Licence Committee - minutes

Centre 0333 (Harley Street Fertility Clinic)
Executive Update – Interim Inspection

Thursday, 10 January 2019

Church House, Dean's Yard, Westminster, London SW1P 3NZ

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore	
Members of the Executive	Dee Knoyle Sandrine Oakes (Observer) Nicola Lawrence (Observer) Sara Parlett (Observer)	Committee Secretary HFEA Inspector (induction) HFEA Inspector (induction) HFEA Inspector
Legal Adviser	Dawn Brathwaite	Mills & Reeve LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- Executive Update
- Minutes of Executive Licensing Panel (ELP) - 16 August 2018
- Interim inspection report – considered by Executive Licensing Panel - 16 August 2018
- Minutes of Executive Licensing Panel (ELP) - 6 October 2017 – inspection whistle blowing concerns
- Minutes of Executive Licensing Panel (ELP) - 20 May 2016 – renewal inspection report

1. Background

1.1. Harley Street Fertility Clinic, centre 0333 is located in Central London. The centre has held a treatment (including embryo testing) and storage licence with the HFEA since July 2014 and provides a full range of fertility services including embryo testing. In relation to activity levels this is a small centre.

Compliance history

1.2. The centre has been subject to announced and unannounced inspections and a number of management reviews with the Executive over the last few years. Recommendations for improvements had been made to address critical, major and other areas of non-compliance.

Last Inspection – Interim 17 April 2018

1.3. The last inspection was carried out on 17 April 2018 and there were four critical, four major and two other areas of non-compliance identified.
Critical areas of non-compliance:

- The PR should take immediate action to reduce the centre's persistently high multiple clinical pregnancy rate, currently at 28%.
- The PR must ensure that there is effective written consent in place for all stored gametes and embryos.
- The PR must ensure compliance with medicines management regulations and best practice guidance.
- The PR must ensure compliance with the requirements of clinical waste regulations.

Major areas of non-compliance:

- The PR should ensure that all critical points of laboratory and clinical processes are documented.
- The PR should ensure that the quality management system is used effectively to improve the quality and effectiveness of the services provided.
- The PR should ensure that there is a suitable system in place to summon help in the event of an emergency in the recovery area.
- The PR should ensure that CE marked medical devices are used wherever possible.

Other areas of non-compliance:

- The PR should ensure that the centre implements guidance from the HFEA regarding patient and donor screening requirements.
- The PR should ensure that the information on the centre's website is compliant with regulatory requirements.

1.4. Since the inspection visit and teleconference meetings with the Executive, the PR had provided evidence that action had been taken to fully implement most of the recommendations, and committed, where required, to audit the effectiveness of those actions within the prescribed timescales. The PR had also committed to implementing the recommendations to address the two outstanding areas of non-compliance within the prescribed timescales, concerning one major area of non-compliance relating to CE marked medical devices and one other relating to the information displayed on the centre's website.

Executive Licensing Panel (ELP) Decision on 16 August 2018

Recommendations made by the Executive to the Executive Licensing Panel (ELP)

1.5. Prior to the submission of the interim inspection report to the Executive Licensing Panel (ELP) for consideration at its meeting held on 16 August 2018, the Executive provided focused support to the PR by way of teleconference meetings, to enable the PR to comply with the recommendations in the report. The PR fully engaged with these meetings and confirmation of full implementation of the recommendations relating to multiple births, consent to the storage of cryopreserved materials and medicines management was provided and submitted to the panel for consideration.

1.6. The Executive made a recommendation to the panel to allow the continuation of the centre's licence. However, due to the nature and number of non-compliances at the inspection, some of which were noted at previous inspections, the Executive also recommended a further unannounced inspection takes place within twelve months of the interim inspection which was carried out in April 2018, to ensure that compliance has been maintained and corrective actions have been effective.

Considerations - Executive Licensing Panel (ELP)

1.7. The ELP considered the long history of non-implementation of recommendations and in particular, the lack of action in the area of multiple clinical pregnancies. The centre's multiple clinical pregnancy rate had been at 26% since October 2014 and was currently 28%, meaning that the multiple live birth target of 10% was likely to be exceeded. The panel was concerned with the apparent lack of awareness from the PR with respect to this matter.

1.8. The panel did not feel it had sufficient evidence that the centre would be able to implement the recommendations without considerable long-term support from the Executive.

