Licence Committee - minutes

Centre 0105 (London Women's Clinic) Renewal Inspection Report

Thursday, 8 March 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Andy Greenfield (Chair) Lee Rayfield Ruth Wilde Kate Brian Anita Bharucha	
Members of the Executive	Dee Knoyle	Committee Secretary
Legal Adviser	Gerard Hanratty	Browne Jacobson LLP
Specialist Adviser		
Observers		

Declarations of interest:

- Members of the committee declared that they had no conflicts of interest in relation to this item however volunteered the following information:

  Ruth Wilde confirmed that she worked for London Women's Clinic from 2009 to 2011 and has no conflicts of interest with this item.

The committee had before it:

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

The following papers were considered by the committee:

- Renewal - Executive update
- Renewal - full paper set originally considered by the Executive Licensing Panel on 22 January 2018 including:
    - Renewal Inspection Report
    - Renewal Application Form
    - Licensing Minutes
- Executive Licensing Panel minutes - 22 January 2018 - adjournment of consideration of renewal inspection report
- Executive Licensing Panel minutes - 2 February 2018 - referral of consideration of renewal inspection report, to the Licence Committee

1. Background

1.1. The London Women's Clinic, centre 0105, has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including embryo testing. The centre's current licence was varied in April 2014, July 2014 and February 2016 to reflect a change of premises. The centre is part of a nationwide group of centres and has several satellite and transport centres.

1.2. A renewal inspection was carried out at the centre, on 24 and 25 October 2017 and two critical, six major and five 'other' areas of non-compliance were identified:

Critical areas of non-compliance:

- The PR should ensure that embryos are only used for staff training with the consent of both gamete providers.
- The PR should ensure that effective consent to legal parenthood is obtained.

Major areas of non-compliance:

- The PR should ensure that traceability records are accurate and support the traceability of the centrifuges and ICSI rigs used during processing.
- The PR should ensure that audits have documented corrective and preventative actions including dates for implementation and closure.
- The PR should ensure that audits are conducted of the transport and satellite services provided to patients.
- The PR should ensure that CE marked medical devices are used where available.
- The PR should ensure that all near miss adverse incidents are investigated and reported to the HFEA.
- The PR should establish an action plan to resolve the case in which a set of embryos is being stored beyond the consented storage period.

'Other' areas that require improvement:

- The PR should ensure that for all controlled drugs, the date, time and amount given to a patient is documented on a prescription sheet in the patient record.
- The PR should complete a risk assessment for the six-bed recovery area to ensure the area allows the safe recovery of patients after procedures.
- The PR should ensure that Embryo and Gamete Movement – Out (GO) forms are completed and submitted to the HFEA within the required timeframe following the export of gametes or embryos.
- The PR should ensure that all information is kept confidential and only disclosed in circumstances permitted by law.
- The PR should actively encourage patient feedback as a form of quality assurance.

1.3. At its meeting on 22 January 2018, the Executive Licensing Panel considered the renewal inspection report and noted that further audit updates and summaries on the non-compliances concerning the use of embryos for training staff, legal parenthood, traceability, the Quality Management System (QMS), equipment and materials, adverse incidents, storage of gametes and embryos, medicines management and pre-operative assessment and the surgical pathway were due for receipt by 25 January 2018. Therefore, the panel decided to adjourn consideration regarding the renewal of the centre's licence, requesting the inspectorate provides an update report for consideration at its meeting on 2 February 2018, to include the additional audit information and summaries, due from the centre by 25 January 2018.

1.4. At its meeting on 2 February 2018, the Executive Licensing Panel considered the centre's update report since the renewal inspection. The panel was informed that the PR had failed to implement some of the recommendations to address the non-compliances within the agreed timescale. The panel did not feel confident in the PR's ability to ensure regulatory compliance in a timely manner, for patient safety to be upheld.

1.5. The panel decided to adjourn renewal of the centre's licence, requesting the matter to be referred to the Licence Committee for consideration. The panel noted that further updates on the use of embryos for training staff, legal parenthood, equipment and materials, adverse incidents, storage of gametes and embryos and medicines management were due for receipt by 16 February 2018 and requested that the inspectorate provide an update on progress regarding these non-compliances to the Licence Committee.

1.6. The panel agreed to issue Special Directions under Section 24 (5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation of licensed activity upon expiry of the centre's licence on 28 February 2018, to allow time for the renewal to be considered by the Licence Committee and for the administration of the outcome of their consideration to be completed. The Special Directions were issued from 1 March 2018 until any new licence comes into effect, or 31 May 2018, whichever was sooner. The panel agreed that the additional Condition, following a grade 'A' incident in 2012, imposed on the centre's licence was to continue whilst operating under Special Directions. This condition suspended the centre (and other centres within the LWC group) using donor sperm procured, processed and stored at the centre prior to the introduction of the electronic witnessing system in May 2010.

