, CoP Interpretation of mandatory requirements 23A). Specifications for materials, notably the class of CE marking necessary, are not included in SOPs (SLC T31). There are no SOPs for; • the provision of information to patients • clinical and non-clinical emergencies • fire evacuation procedures (SLC T33b).	The PR should review the QMS to ensure it is updated to reflect regulatory requirements notably, but not exclusively, those identified in this report. Evidence to this effect, including the QMS review report, the revised audit schedule including audits performed and planned and lists of the SOPs updated or produced, should be submitted to the lead inspector by 10 November 2017. A selection will be requested for review to ensure the recommendation has been fully implemented. In responding to this report, the PR must provide assurance that the welfare of the child form, and all other consent forms in use at the centre, are the current versions available on the HFEA website.	The review date for the QMS was June 2017 and the inspection happened in May'17. The full review of the QMS is underway and expected to be completed by October 2017. There is an independent rolling audit programme undertaken by the Hospital Clinical Governance team looking into all aspects of the practice. We endeavor to incorporate the points raised during the inspection process and complete by October 2017. All the consent forms in use are now updated versions available on the HFEA website. New SOP development on 1) provision of information to patients (2) clinical and non-clinical emergencies (3) Fire safety procedures (4) specifications for materials i.e. CE markings, are in progress and will be completed by October 2017.	The PR has provided assurance that the welfare of the child form, and all other consent forms in use at the centre, are the current versions available on the HFEA website. Review of the QMS has started. Further action required

Practice audits have not been performed in the last two years (SLC T36). The QMS process by which regulatory changes and other learning are acted upon are not robust (SLC T32).		Fire safety officer has been contacted and it was mentioned that in Scotland we do not have any established Fire Warden but the most senior person available is deputed for this. All has mandatory annual fire safety training. I have arranged a training in June that was well attended.	
3. Equipment and materials The sperm procurement pots were not CE marked at an appropriate level (SLC T30; recommendation 3). The new incubator/oven has not been validated (SLC T24; recommendation 3).	The PR should ensure that CE marked products are used. The PR should inform the lead inspector of the action taken regarding the sperm procurement pots by 10 November 2017. The PR should ensure that all critical equipment is validated. The incubator/oven should be validated, as necessary. The PR should provide evidence of this to the centre's inspector by 10 November 2017.	CE marked pots are in use since last inspection, however, as pointed out during the recently concluded inspection extra more advanced CEII marked pots are needed. Talks are underway between the Lab and other centres in Scotland about their use and procurement process. The new incubator / oven validation will be carried out by the Lab by October 2017.	The executive acknowledges the PR's response and the commitment to fully implementing this recommendation. Further action required
4. Staffing Staffing resources available may not be sufficient to facilitate essential compliance activities:	The PR should ensure that staff are available in sufficient number and be competent in the tasks they perform.	Staff competencies are currently underway and will be carried out annually. There is a hospital Infection Control Lead who could be contacted as per need basis.	The executive acknowledges the PR's response and the commitment to fully implementing this recommendation.

• nursing staff competencies have not been assessed in the last two years. • there is no infection control lead. • patient feedback reflected concerns about the increase in waiting times at the centre. • QMS has not been updated for two years (SLC T12).	The PR should inform the lead inspector of who will take a lead at the centre for • infection control • ensuring nursing staff competencies are assessed Assurance that these have three areas have been addressed should be submitted to the lead inspector by 10 August 2017.	Organisational Infection Control SOPs are in place and used when necessary. The unit had 5 members of staff when the AFU was established but currently has 3. Individual job planning will reflect adequate cover for AFU for safe practice. The management is aware of long waiting times but at present cannot resource any extra funding to bring down waiting times. Now that the SAS doctor has returned from maternity leave and her independent clinic is in place, it is anticipated that the waiting times will gradually decrease in time.	Further action required

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
5. Safety and suitability of premises and facilities Staff were not able to describe the local procedures to be followed in the event of a fire on their premises (the PR informed the inspection team that this would be discussed with the fire officer with some urgency) (SLC T2).	The PR should contact the fire safety officer, and discuss how to ensure that all staff are aware of local procedures in the event of a fire on the premises. In responding to this report the PR should assure the lead inspector that all staff have now been informed.	Fire safety officer has been contacted and it was mentioned that in Scotland we do not have any established Fire Warden but the most senior person available is deputed for this. All has mandatory annual fire safety training. I have arranged a training in June that was well attended.	The executive is assured that all staff at the centre have had fire safety training post inspection. No further action.

Reponses from the Person Responsible to this inspection report
All the points raised during the recent inspection process will be addressed as far as practicable within the next 3 months. However, CEII marked pots have not been previously mentioned in any of the inspections and surely high success rates without any adverse events in the previous 2 years is a reflection of safety of the process. Again, fire safety issues were never previously covered by inspection and it seems the process in Scottish hospitals are slightly different to the English hospitals. We abide by our local protocols as all staff has to undertake annual online Fire safety training or one face-face training every 3 years. All staff in AFU is compliant with local requirements.