Executive Licensing Panel - minutes

Centre 0276 (Reproductive Medicine Clinic, Bristol)

Renewal Inspection Report

Tuesday, 26 March 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dan Howard Helen Crutcher	Director of Strategy and Corporate Affairs Chief Information Officer Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Joanne Anton Danielle Vincent Yvonne Akinmodun	Licensing Manager Policy Manager Communications Manager Head of Human Resources

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 considered the papers, which included a completed application form, inspection report and licensing minutes up to the last licence renewal.

1.2. The panel noted that Reproductive Medicine Clinic, Bristol is located within St. Michael's Hospital, which is part of University Hospital Bristol, NHS Foundation Trust. The centre has held a treatment (insemination using partner sperm) licence with the HFEA since 2007.

1.3. The panel noted that the centre provides partner intrauterine insemination treatment only to NHS patients. As the centre does not have facilities on site for the analysis or preparation of semen for use in treatment, this service is provided by the Bristol Centre for Reproductive Medicine (HFEA licensed centre 0295) nearby. The male partner attends centre 0295 to produce a semen sample which is prepared for insemination. The sample is transported back to the Reproductive Medicine Clinic by the patient(s) where the insemination is performed.

1.4. The panel noted that, in 2017, the centre provided 25 cycles of partner intrauterine insemination. In relation to activity, this is a very small centre.

1.5. The panel noted that one twin pregnancy has been reported by the centre, in the last two years. The Person Responsible (PR) is committed to minimising multiple birth rates and keeps these rates under review as part of the centre's quality objectives.

1.6. An inspection was carried out at the centre on the 15 January 2019

1.7. The panel noted that at the time of the inspection, there were two 'other' areas of non-compliance concerning infection control, and record keeping and document control. Since the inspection visit, the PR has given a commitment to fully implement both recommendations, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

1.8. The panel noted that, the inspection team recommended 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 her duty under section 17 of the HFE Act 1990 (as amended).

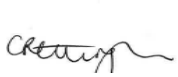
2.4. The panel raised particular concern regarding the nature of the non-compliance relating to infection control. However, it noted the actions that had been taken since the inspection and the PR's commitment to fully implementing the recommendations regarding this non-compliance.

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

Clare Ettinghausen

Date

2 April 2019

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 and donors. 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: 15 January 2019

Purpose of inspection: Renewal of a licence to carry out Treatment (insemination using partner sperm).

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: Grace Lyndon (Lead), Karen Conyers and Sandrine Oakes (HFEA observer).

Date of Executive Licensing Panel: 26 March 2019

Centre name	Reproductive Medicine Clinic, Bristol
Centre number	0276
Licence number	L/0276/4/b
Centre address	Level D, St Michael's Hospital, Southwell Street, Bristol, BS2 8EG
Person Responsible	Dr Amanda Jefferys
Licence Holder	Mr Ian Barrington
Date licence issued	1 July 2015
Licence expiry date	30 June 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Reproductive Medicine Clinic, Bristol is located within St. Michael's Hospital, which is part of University Hospital Bristol, NHS Foundation Trust. The centre has held a 'Treatment (insemination using partner sperm)' licence with the HFEA since 2007.

The centre provides partner intrauterine insemination treatment only to NHS patients. The centre does not have facilities on site for the analysis or preparation of semen for use in treatment and this service is provided by the Bristol Centre for Reproductive Medicine (HFEA licensed centre 0295) nearby. The male partner attends centre 0295 to produce a semen sample which is prepared for insemination. The sample is transported back to the Reproductive Medicine Clinic by the patient(s) where the insemination is performed.

A variation of the centre's licence to change the Person Responsible (PR) was granted by ELP on 25 April 2018.

The centre provided 25 partner intrauterine insemination cycles in 2017. In relation to activity levels this is a very small centre.

Pregnancy outcomes

In 2017, the centre reported 25 cycles of partner insemination with three pregnancies which is in line with the national average.

Multiple births

The single biggest risk of fertility treatment is a multiple pregnancy. One twin pregnancy has been reported by the centre in the last two years.

The PR is committed to minimising multiple birth rates and keeps these rates under review as part of the centre's quality objectives.

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, Standard Licence Conditions (SLCs) 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 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 her 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 the centre's 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, including two 'other' areas of non compliance which has resulted in the following recommendations.

Since the inspection visit, the PR has given a commitment to fully implement both recommendations, providing evidence that actions have been taken and making a commitment, where required, to audit the effectiveness of those actions within the required timescales.