Executive Update to the Licence Committee – 8 March 2018

1.7. The committee was informed that the centre has provided good evidence of progress with implementing the recommendations from the renewal inspection report.

2. Consideration of application

Application

2.1. The committee noted that an application for the renewal of the treatment (including embryo testing) and storage licence was submitted by the Person Responsible (PR).

2.2. The committee noted that the application contains the supporting information required by General Direction 0008 and that the appropriate fee has been paid.

Inspection Process

2.3. The committee noted that in the 12 months to 30 September 2017, the centre provided 2,927 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

2.4. The committee noted that for IVF and ICSI, HFEA-held register data for the period 1 August 2016 to 31 July 2017 showed the centre's success rates were in line with national averages with the following exception:

- success rates following FET (frozen embryo transfer) in women aged 16 to 39 years old were higher than average at a statistically significant level.

2.5. The committee noted that in 2016, the centre reported 101 cycles of partner insemination with 11 pregnancies. This represented a clinical pregnancy rate of 11%, which was in line with the national average.

2.6. Between 1 August 2016 and 31 July 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 12%. This represented performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

2.7. The committee noted that the renewal inspection took place on 24 and 25 October 2017. The renewal inspection report covers the centre's performance since the last inspection, findings from the inspection visit and communications received from the centre. The committee noted that at the time of the renewal inspection two critical, six major and five 'other' areas of non-compliance, as set out above, were identified and recommendations were made for improvement. The PR had committed to fully implementing all of the recommendations.

2.8. The committee noted that the centre had two management reviews in accordance with section 3.1 of the HFEA's Compliance and Enforcement Policy.

Recommendation

Licence

2.9. The committee noted that, after the management reviews, the Executive recommended the renewal of the centre's treatment (including embryo testing) and storage licence for a period of three years, rather than the usual four. In considering the length of licence to recommend, the Executive had regard to the HFEA Guidance on Licensing. Where there is a history that indicates a previous failure to implement recommendations for improvement in the time since the last renewal, or concerns relating to the quality of service, a three-year licence is considered appropriate.

Additional Licence Condition

2.10. The existing additional licence condition is to be added to the renewed licence:

'To suspend the centre using donor sperm (this would apply to all clinics across the group) in relation to samples processed prior to the introduction of the electronic witnessing system in May 2010. If sibling stock is required and only available from sperm banked at that time (that is the donor cannot be contacted or declines to re-attend to provide further samples), the centre should document the risk analysis carried out (including verifying witnessing), provide careful counselling to the patient regarding the potential risk prior to obtaining the patient's consent and if the centre considers that these samples can be used safely then they could continue with that patient's treatment using those specific samples.'

Interim Inspection

2.11. An interim inspection will be conducted within 12 months of the renewed licence coming into force, in order to allow the inspectorate to observe directly whether there are improvements in practices, processes and the centre's overall compliance.

3. Decision

3.1 The committee had regard to its decision tree, the HFEA Compliance and Enforcement Policy and HFEA Guidance on licensing.

Administrative Requirements

Supporting Information under General Direction 0008

Application

3.2 The committee was satisfied that the application was submitted in the form required and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Proposed Person responsible (PR) – Mrs Tourandokht Arian-Schad

3.3 The committee noted that the proposed PR, Mrs Tourandokht Arian-Schad, is willing to assume the responsibility of the role of PR.

3.4 The committee considered the suitability of the PR and her failure to implement the recommendations to address the non-compliances in a timely manner. The committee was satisfied that good evidence of progress has been provided by the PR since the renewal inspection and the inspectorate will continue to liaise with the PR to ensure that the outstanding actions and audits, due either 25 April 2018 or 25 July 2018, are completed.

3.5 The committee was satisfied that the proposed PR possesses the required qualifications and experience and that the character of the proposed PR is such as is required for supervision of the licensed activities. It was further satisfied that the proposed PR will discharge their duties under section 17 of the HFE Act 1990 (as amended). The committee noted that the inspectorate was satisfied that the proposed PR had satisfactorily completed the PR entry programme. The committee agreed to the appointment of the proposed PR.

Activities

3.6 The committee was satisfied with the suitability of the activities applied for.

Premises – 113-115, Harley Street, London, W1G 6AP

3.7 The committee was satisfied that the premises and facilities are suitable for the conduct of the licensed activity applied for.

3.8 The committee was satisfied that the third party premises are also suitable.

Licence

3.9 The committee agreed in summary:

- to renew the centre's treatment (including embryo testing) and storage licence for a period of 3 years
- the existing licence condition remains on the renewed licence:

  'To suspend the centre using donor sperm (this would apply to all clinics across the group) in relation to samples processed prior to the introduction of the electronic witnessing system in May 2010. If sibling stock is required and only available from sperm banked at that time (that is the donor cannot be contacted or declines to re-attend to provide further samples), the centre should document the risk analysis carried out (including verifying witnessing), provide careful counselling to the patient regarding the potential risk prior to obtaining the patient's consent and if the centre considers that these samples can be used safely then they could continue with that patient's treatment using those specific samples.'
- an interim inspection is to be conducted within 12 months of the renewed licence coming into force.