1.9. Despite reports of historic engagement between the inspectorate and the PR, non-compliances which had been identified on earlier inspections remained, with some new ones.

1.10. The panel was also concerned that the centre's website, which provided data about success rates that related to other licenced centres' data, and which did not contain any data about the centre's own success rates, could be misleading patients.

Decision - Executive Licensing Panel (ELP)

1.11. The ELP did not feel confident in the PR's ability to ensure regulatory compliance in a timely manner and decided to adjourn its decision on the interim inspection, referring it to the Licence Committee to consider with the relevant updates.

2. Consideration – Licence Committee

Executive Update

2.1. The committee noted the Executive update.

2.2. The committee considered the centre's history of non-compliance and historic failure to carry out the recommendations made by the Executive.

2.3. The committee noted the number and severity of the non-compliances identified at the interim inspection and was very concerned.

2.4. The committee noted that the PR is now engaging with the Executive and making good progress towards full implementation of the recommendations.

Executive's Recommendation

2.5. The committee considered the Executive's recommendation to allow the continuation of the centre's licence.

2.6. The committee also considered the recommendation to conduct a further unannounced inspection within twelve months of the interim inspection to ensure that compliance has been maintained and corrective actions have been effective.

Executive Licensing Panel (ELP) - Referred Decision to Licence Committee on the continuation of the licence

2.7. The committee considered that the ELP did not have sufficient evidence to show that the centre would be able to implement the recommendations and ensure regulatory compliance in a timely manner without considerable long-term support from the Executive.

2.8. The committee noted the panel's concern that the data published on the centre's website could be misleading.

2.9. The committee noted that the panel had adjourned its decision on the continuation of the centre's licence and referred the matter to the Licence Committee for consideration.

3. Decision

3.1. The committee shared the concerns of the Executive Licensing Panel.

3.2. The committee noted that the Person Responsible is making progress and engaging with the Executive and that this has been achieved with much support.

3.3. The committee endorsed the Executive's recommendation for the continuation of the centre's licence and agreed that, due to the nature and number of non-compliances at the inspection on the 17 April 2018 and the recurrence of non-compliances noted at previous inspections, a further unannounced inspection should take place within 12 months of 17 April 2018 to ensure that compliance has been maintained.

3.4. The committee agreed that the report of the unannounced interim inspection should be submitted to the Licence Committee for consideration in due course.

4. Chair's Signature

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

Signature

Name

Kate Brian

Date

5 February 2019

Licence Committee 10 January 2019

Centre number	0333
Centre name	Harley Street Fertility Clinic
Person Responsible	Dr Geetha Venkataraman

Update to interim inspection report

1. The interim inspection report for Harley Street Fertility Clinic, was reviewed by the Executive Licensing Panel (ELP) on 16 August 2018.

2. In the minutes of the meeting the ELP decision stated:
   2.1 The panel considered the long history of non-implementation of inspectors' recommendations and in particular, the lack of action in the area of multiple clinical pregnancies, which had increased since the earlier inspection of the clinic to 28% when the guideline is 10%. The panel were concerned at the apparent lack of awareness from the PR with respect to this.

   2.2 Despite reports of historic engagement between the inspection team and the PR, non-compliances which had been identified on earlier inspections remained, with some new ones.

   2.3 The panel did not feel it had sufficient evidence that the centre would be able to implement the recommendations without considerable long-term support from the executive.

   2.4 The panel were concerned that the centre's website, which provided data about success rates that related to other licenced centres' data and which did not contain any data about the centre's own success rates was concerning due to how misleading this could be to patients.

   2.5 The panel did not feel confident in the PR's ability to ensure regulatory compliance in a timely manner and decided to adjourn a decision on the interim inspection, referring it to the Licence Committee to consider. The Licence Committee (LC) should be provided with updates about each of the critical non-compliances; evidence that the centre's website was updated with accurate data and information, and evidence about the outcome of an audit of medicines management.

3. Prior to the submission of the interim inspection report to the ELP, the Executive provided focussed support to the PR by way of teleconference meetings, to enable the PR to comply with the recommendations in the report. The PR fully engaged with these meetings and confirmation of full implementation of the recommendations relating to multiple births, consent to the storage of cryopreserved materials and medicines management was provided to the ELP for their consideration on 16 August 2018. As such, no further update to the LC is provided for these recommendations.