'Other' areas of practice that require improvement:

- The PR should ensure that infection control measures and practices are compliant with regulatory and best practice guidance.

- The PR should ensure discussions and advice regarding patient travel history in relation to Zika and Ebola are clearly documented within the patient's notes.

Recommendation to the Executive Licensing Panel

The centre has no critical or major areas of non compliance.

The inspection team notes the success rates are consistent with the national average.

The inspection team 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 this report being implemented within the prescribed timescales.

Centre 0276 does not import gametes and therefore has not been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

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 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. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes (relevant third parties) are suitable.

Laboratory accreditation (Guidance note 25)
The centre's third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is 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 are partially compliant with guidance.

Medicines management (Guidance Note 25)
The centre does not have medicines on their premises therefore this area of practice was 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.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre does not perform surgical procedures as part of its licensed activities therefore this area of practice is not applicable to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre is providing only insemination treatments, but such 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.

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 patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
The centre does not distribute gametes therefore this area of practice is not applicable to this inspection.

Receipt of gametes (Guidance note 15)
The centre's processes for the receipt of the prepared sperm samples from centre 0295 are compliant with HFEA requirements.

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

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes during any step from procurement to use for human application or disposal;
- to identify the donor and 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 with particular gametes and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is compliant with HFEA requirements with one exception detailed in the infection control section of this report. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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 treatment links therefore this area of practice is not applicable to this inspection.

Equipment and materials (Guidance note 26)
The centre does not have any critical equipment that requires validation, servicing or

monitoring therefore this area of practice is not applicable to this inspection.

Process validation (Guidance note 15)
The centre does not perform any critical processing procedures therefore this area of practice is not applicable to this inspection.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre has had no incidents since the last inspection. The inspection team was confident after discussion with the PR that procedures are in place to ensure that staff are aware of how to report an incident and investigate it should the need arise. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Infection control (Guidance Note 25)
Whilst it is noted that the centre is visibly clean and there have been no incidents relating to infection control reported since the centre was first licensed, the following issues were noted during the inspection:

- Soiled clinical waste was stored in a dirty store room on the floor, next to shelves of clean stores; There was a number of sharps bins piled one on another. The cardboard box was too small for the sharps bins it contained and some of the sharps bins were not standing upright to prevent any liquid spillage.
- There was no date or signature on the sharps bin (in the phlebotomy room) as required for appropriate waste management procedures.
- Seating in the scanning room for scanning staff was porous. The material was stained and could not be wiped clean.
- There were a number of items noted in the phlebotomy room trolley which were past their expiry date.

Audits of infection control practices are routinely undertaken however the scope is limited and covers the cleaning aspect of infection control only. The inspection team would expect audits to include other areas, e.g. hand hygiene. Where non-compliances are identified, the audit reports do not include corrective actions, timescales for implementation and confirmation that actions have been completed. Despite the audits being undertaken on a monthly basis, similar issues seem to reoccur month after month.

A number of the non compliances noted above are not in line with the Trust's own management of waste policy.

SLC T2, T36 and CoP 25.19; 25.20.

DH Health and Social Care Act 2008: Code of practice on the prevention and control of infections and related guidance.

DH Health Technical Memorandum 07-01 Safe Management of Healthcare Waste (2013).

Recommendation 1.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

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 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
Nothing identified at this inspection.

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 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.

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
Nothing identified at this inspection.

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 create embryos or perform embryo testing and therefore this area of

practice is not applicable to this inspection.
What the centre could do better Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Three patients have provided feedback in the last 12 months, giving an average five star rating to the clinic.

The centre's own most recent patient survey responses were also reviewed. The centre received 19 responses during November 2018 which were positive overall, complimenting the nursing staff, and 83% of patients said they would recommend the centre to a friend or family member.

No patients attended the clinic on the day of inspection and so inspectors were unable to speak directly to any patients.

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;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

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 centre is not required to provide counselling for basic partner IUI services. However, all patients are offered counselling as part of the consultation process and in conjunction with their third party agreement with centre 0295.

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

The centre does not undertake egg sharing or sperm sharing arrangements and therefore this area of practice was not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not provide surrogacy treatments therefore this area of practice was 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.

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 provide treatment using donor gametes and therefore 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)

Requirements related to consent to disclosure to researchers are not relevant to basic partner IUI services and therefore this area of practice is not relevant to this inspection.
What the centre could do better Nothing identified at this 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 therefore this area of practice was not applicable to this inspection.