3.10 The committee requested that the centre's future renewal inspection report is submitted to the Licence Committee for consideration.

4. Chair's signature

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

Signature

Name

Andy Greenfield

Date

29 March 2018

Licence Committee
8 March 2018

Centre number	0105
Centre name	London Women's Clinic
Person Responsible	Mrs Tourandokht Arian-Schad

Update to renewal inspection report

Background

1. The renewal inspection report for London Women's Clinic was considered by the Executive Licensing Panel (ELP) on 22 January 2018.

2. The panel noted that at the time of the inspection on 24 and 25 October 2017, there were two critical, six major and five 'other' areas of non-compliance identified.

3. The panel noted that further audit updates and summaries on the non-compliances concerning the use of embryos for training staff, legal parenthood, traceability, the QMS, equipment and materials, adverse incidents, storage of gametes and embryos, medicines management and pre-operative assessment and the surgical pathway were due for receipt by 25 January 2018.

4. The panel decided to adjourn consideration regarding the renewal of the centre's licence, requesting the inspectorate to provide an update report, to the 2 February 2018 ELP meeting, on the additional audit information and summaries, due from the centre by 25 January 2018.

5. An update report was provided to ELP on 2 February 2018. ELP noted that some of the recommendations should have been fully implemented by 25 January 2018, but the non-compliances had not yet been fully addressed. The panel therefore did not feel confident in the PR's ability to ensure regulatory compliance in a timely manner, for patient safety to be upheld, due to failure to implement corrective actions within the agreed timescales.

6. The panel decided to adjourn renewal of the centre's licence, requesting the matter to be referred to the Licence Committee for consideration.

7. The panel agreed to issue Special Directions under Section 24 (5A)(b) of the HF&E Act 1990 (as amended), to permit the continuation of licensed activity upon expiry of the centre's current licence, to allow time for the renewal to be considered by the Licence Committee and for the administration of the outcome of their consideration to be completed within the usual timeframe.

8. Annex 1 provides an update on evidence that has been provided by the PR towards implementation of the recommendations made in the renewal inspection report.

Summary

9. In summary, the centre has now provided good evidence of progress with implementing the recommendations from the renewal inspection report.

10. The executive will continue to liaise with the PR to ensure that the outstanding actions and follow audits due either 25 April 2018 or 25 July 2018 are implemented.

Louise Winstone,
Inspector

Annex 1: Recommendations that required further action

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
1. Use of embryos for training staff In one of four patient records reviewed, the centre had used embryos in staff training without the consent of the egg provider. SLC T94. The centre's SOP for the use of embryos in staff training does not include the process information required by SLC T92, T93 and T95. Verbal information provided to patients prior to consenting to the use of embryos in training of staff does not include details of whether any information will be available following the training	The PR should ensure that embryos are only used for staff training with the consent of both gamete providers and that the SOP and patient information supporting the use of embryos in training is compliant with all HFEA CoP requirements. The PR should investigate the circumstances that led to these embryos being used without the consent of the egg provider. It is also expected that the egg provider is informed of the use of these embryos without her consent. A retrospective audit of all embryos used in training since this licence was issued on 1 March 2014 should be performed, to determine if	Further to observations made during inspection, the SOP_GLO_Research and Training has been updated (see attached). We have also implemented the use of a more robust log (FRM_GLO_Training Record Consent Verification And Gamete Traceability Form -as attached). This document provides a clear pathway for appropriate preparation prior to any embryo use. This will be reviewed in March 2018 and updated as appropriate to ensure it is fit for purpose. The medical records of the patient identified at inspection were reviewed. It was noted that although a check box (5.2)	The Executive acknowledges the PR's response and her commitment to fully implement the recommendation. The updated SOP has been provided and has been appropriately reviewed. The retrospective audit has also been provided and gives the inspection team no further cause for concern. The inspectors acknowledge that an internal consent form has now been identified and consideration was given to down grading this to a major area of non compliance. However, there are concerns that the executive was only notified of this consent form two months