4. The ongoing monitoring of post inspection actions by the centre's inspector has enabled a further progress update to be provided in the table below (Annex 1). The centre's actions taken since the ELP meeting on 16 August 2018 are recorded in the Executive Review column.

5. Annex 1 provides an update on the implementation of the recommendations made in the interim inspection report.

Grace Lyndon
Inspector

Annex 1: Recommendations that required further action

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
1. Multiple births The centre's multiple clinical pregnancy rate has been at, 26% since October 2014 and is now 28% meaning that the multiple birth target is likely to be exceeded. The PR was unaware of the centre's multiple pregnancy rate. The centre has not looked at their data or audited practice against their eSET policy. Considering the ongoing nature of this observation, the	The PR should take immediate action to reduce the centre's persistently high multiple clinical pregnancy rate, currently at 28%. The PR should commission an independent review of their multiple birth minimisation strategy including any barriers to its implementation and how the strategy and elective single embryo transfer (eSET) policy is embedded into practice, including how this information is communicated to patients. A formal summary of this review, including actions that will be taken in response to the findings, should be	We shall commission an independent review of the Clinic's multiple birth minimisation strategy, including any barriers to its implementation and how the strategy and eSET policy is embedded into practice, including how this information is communicated to patients. A formal summary of this review, including actions that will be taken in response to the findings, will be provided to the Clinic's HFEA inspector by 17 September 2018	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required. **Executive update following teleconference meetings:** The Executive acknowledges receipt of the independent review of the multiple birth minimisation strategy. The PR has implemented a number of the recommendations from this review and has committed to monitoring the centre's multiple pregnancy

risk to patients or children who may be born as a result of treatment and that the centre has not addressed this issue, the compliance has been graded as critical. SLC T2; General Direction 0003	provided to the centre's inspector by 17 September 2018. The inspectorate will continue to closely monitor the centre's multiple pregnancy rate. We must allow sufficient time for the centre to seek advice, implement changes, and for any impact to be shown in the centre's CUSUM plot taking into account a three-month data lag. Therefore, if our data suggest that the centre are making no progress towards meeting the 10% multiple live birth target by 17 January 2019 we will consider whether it is appropriate to take further regulatory action which may entail analysis of the suitability of the centres practices in relation to multiple births.		rates (MPR) going forward. **No further action beyond review of HFEA data of the centre's MPR in January 2019.**
2. Consent to storage of cryopreserved materials: On inspection the following issues were noted: • The consented storage period for three sperm samples and 16 embryo samples had expired. Consent expiry dates	The PR must ensure that there is effective written consent in place for all stored gametes and embryos. The PR must establish an action plan for resolving the cases where sperm and embryos are in storage beyond their consented storage period. A copy of the plan should be provided	We have established an action plan to resolve the casees where sperm or embryos are in storage beyond the consented period. A copy of the plan is enclosed with this response. We shall provide montly	The Executive acknowledges the PR's response and commitment to implementing this recommendation. However, the Executive is concerned that the action plan submitted with this report indicates that the PR intends

for these samples ranges from 11 January 2017 to 24 January 2018. • The centre does not have an active system for managing storage consent expiry. The electronic data system, used by the centre, does not contain data relating to the date of sample storage; the consented storage period or the expiry of the consented storage period. The inspection team are not assured that the centre recognises the gravity of this non-compliance. Schedule 3 HF&E Act 1990 (as amended) SLC T57; T79. Human fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009.	to the centre's inspector when responding to this report. The PR must provide monthly updates to the centre's inspector on progress with implementing the proposed action plan. It is expected that there will be effective written consent for all stored samples by 17 July 2018. The PR is reminded of the guidance issued by the HFEA in CH (03) 03 (https://portal.hfea.gov.uk/knowledge-base/chairs-letters/756) in relation to the timely disposal of cryopreserved material where there is consent to do so. The PR must ensure that there is an effective system in place to ensure effective management and monitoring of consent expiry dates.	updates to the Clinic's inspector on progress with implementing the proposed action plan. We expect to have effective written consent for all stored samples by 17 July 2018. We appreciate the gravity of this non-compliance and so have assigned responsibilty for ensuring compliance with this duty directly to our laboratory manager.	to send new consent forms for 'storage renewal' if contact with the patient is made. If the PR takes this action, she will be in breach of the statutory storage regulations. The Executive remains concerned that the PR lacks an understanding of her statutory duties under section 17 (e) and schedule 3 of the HF&E Act 1990 (as amended). The Executive is not assured that the centre has effective systems in place to ensure effective and lawful consent is in place for all stored gametes and embryos. The Executive will have further discussions with the PR outside of this report. Further action required. **Executive update following teleconference meetings:** The Executive confirms that the centre has taken action to