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

Screening of patients and 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 and processing of gametes.

Storage of gametes (Guidance note 17)
The centre does not store gametes and therefore this area of practice was not applicable to this inspection.

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

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre does not use embryos for training staff therefore this area of practice was not applicable to this inspection.

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

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre provided an annual return for treatments undertaken in 2017 within the required timeframe (General Direction 0005).

What the centre could do better

Record keeping and document control (Guidance note 31)
Travel history discussions are being held with patients undertaking treatment cycles in relation to Zika and Ebola risks. However, the outcome of the discussions or the advice given is not consistently documented in the patient's notes.

This issue was raised at the interim inspection in 2017 and changes were to be implemented to ensure that these discussions would be documented. However, these measures have not been implemented.

SLC T46d.

Recommendation 2.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, no formal recommendations for improvement were made.

On-going monitoring of centre success rates

As this centre only provides IUI partner treatment, their success rates are not subject to ongoing monitoring through the HFEA risk tool.

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.

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	Executive Review
Nothing 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.

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	Executive Review
Nothing identified			

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.

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	Executive Review
1. Infection Control A number of issues related to infection control practices at the centre were noted, as detailed within the report. SLC T2 and T36. CoP 25.19; 25.20. DH Health and Social Care Act 2008: Code of practice on the prevention and control of infections and related guidance. DH Health Technical Memorandum 07-01 Safe Management of Healthcare Waste (2013).	The PR should ensure that infection control measures and practices are compliant with regulatory and best practice guidance. The PR should review their infection control practices in relation, but not exclusively, to the issues identified in this report. The PR should provide a summary report of this review, including the actions taken to achieve compliance and timeframes for implementation to the centre's inspector by 15 April 2019. Three months after the implementation of corrective	In reponse to the recent HFEA inspection we have already changed a number of practices within the clinic department to ensure compliance: - Soiled linen has been moved off the floor and clean equipment has been moved to a separate store cupboard - Sharps bins are now stored in a safe manner and signed appropriately, the importance of this has been cascaded to clinic staff and these aspects will be checked on a weekly basis by the nurse in charge. - The non-wipe clean stool in the scan room has been removed and replaced with a wipe-clean stool - Expired items have been removed from the phlebotomy room and these will be	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The PR has provided a summary of the review into this area of practice and actions taken to address the findings on inspection. The executive awaits the summary audit by 15 July 2019. **Further action required**

	actions, the PR should audit the infection control practices to ensure corrective actions have been effective in maintaining compliance. A summary of these audits should be sent to the centre inspector by 15 July 2019.	checked for on a monthly basis. - Infection control audits are held 2 yearly as per trust policy and we are due a further audit imminently. - Hand hygeine audits are undertaken monthly and inputted on to the trust database, in January the outpatient clinic area scored 100%, December data was sent on to inspectors after the inspection. - We will be reviewing all infection control practices within the clinic area and will report back with these together with an audit of practice in July.	
2. Record keeping and document control Travel history discussions are being held with patients undertaking treatment cycles in relation to Zika and Ebola risks. However, the outcome of the discussions or the advice given is not consistently documented in the patient's notes. This issue was raised at the	The PR should ensure discussions and advice regarding patient travel history in relation to Zika and Ebola are clearly documented within the patient's notes. Confirmation of this should be provided when responding to the report.	Evidence of discussion regarding travel to Zika areas is on our treatment checklist, this information was sent on to inspectors following the inspection. We will be adding travel to Ebola areas to this checklist and will alert staff as to high risk areas. We will audit this documentation after implementation.	The executive acknowledges the PR's response and her commitment to fully implementing this recommendation. The executive has received the updated treatment checklist for patients recording any travel history. The executive awaits the summary audit by 15 July

interim inspection in 2017 and changes were to be implemented to ensure that these discussions would be documented. However these measures have not been implemented. This non-compliance has been classified as an 'other' because the inspection team is assured that patients are routinely asked about their travel history, and this is taken into account, but these discussions are not consistently documented. SLC T46d.	Three months after the implementation of the new process, the centre should audit to ensure the process has embedded effectively by carrying out an audit. A summary of this audit should be sent to the centre's inspector by 15 July 2019.		2019. **Further action required**

Reponses from the Person Responsible to this inspection report
We are delighted with the generally positive inspection report and that there were no major non-compliances. We have already addressed many of the minor concerns raised and have a plan to address the remainder which we will be embedding into practice in the coming months.