and if this information will be fed back to the patients. SLC T97b.	embryos have been used without consent in any other cases. The findings of the investigation and audit should be submitted to the centre's inspector when responding to this report. The PR should conduct a full review of the centre's procedures for using embryos in training. This should include a review of the SOP and of the information provided to patients prior to them giving consent. A summary of the review, including details of any resulting corrective actions, should be submitted to the centre's inspector by 25 January 2018. Six months after the implementation of corrective actions (if embryos have been used in training during this period), a further audit of embryo use in training should be performed and a summary of the audit should be submitted to the centre's inspector by 25 July 2018.	on the WT form had not been completed, the gamete provider had signed an internal consent form agreeing to research and training. Despite this, the couple were called and invited to meet with the counsellor and consultant to discuss the use of the embryo in training without her HFEA WT consent form being fully completed. A retrospective audit was undertaken which identified all embryos used in training from 1 March 2014 – 31 October 2017. See attached. A further update will be provided of the conclusion of these actions by 25 January 2018. Further investigations and audits will be completed as requested in the report within the given time frame.	after the inspection and on the day of inspection, there was no indication from staff that internal consent to training forms were completed by patients. In consideration of this and concerns that staff may not be fully aware of the centre's procedures, it was agreed to keep this area of practice as a critical area of non compliance. A full review of the centre's procedures for using embryos in training is to be provided to the centre's inspector by 25 January 2018 and a follow up audit by 25 July 2018. Further action is required. **Progress update, 25 January 2018** The PR has provided an updated SOP and training record consent verification and gamete traceability form. This revised SOP no longer includes the required process information required by SLC T92, T93 and T95: the activities for which embryos can be used to train

			staff; that embryos appropriated for training staff cannot be kept/used for the provision of treatment services; or the procedures by which the centre ensures that there is no actual or perceived conflict of interest between the use of embryos in training and the use of embryos in providing treatment. Details of the information provided to patients has not been submitted. **Further action is required:** The PR should conduct a further review of the centre's procedures for using embryos in training and is asked to review and revise the SOP to ensure it includes the information required by the relevant licence conditions. The executive also requests an explanation as to why the SOP has been revised to remove relevant details. This should be submitted along with details of the information provided to patients by 16 February 2018.

			A follow up audit is due by 25 July 2018. **Progress update, 16 February 2018** The PR has provided a revised SOP that now includes the information required by the relevant licence conditions. The PR has apologised for the missing section in the previous SOP submitted stating 'during the submission process I appear to have inadvertently deleted part of the document'. The information provided to patients has also been submitted. A follow up audit is due by 25 July 2018. Further action is required.
2. Legal Parenthood The centre's consent audit conducted on 4 July 2017 identified a missing signature on one of the page declarations in a PP legal parenthood consent form.	The PR should ensure that effective consent to legal parenthood is obtained. When responding to this report, the PR should provide a summary of the actions taken to contact the patient affected by the non conformance, and the	A Non-Conformance form is attached documenting the background and subsequent actions relating to the parental consent anomaly identified at inspection. The PR has taken legal advice relating to this case. The actions take into account the advice given. A	The Executive acknowledges the PR's response and her commitment to fully implement the recommendation. A copy of the summary of the actions taken to address the Legal Parenthood consent non conformance identified and the

The centre has not undertaken an adequate audit of consent to legal parenthood since the audit requested by the HFEA in 2014. Section 44(1) of Part 2 of the HF&E Act 2008.	outcome of those actions, confirming if a correctly completed consent form has been provided by the patient. Should this not be the case, the PR should provide details on the legal advice obtained and actions planned in response to this advice, including how the centre intends to communicate with and support the couple affected. When responding to this report, the PR must provide evidence of the immediate corrective actions taken to ensure the centre's legal parenthood processes are robust until they have an opportunity to conduct a full investigation. The PR should conduct a root cause analysis into the circumstances which led to the failings in the completion of the parenthood consents in this case, and why consent form checks failed to identify the anomaly. This analysis should include an explanation of why timely corrective action was not	root cause analysis has been conducted and CAPA points identified. A further update will be provided by 25 January 2018. An independent auditor is currently undertaking a legal parenthood audit for treatments undertaken between 1 January 2014 and 31 October 2017. The findings, actions and CAPA will be provided as requested by 25 January 2018. The Audit Schedule for 2018 now includes an audit specific to Legal parenthood. In previous years this audit was accomplished within the main consent audit. This audit will be completed on a 3-monthly rotation. On the 24th November and 8th December, a training course in 'Legal Aspects of Reproductive Care' was provided for all LWC staff. This was run by a specialist fertility lawyer and	root cause analysis and legal parenthood audit is to be provided to the centre's inspector by 25 January 2018. Further action is required. **Progress update, 25 January 2018** A root cause analysis of the circumstances which led to the failings in this case has been performed and corrective actions have been implemented. The PR has provided evidence of the actions taken to ensure legal parenthood consent procedures are robust going forward, including confirmation that refresher training has been provided to staff. A specific legal parenthood consent audit will be conducted on a three monthly basis. The PR provided confirmation in December that the patient affected had been contacted and appropriate support had been offered to the couple. No further