			ensure that there is effective written consent in place for all stored samples. **No further action required.**
3. Medicines management. On inspection the following issues were noted: • A significant number of entries in the controlled drugs register are illegible. • On some pages the strength and volume of the drug is not recorded • The carry-over of drugs from one page to another is not recorded or witnessed. • The controlled drugs register only contains single patient identifiers (eg. just the patient's name), which are illegible in the majority of cases. • The controlled drugs audit does not record corrective actions, or the date by which they should be implemented.	The PR must ensure compliance with medicines management regulations and best practice guidance. The PR should investigate why non-compliances identified in this report have not been addressed from previous inspections. The PR should commission an independent review of the centre's medicines management practices. A summary report of this review, including staff training requirements and corrective actions taken, should be provided to the centre's inspector by 17 July 2018.	We shall commission an independent review of the Clinic's medicines management practices. We shall provide a summary report of that review to our inspector, including staff training requirements and corrective actions taken, by 17 July 2018.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required **Executive update following teleconference meetings:** The Executive confirms receipt of the independent review of medicines management practices and acknowledges the centre's actions in implementing the recommendations from this review. The Executive would encourage the PR to audit practice regularly, to ensure that corrective actions taken have been effective in achieving and maintaining compliance. **No further action required.**

• The quarterly controlled drugs audits lacked scope in that they did not identify issues noted in this report and identified at previous inspections. **Critical non-compliance with Medicines management practice was noted at the last inspection in June 2017.** SLC T2 DH: Controlled Drugs (Supervision of management and use) Regulation 2013. DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'. Misuse of Drugs (safe Custody) Regulations 2001. NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. NMC (2015) 'Standards for			

medicines management'.			
4. Infection control: During the inspection, the centre was found to be non-compliant with infection control practices because: • Two out of the three clinical waste bins stored outside of the clinic were unlocked and were accessible to the public. • Temporary closures on sharps bins were not in use • Recycling waste was stored in a corridor which led to a fire escape and could impede exit in the event of a fire. **Infection control non-compliance was noted at the inspection in 2017 so has been escalated to critical in this report.** SLC T2 HTM 07-01 Safe Management	The PR must ensure compliance with the requirements of clinical waste regulations. The PR should investigate why non-compliance noted at previous inspections has occurred again. The PR should provide a summary report of this investigation, including staff training requirements (where appropriate) and any corrective actions taken, to the centre's inspector, when responding to this report. Three months after the implementation of any corrective actions, the PR must audit infection control practices including, but not exclusively, those areas of non-compliance identified in this report, to ensure that corrective actions taken have been effective in achieving and maintaining compliance with regulatory requirements. A summary report of this audit should be provided to the centre's inspector by 16 October 2018.	We have investigated the non-compliance with regards to clinical waste and have enclosed a summary report of this investigation with this response. We shall audit our infection control practices, with particular regard to the areas of non-compliance identified in this report, to ensure the corrective actions taken have been effective in achieving and maintaining regulatory compliance. We shall provide a summary a report of that audit to our inspector by 16 October 2018.	The Executive acknowledges receipt of the summary report and the PR's response and commitment to implementing this recommendation. No further action beyond submission of the audit summary due by 16 October 2018. **Progress update since ELP meeting 16 August 2018:** The Executive acknowledges receipt of the summary report. No further action required.

of Healthcare Waste. Regulatory Reform (fire safety) Order 2005.	The PR must ensure that recycling waste is appropriately disposed of and that fire exits are kept clear at all times.		