	taken when the consent form anomaly was first identified. A copy of the root cause analysis should be provided to the centre's inspector by 25 January 2018. An audit of legal parenthood consenting in treatments between 6 April 2009 and 31 December 2013 in which such consent was required, has previously been provided to the HFEA and is not requested again. The PR should however conduct a further audit of all treatments provided since 1 January 2014, where legal parenthood consent is required, and provide a copy of the findings including corrective actions, such as staff re-training, to the centre's inspector by 25 January 2018.	addressed the issue of legal parenthood and consent.	update has been provided to the executive. The PR has provided the results of a legal parenthood audit, which reviewed all relevant cases which resulted in a live birth from January 2014 to October 2017. This has noted a further two anomalies: • Case 1 - 2015: The partner has signed, but has not dated, the declaration page of the PP consent form. • Case 2 – 2017: the partner has signed and dated the PP form. However the partner has written their year of birth instead of the year of signature. The audit notes that these anomalies will be 'managed through the Incident/Audit schedule', but has provided no further information. Nor have these anomalies been reported formally to the HFEA as incidents.

			The PR is asked to provide an update and report these incidents by 16 February 2018. Further action required. **Progress update, 16 February 2018** The PR has reported the above three anomalies to the HFEA through the incident reporting system. The PR has also provided an update on the actions taken to communicate this information to the couples affected. It is unclear at this stage if the couples affected by anomalies wish to seek parenthood through the courts, however the PR has committed to keep the centre's inspector informed. The executive asks that a summary of the next scheduled legal parenthood audit is submitted to the centre's inspector for review. Further action is required.

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
3. Traceability The centre does not keep a record for traceability purposes of the centrifuges used to process sperm for use in treatment or of equipment used to perform ICSI. An audit on inspection of six batches of materials in use in the laboratory found the batch number of one item did not match that recorded as being in use on the centre's traceability database. SLC T99.	The PR should ensure that traceability records are accurate and are maintained for the centrifuges and ICSI equipment. The PR should provide confirmation that this information is being recorded to the centre's inspector by 25 January 2018. The PR should review the centre's procedures for managing the traceability of consumables/reagents to ensure they are effective. A summary of the review, including details of any resulting corrective actions,	The laboratory record has been updated (see attached) to clearly identify which centrifuge and/or ICSI rig is used for each treatment. This record is then stored electronically on the patient records following cycle completion. An audit will be undertaken to ensure that this change in recording has been effectively implemented and will be submitted by 25 January 2018. A laboratory audit is currently underway to identify any anomalies within the traceability pathway of the consumables/reagents used in	The Executive acknowledges the PR's response and her commitment to fully implement the recommendation. A summary of the audit and a review of the centre's traceability procedures are to be provided to the centre's inspector by 25 January 2018. A follow up audit is due by 25 April 2018. Further action is required. **Progress update, 25 January 2018** The PR has implemented procedures for maintaining

	should be submitted to the centre's inspector by 25 January 2018. Three months after the implementation of corrective actions, a traceability audit should be performed and the report submitted to the centre's inspector by 25 April 2018.	the laboratory. This audit analyses the accuracy of recordings made on RI in relation to those consumables/reagents used in individual patient treatment cycles. The findings, actions and CAPA will be provided as requested by 25 January 2018. Further investigations and audits will be completed as requested in the report within the given time frame.	traceability records of the centrifuges and ICSI equipment. Frequent audits are being performed to ensure effective implementation. The PR has reviewed the centre's procedures for managing the traceability of consumables and reagents and corrective actions have been implemented. A follow up audit is due by 25 April 2018.
4. Quality management system Audits conducted by the centre that identified non conformances did not all detail CAPA or have due dates and closure dates for the CAPA. SLC T36.	The PR should ensure that audits have documented CAPA including dates for implementation and closure. The PR should review the findings of all audits that have been performed since the date of the last inspection and ensure that, where relevant, CAPA with dates for implementation and closure are documented. A summary of the review, including details of any corrective actions, should be submitted to the	A retrospective audit is currently being undertaken to ensure that CAPA implementation and closure are clearly documented. A review report will be submitted by 25 January 2018. The agenda for the 2018 Monthly Clinical Governance Meetings has been amended to ensure that appropriate time is given for discussion of ongoing audits and their outcomes within these multi-disciplinary meetings.	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation. A summary of the review is to be provided to the centre's inspector by 25 January 2018. Further action is required. **Progress update, 25 January 2018** The PR was asked to review the findings of all audits

	centre's inspector by 25 January 2018. The PR should ensure that a regular and thorough legal parenthood audit is included on the audit schedule and provide confirmation of this when responding to the report.	The 2018 implementation plans for additional modules of the Q-Pulse Quality Management System, include the groupwide use of the audit module. This will ensure an electronic record of all audits undertaken and the subsequent CAPA, any due dates and closure dates. This will enable a clear link between actions, meetings, SOP alterations and subsequent improvements that will be easily available for all staff members. The effective completion of audits and any actions required will be allocated to departmental Quality Leads. Job descriptions, competencies and responsibilities will be updated to reflect this change. The Audit Schedule for 2018 now includes an audit specific to Legal parenthood. In previous years this audit was accomplished within the main consent audit. This audit will	performed since the date of the last inspection (October 2015). The PR has submitted a review of 22 of the 150 audits completed in 2017 only. This review has found that all required corrective action from these audits was implemented. The centre is planning to review the remaining 128 audits completed in 2017 by the end of March 2018. The PR is asked to submit the findings of this review by 1 April 2018. Based on the findings of this review, the executive will determine whether it is proportionate to require a review of audits completed in 2015/2016, as originally requested and agreed to by the PR. The findings of the review of the remaining 128 audits completed in 2017 is due by 1 April 2018. Further action is required.

		be completed on a 3-monthly rotation.	
5. Transport and satellite agreements The centre has not audited the suitability and compliance of services provided by their transport and satellite centres. SLC T36.	The PR is reminded that she is responsible for ensuring that all the centre's transport and satellite centres provide the satellite/transport services in a manner compliant with HFEA requirements. The compliance of such services should be audited by the primary centre at least every two years. The PR should work with the transport and satellite centres to provide an action plan to ensure all the centre's transport and satellite services are audited. It is expected that these audits will be completed by 25 April 2018. The action plan should be provided to the centre's inspector with the response to this report. Summaries of the audits completed should be provided to the centre's inspector by 25 April 2018.	A plan is now in place for the audit of the satellite and transport centres by the Quality Manager and an Independent Auditor. The SOP is attached. As per the attached assessment plan, the initial audit for each satellite/transport centre will be accomplished by 25 April 2018. The centres will then be audited on a 2-year rotation.	The Executive acknowledges the PR's response and her commitment to fully implementing the recommendation. The audits of the satellite and transports centres have been scheduled and a summary of the audits is to be provided to the centre's inspector by 25 April 2018. Further action is required.

6. Equipment and materials The Cryotech vitrification media used by the centre is not currently CE marked to the appropriate standard, albeit appropriate certification is expected to be in place by March 2018. This issue was noted at the previous inspection. The use of this vitrification kit without the appropriate CE mark, and any associated risks, is not discussed with patients. SLC T30.	The PR should ensure that CE marked medical devices are used where available. It is acknowledged that the centre has attempted to introduce an alternative and appropriately CE marked vitrification media, but have found it does not work as well. In consideration of this, and that the executive would not recommend making precipitous changes that could impact on the quality and safety of gametes and embryos, the inspection team recommend that the PR provides monthly updates to the centre's inspector regarding progress made by the company towards achieving CE mark status for the vitrification medium. If this timeline significantly increases, the centre must consider use of other alternatives CE marked at the appropriate level. In the interim, patient information should be	Attached is the most recent correspondence from the vitrification manufacturer. Research is also underway to find a suitable alternative if CE marking for the media is not acquired by 31st March 2018. The amended patient information will be provided as requested by 25 January 2018.	The Executive acknowledges the PR's response and her commitment to fully implement the recommendation. The amended patient information is to be provided to the centre's inspector by 25 January 2018. Further action is required. **Progress update, 25 January 2018** The PR has not provided an update on when the company is likely to achieve CE mark status for its vitrification kit. The PR has submitted revised patient information, however this does not include information on any possible risks associated with the use of non-CE marked media. An update and revised patient information to be provided by 16 February 2018. **Further action is required.**

	reviewed and amended to reflect the use of a reagent that is not appropriately CE marked and should include information on any possible risks associated with this. A copy of the amended patient information should be provided to the centre's inspector by 25 January 2018.		**Progress update, 16 February 2018** The PR has submitted revised patient information, that includes information on any possible risks associated with the use of non-CE marked media. At this stage there is no further update on when the company is likely to achieve CE mark status for its vitrification kit. The PR is to keep the centre's inspector informed and to seek an alternative vitrification media should CE marked status not be attained. Further action is required.
7. Adverse Incidents The centre has not reported a near miss and an incident to the HFEA, nor has the centre appropriately investigated these events for learning or implemented CAPA in a timely manner.	The PR should ensure that all near misses and adverse incidents are investigated and reported to the HFEA. The PR should investigate why the near miss and incident identified were not reported to the HFEA or investigated appropriately. A	Please can an amendment be made to the report on page 13 where it states '…this sample was the last remaining vial….' . As per the attached incident form, 1 amp of sibling imported donor sperm remains in storage for this patient. The patient is planning for treatment in early 2018.	The Executive acknowledges the PR's response and the amendment has been made to the report. A summary of the audit and reviewed SOP is to be submitted to the centre's inspector by 25 January 2018.