‘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
5. Witnessing. Staff do not record the witnessing of the clear down of workspace between egg collections. The witnessing steps performed during an intra uterine insemination are not documented. The PR confirmed that these steps are performed but are not recorded.	The PR should ensure that all critical points of laboratory and clinical processes are documented. The PR should review the centre’s witnessing practices and ensure corrective actions are implemented to achieve compliance with this recommendation. Three months after the implementation of corrective actions, the PR should audit witnessing checks to ensure that corrective actions	We have added the required witnessing to our laboratory paperwork. A copy of the new paperwork is enclosed with this response. We will begin to use this new form by 1 June 2018. Accordingly, we shall perform an audit of the witnessing checks to ensure the above corrective action is effective three months later. We shall provide a summary report of that audit to our inspector by 17 October.	The Executive acknowledges the PR’s response and receipt of the witnessing papers. No further action beyond submission of the audit report due 17 October 2018. **Progress update since ELP meeting 16 August 2018:** The Executive acknowledges receipt of the audit summary. No further action required.

	implemented have been effective. A summary report of this audit should be provided to the centre's inspector by 17 October 2018.		
6. The Quality Management System. On inspection the following issues were identified: • The timeframe for the implementation of corrective actions was not documented on the audits. • There was no indication on the audits as to whether corrective actions had been implemented or completed. • On one consent to treatment (WT) form, the audit identified that a signature was missing, but there was no documented corrective action to address this non-conformance. • It was unclear from	The PR should ensure that the quality management system is used effectively to improve the quality and effectiveness of the services provided. The PR should review the centre's auditing practices and ensure they are robust in ensuring that non-compliances are acted upon; corrective and preventative actions are recorded and implemented and effective in achieving improvements in quality standards. The PR should provide a summary report of this review, including corrective actions taken to address this non-compliance, to the centre's inspector by 17 July 2018. Three months after the	We shall review our auditing practices to ensure they are robust in ensuring that non-compliances are acted upon, corrective and preventative actions are recorded and implemented, and effective in achieving improvements in quality sstandards. We shall provide a summary report of this review to our inspector by 17 July 2018. Three months after implementing corrective actions from the above review, we shall audit our practices to ensure the corrective actions have been effective in achieving compliance. We shall provide a summary report of that audit to our inspector by 17 October 2018. We will review all of our QMS	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required. **Executive update following teleconference meetings:** The Executive acknowledges the review of the QMS and actions taken in implementing this recommendation. No further action beyond submission of an audit summary, due by 17 October 2018. **Progress update since ELP meeting 16 August 2018:** The QMS audit summary has been provided by the centre. No further action required.

reviewing the legal parenthood audit if the audit had considered whether consent had been given before treatment; if counselling was offered and if the consent forms had been completed correctly. • The centre has not performed an electronic mismatch audit and the witnessing audit does not specify whether if manual and/or electronic witnessing was audited. • A witnessing SOP provided to the inspection team for review on the day of the inspection, was out of date. It was later found that this SOP had been superseded. SLC T34; T36	implementation of corrective actions, the PR should audit practice to ensure that the actions implemented have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 17 October 2018. The PR should ensure that only the current versions of documents are in use. The PR should review all QMS documents to ensure that current versions are in use and that there is a process for archiving old documents. A summary report of this review, should be provided to the centre's inspector by 17 October 2018.	documents to ensure that only current documents are in use. We will perform a mismatch audit at the end of every month and will add this to the quarterly KPIs for regular review. All lab SOPs are currently undergoing review, which will be complete by September 2018. We will ensure that only current versions of all QMS documents are in use and that all staff use the archiving process for storing old versions of documents. We will provide a summary report of this review by 17 October 2018.	
7. CE marking. The following items were not CE marked for Class II medical use:	The PR should ensure that only CE marked medical devices are used wherever possible.	We shall ensure a plan is developed and implemented such that CE marked medical devices are used wherever	The Executive acknowledges the PR's response and commitment to implementing this recommendation.