Guidance Note 27.6; General Direction 0011.	summary of the findings of this report should be provided to the centre's inspector by 25 January 2018. The PR should review the SOP that was developed in response to the similar non compliance noted at the centre's last renewal inspection to determine if it remains fit for purpose and investigate why this procedure was not implemented. A report of this investigation, including corrective action such as staff training, should be provided to the centre's inspector by 25 January 2018.	An audit is underway to assess the level of unreported near misses over a 12-month period. This audit, its findings, actions and CAPA will be provided as requested by 25 January 2018. A reviewed SOP will also be submitted at this time.	Further action is required. **Progress update, 25 January 2018** The PR has submitted a review of non-conformances identified at the centre in 2017 and corrective action has been identified and implemented. The centre's SOP for adverse incidents has been submitted. However, information to demonstrate that an investigation has been conducted to identify why the near miss and incident identified were not reported or investigated appropriately has not been provided. Although the centre's SOP has been provided, it is not clear if this has been updated since the inspection to ensure it is fit for purpose. The PR should provide this information by 16 February 2018. Further action is required.

			Progress update, 16 February 2018 The PR has provided evidence that the centre's SOP for adverse incidents has been reviewed and updated. Evidence of staff training in near misses and adverse incidents performed on 12 February 2018 has also been provided. No further action is required.
8. Storage of gametes and embryos The centre have inappropriately applied a one year cooling off period to allow embryo storage to continue beyond the expiry of storage consent. HF&E Act 1990 (as amended); Schedule 3, 8 (2).	The PR should establish an action plan for resolving this case in which a set of embryos is being stored beyond the consented storage period. A copy of this plan should be provided to the centre's inspector when responding to this report. The PR is reminded of guidance issued in Chairs letter (03) 03 (CH (03)03) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions to take should there be a possibility of legal challenge to	On the 24th November and 8th December, a training course in 'Legal Aspects of Reproductive Care' was provided for all LWC staff. This was run by a specialist fertility lawyer and addressed the meaning of the 'cooling-off' period and how to apply it appropriately in relation to stored gametes and embryos. Further to the finding of the embryos stored beyond the consented storage period, legal advice was sort. Subsequently the embryos were discarded.	The Executive acknowledges the PR's response and her commitment to fully implement the recommendation. A copy of the revised procedure is to be provided to the centre's inspector by 25 January 2018. Further action is required. **Progress update, 25 January 2018** The PR has provided a copy of the revised SOP for management of cryopreserved material.

	the disposal of cryopreserved material. The PR should review the centre's procedure for applying a 'cooling-off' period to ensure it is compliant with requirements. A copy of the revised procedure and evidence of staff training should be provided to the centre's inspector by 25 January 2018.		The SOP is clear that the cooling off period cannot apply beyond the end of the period for which valid consent exists. However, the SOP also states that where there is a dispute about stored gametes, a one year cooling off period is normally applicable. However, the Act only allows for cooling off period to be applied to embryos in storage. The PR is requested to further review the centre's procedure for applying a cooling off period. A copy of the revised procedure and evidence of staff training should be provided by 16 February 2018. **Progress update, 16 February 2018** The PR has provided an amended SOP which now clearly and accurately defines the cooling off period. Evidence of staff training performed on 12 February 2018 has also been provided.

			No further action is 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
9. Medicines Management In three out of eight patient records reviewed on inspection there was no record of a controlled drug being recorded in the patient's prescription sheet, yet it was recorded as given in the controlled drug book in theatre. Therefore, it was not possible to see in the patients record the time and dose of administration. The Misuse of Drugs Regulations 2001, section 15. SLC T2.	The PR should ensure that all controlled drugs are written clearly, showing the date, time and amount given in the patients record, this should be reflected in the SOP. The PR should communicate the importance of this to the medical staff involved, and audit controlled drug prescribing practices to ensure practice has changed. A copy of the updated SOP and audit should be submitted to the centre's inspector by 25 January 2018.	The SOP_GLO_Safe Handling of Controlled Drugs (CDS) has been updated to include direct reference to the recording of drugs received by patients whilst in the recovery ward. See section 7.9 in the attached SOP. This update to the SOP will be discussed at the Nurses Departmental Meeting in January 2018. The theatre and recovery team have already been made aware of the change. An audit is currently underway to provide evidence of compliance to this step. The results will be submitted as requested by 25 January 2018.	The Executive acknowledges the PR's response and her commitment to fully implement the recommendation. A summary of the audit is to be provided to the centre's inspector by 25 January 2018. Further action is required. **Progress update, 25 January 2018** The PR has provided the results of an audit of medicines management. However, the records audited were from the period 5 July to 29 September 2017. It is unclear how an audit of procedures in place **before** corrective action had been implemented can provide information on how effective that corrective action is.