• Oosafe 4 well dishes; • Oosafe 60mm round dishes • Oosafe 5ml tubes • Vitrification media	We would not recommend precipitous changes that might impact on the quality of treatment, however the PR should ensure that a plan is developed and implemented so that CE marked medical devices are used. This plan should be provided to the centre's inspector by 17 July 2018 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. The plan should be fully implemented by 17 April 2019.	possible. We shall provide a copy of that plan to our inspectory by 17 July 2018, including the timescales by which the products identified above will either be replaced with a suitable CE marked alternative, or will obtain CE marking. We will ensure that plan is fully implemented by 17 April 2019	Further action required. **Executive update following teleconference meetings:** The Executive acknowledges receipt of the plan to implement the use of appropriately CE marked products, and the PR's commitment to fully implementing this recommendation. No further action beyond confirmation of full implementation due by 17 April 2019. **Progress update since ELP meeting 16 August 2018:** No further action required beyond confirmation of full implementation by 17 April 2019.
8. Compliance with HFEA standard licence conditions. There are no emergency call bells in the patients' post-procedure recovery area. Staff are reliant on making a phone call to a top floor office in the event of an emergency.	The PR should ensure that there is a suitable system in place to summon help in the event of an emergency in the recovery area. The PR should inform the centre's inspector of the	We have contacted vendors to have a suitable system installed within the Clinic by 17 July 2018.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. The Executive awaits confirmation from the PR once a suitable system is in place.

SLC T9 (b)	measures taken to address this non-compliance. It is expected that a suitable system is in place by 17 July 2018.		Further action required. **Executive update following teleconference meetings:** The PR has confirmed that a suitable system for summoning help in an emergency, has been installed. No further action.

‘Other’ areas of practice that requires improvement

Other 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
9. Implementing guidance from the HFEA. • The centre has not implemented guidance relating to screening for Ebola into its policy or protocols. SLC T50; T52 European Tissues and Cells Directive (EUTCD) 2017. Advisory Committee on Dangerous Pathogens (ACDP) 2017.	The PR should ensure that the centre implements guidance from the HFEA regarding patient and donor screening requirements. The PR should review the centre’s screening policy and procedures and ensure that they are compliant with the requirements for additional screening of patients and donors. The PR should ensure that the information provided to patients about Ebola, accurately reflects current practice guidance. The PR should provide a	The Clinic's current practice with regard to screening for Ebola is to discuss a patient's travel history at their initial consultation so that they can be screened appropriately. To this end: there are specific entries for Zika virus and Ebola virus in the Clinic's patient history template that is used for every new patient consultation. Please find a copy of that template attached for your review. As requested, we shall perform a review of our patient information and Ebola virus screening processes to our inspector by 17 October 2018,	The Executive acknowledges receipt of the revised patient history template and the PR’s commitment to fully implementing this recommendation. No further action beyond submission of audit due 17 October 2018. **Progress update since ELP meeting 16 August 2018:** Screening review received. No further action beyond submission of screening audit due by 17 January 2019.

	summary report of the review including the actions taken to ensure compliance with this recommendation, to the centre's inspector, by 17 October 2018. Three months after the implementation of corrective actions, the PR should audit patient and donor screening to ensure that actions implemented, have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 17 January 2019.	including corrective actions taken to ensure compliance with this recommendiation. We shall audit our patient and donor screening three months after implementing the above corrective actions to ensure those actions were effective in achieving and maintaining compliance. We shall provide a summary report of this review to our inspector by 17 January 2019.	
10. The centre's website. The following issues were identified on inspection: • The centre's website provides data about success rates that relate to other licenced centres. • The website does not contain any data about the centre's own success rates. • The success rate data	The PR should ensure that the information on the centre's website is compliant with regulatory requirements. The PR should audit the centre's website against regulatory requirements and make the necessary corrections. The PR should inform the	We shall ensure our website is fully compliant with regulatory requirements. As a temporary measure, we have removed the non-compliant data from our website and replaced this with a placeholder. We shall inform our inspector once the corrections have been made so that they may be reviewed for compliance.	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required beyond confirmation that the website has been amended. **Progress update since ELP meeting 16 August 2018:** The clinic has removed all

provided on the website is more than three years old (2012). • The national rates quoted on the website are from 2011 and not compared like for like. CH (11) 02. Code of Practice 4.12.	centre's inspector, when the required corrections have been made so that a subsequent review for compliance can be undertaken. It is expected that the centre's website will be fully compliant with regulatory requirements by 17 October 2018.	We shall ensure our website is compliant before 17 October 2018.	success rate data relating to other centres but has still to provide data relating to its own success rates. The centre is in the process of producing information on success rates using their most recent data. The Executive is satisfied that the non-compliance identified in the report has been fully addressed and will encourage the centre to publish its data on the website as soon as it can outside of this report, as an absence of this data could be detrimental to the centre attracting clients. No further action required