			The PR notes that further audits are to be performed in January 2018. The PR is asked to provide copies of these audits by 16 February 2018. Further action is required. **Progress update, 16 February 2018** The PR has provided an audit of medicines management. The records audited covered the period 31 October 2017 to 31 January 2018. No further action is required.
10. Pre-operative assessment and the surgical pathway In the post procedure/recovery area there was no emergency call bell system at the patient's bedside in any of the six bays. SLC T2.	The PR should complete a risk assessment for the six-bed recovery area, documenting how staff ensure patients are observed safely post procedure. The risk assessment should include risk control measures. The inspection team were informed about plans to install emergency call bells at the patient's bedside, the timeline of any work should be	Work has been done to identify suitable equipment to provide an emergency call bell to each bed in the recovery area. The plan for installation will be provided by 25 January 2018. A thorough risk assessment has been completed (see attached). The risks identified will be incorporating into the	The Executive acknowledges the PR's response and her commitment to fully implement the recommendation. The PR is to provide confirmation of the installation of emergency call bells by 25 January 2018. Further action is required.

	completed no later than 25 January 2018. A copy of the risk assessment should be sent to the centre's inspector when responding to this report, followed by an update when the work is completed.	long-term improvement plans for the recovery area.	**Progress update, 25 January 2018:** The PR has provided evidence of the intention to install a Medicare Nurse Call System to the recovery area. The PR is asked to inform the executive when this work will be carried out. Further action is required. **Progress update, 16 February 2018** The PR has stated 'I have now had further clarification from the facilities department, that the final phase for the installation of the Nurse-Call System in the Recovery Area will be completed on Tuesday 27 February. Once the work is complete and the system is performing appropriately, I will send through a final summary for you'. Further action is required.
11. Imports and exports The centre exported donor eggs back to the Ukraine but	The PR should ensure that GO forms are completed and submitted to the HFEA within	The EDI GO form for the return of eggs to the Ukraine has now been submitted.	The Executive acknowledges the PR's response and her

did not submit GO forms to the HFEA within the required timeframe. General Direction 0006.	the required timeframes following the export of gametes or embryos. The PR should audit all gamete and embryo exports that have taken place during the previous 12 months to ensure that GO forms have been submitted within the prescribed timeframes. A copy of this audit including corrective actions should be submitted to the centre's inspector by 25 April 2018.	An audit is underway for the period October 2016 – October 2017 to confirm that the submission of GO forms for gamete and embryo export is accomplished within the timeframe required by the HFEA. This audit will also include GI form submission for imports over the same period. The findings of this audit will be submitted by 25 April 2018 together with the relevant SOP if amendment needs have been identified	commitment to fully implement the recommendation. A summary of the audit is to be submitted by 25 April 2018. Further action is required.
12. Patient feedback The centre does not actively seek feedback from patients. Guidance Note 23.17.	The PR should actively encourage patient feedback as a form of quality assurance. When responding to this report, the PR should explain how, they will put measures in place to allow patients to comment on the service provided.	The matter of the low response to the clinic survey monkey was addressed in the multi-disciplinary Clinical Governance Meeting on the 23rd November 2017. It was agreed that as of 1st January 2018, all email footers will contain the weblink to the survey. Business Cards will also be produced which contain all feedback information and will	The Executive acknowledges the PR's response. No further action is required.

		be presented to all patients at consultation.	
13. Confidentiality The inspection team was informed that following a scan, a nurse had shown a patient a list of available appointment dates on the computer, the list containing the names of other patients already booked in for appointments. SLC T43.	The PR must ensure that all information is kept confidential and only disclosed in circumstances permitted by law. The PR should arrange for further training and staff awareness about the importance of confidentiality, to include all staff that perform scans by 25 January 2018. Three months after the implementation of corrective actions, the centre should review its systems to ensure that these corrective actions have been effective. A summary of this review should be submitted to the centre's inspector by 25 April 2018.	On the 24th November and 8th December, a training course in 'Legal Aspects of Reproductive Care' was provided for all LWC staff. This was run by a specialist fertility lawyer and addressed the aspects of Confidentiality and its application in the IVF sector. An additional training course is planned for the LWC Group which focuses on Confidential and Information Governance. This will identify actions required to ensure compliance to GDPR requirements by May 2018. The confidentiality breach identified by a patient interviewed on the day of the inspection has been discussed with the staff member involved. It will also be addressed in the Nurses Departmental Meeting in January 2018.	The Executive acknowledges the PR's response and her commitment to fully implement the recommendation. A summary of the review is to be provided to the centre's inspector by 25 April 2018. Further action is required.

		Privacy screens will be added to the computers in all the ultrasound rooms and the positioning of the desks will be reviewed to reduce the risk of patients being able to read the PC screen. The finalised review will be provided to the HFEA as requested. The submission of AI Confidentiality Breach reports to the HFEA over the period October 2017 to March 2018 will be analysed and the findings submitted as requested by 25 April 2018.	