Executive Licensing Panel - minutes

Centre 0105 (London Women's Clinic)

Executive Update

Friday, 2 February 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Helen Crutcher Anna Quinn	Head of Intelligence Risk & Business Planning Manager Scientific Policy Manager
Members of the Executive	Bernice Ash Kathleen Sarsfield-Watson Niamh Marren Nana Gyamfi	Secretary Communications Manager (Observing) Regulatory Policy Manager (Observing) Licensing Information Officer (Observing)
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

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

1. Background

1.1. The panel noted the London Women's Clinic has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including embryo testing to self-funded patients. The London Women's Clinic is part of a nationwide group of centres and has several satellite and transport centres.

1.2. The panel noted that a renewal inspection was carried out at the centre, on 24 and 25 October 2017 and was considered by the Executive Licensing Panel at its meeting on 22 January 2018.

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

1.4. The 22 January 2018 Executive Licensing Panel noted that 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.

1.5. The 22 January 2018 Executive Licensing 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.

2. Consideration of application

2.1. The panel considered the papers, which included an executive update, inspection report, update on recommendations made in the report and licensing minutes for the last three years.

2.2. The panel noted that the Executive had confirmed that the centre had provided a large number of documents that the inspectorate has reviewed, relatively briefly, in order to be able to provide an update to the 2 February 2018 meeting. In summary, the centre had provided some evidence of progress with implementing the recommendations from the renewal inspection report. However, there are areas where further information is required from the Person Responsible (PR).

2.3. The Executive 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 Executive reported that a short delay in implementation, in these specific cases, is not considered to be a direct risk to patients.

2.4. The panel noted that the Executive will continue to liaise with the PR to ensure all recommendations are implemented. Failure to implement the recommendations to the satisfaction of the Executive will result in the submission of a further report to a licensing committee with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

2.5. The panel noted the inspectorate recommends the renewal of the centre's treatment (insemination using partner/donor sperm) and storage licence for a three year period, rather than the usual four, with an interim inspection being conducted within 12 months of the renewed licence coming into force. This will allow an inspection team to observe directly whether there are improvements in practices, processes and the centre's overall compliance.

2.6. The panel noted that the additional condition, on the centre's current licence, should be included on the new licence as below:

'a) 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.'

3. Decision

3.1. 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, due to failure to implement corrective actions within the agreed timescales.

3.2. 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 use of embryos for training staff, legal parenthood, equipment and materials, adverse incidents, storage of gametes and embryos, and medicines management are due for receipt by 16 February 2018, requesting the inspector to provide an update to the Licence Committee on progress regarding these non-compliances.

3.3. The panel urged the PR to fully engage with the inspectorate and to provide sufficient evidence of the completion of agreed actions within the prescribed timescales.

3.4. 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. These Special Directions would come into force on 1 March 2018 and would remain in force until any new licence comes into effect, or 31 May 2018, whichever is sooner. The Panel also pointed out that the centre should continue, under Special Directions, to observe the condition on the current licence relating to the suspension of use of donor sperm processed before May 2010,

4. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

7 February 2018

Executive Licensing Panel
2 February 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. Annex 1 provides the requested update on the implementation of the recommendations made in the renewal inspection report.

Summary

6. The centre has provided a large number of documents that the inspectorate has reviewed, relatively briefly, in order to be able to provide this update to the 2 February ELP. In summary, the centre has provided some evidence of progress with implementing the recommendations from the renewal inspection report. However, there are areas where further information is required from the PR.

7. The executive notes that some of the recommendations should have been fully implemented by this date and it is not clear if they have been. However, a short delay in implementation, in these specific cases, is not considered to be a direct risk to patients.

8. The executive will continue to liaise with the PR to ensure all recommendations are implemented. Failure to implement the recommendations to the satisfaction of the executive will result in the submission of a further report to a licensing

committee with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

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.
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 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.	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 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	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 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	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 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

	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 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,	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 addressed the issue of legal parenthood and consent.	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 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.

	and provide a copy of the findings including corrective actions, such as staff re-training, to the centre's inspector by 25 January 2018.		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.**

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. **Further action is required.**
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,	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	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**

	should be submitted to the 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.	outcomes within these multi-disciplinary meetings. 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	The PR was asked to review the findings of all audits 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. **Further action is required.**

		consent audit. This audit will 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 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.		
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. Guidance Note 27.6; General Direction 0011.	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 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	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. 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.	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. 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

	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.		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.**
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.	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	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	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.

HF&E Act 1990 (as amended); Schedule 3, 8 (2).	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 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.	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.	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 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.

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.**
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 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.	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 long-term improvement plans for the recovery area.	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. **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.**

11. Imports and exports The centre exported donor eggs back to the Ukraine but did not submit GO forms to the HFEA within the required timeframe. General Direction 0006.	The PR should ensure that GO forms are completed and submitted to the HFEA within 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.	The EDI GO form for the return of eggs to the Ukraine has now been submitted. 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	The Executive acknowledges the PR's response and her 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.	The Executive acknowledges the PR's response. No further action is required.

		Business Cards will also be produced which contain all feedback information and will 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	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.

		Departmental Meeting in January 2018. 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.	

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: 24 and 25 October 2017

Purpose of inspection: Renewal of a licence to carry out treatment (including embryo testing) and storage

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: Louise Winstone, Sara Parlett, Susan Jolliffe, Chris Hall and Divine Wango

Executive Licensing Panel: 19 January 2018

Centre name	London Women's Clinic
Centre number	0105
Licence number	L/0105/19/c
Centre address	113-115, Harley Street, London, W1G 6AP, United Kingdom
Person Responsible	Mrs Tourandokht Arian-Schad
Licence Holder	Dr Kamal Ahuja
Date licence issued	1 March 2014
Licence expiry date	28 February 2018
Additional conditions applied to this licence	a) 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.

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The London Women's Clinic (LWC) has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including embryo testing to self-funded patients. LWC is part of a nationwide group of centres and has several satellite and transport centres.

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

The centre's current licence was varied in April 2014, July 2014 and February 2016 to reflect a change of premises.

Following a grade 'A' incident in 2012, an additional condition was imposed on the centre's licence and remains in place. 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.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 August 2016 to 31 July 2017 show the centre's success rates are in line with national averages with the following exception:

- success rates following FET in women aged 16-39 years old are higher than average at a statistically significant level.

In 2016, the centre reported 101 cycles of partner insemination with 11 pregnancies. This represents a clinical pregnancy rate of 11%, which is in line with the national average.

Multiple births[2]

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

Between 1 August 2016 and 31 July 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged 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 critical, six major and five 'other' areas of non compliance.

Since the inspection visit, the following recommendation has been fully implemented:

'Other' areas that require improvement:

- The PR should actively encourage patient feedback as a form of quality assurance.

The PR has given a commitment to fully implementing the following recommendations:

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.

Recommendation to the Executive Licensing Panel

The centre has two critical and six major areas of concern. The inspection team notes however that success rates following FET in women aged 16-39 years old are higher than average at a statistically significant level and the multiple clinical pregnancy/live birth rates meet the target.

Significant improvement is required in order for the centre to reflect suitable practices. The centre has a quality management system (QMS) and the PR is encouraged to use it to best effect to monitor and improve the quality of the services offered to patients.

The centre was the subject of two management reviews held on 27 November 2017 and 22 December 2017, carried out in accordance with section 3.1 of the HFEA's Compliance and Enforcement policy to discuss the length of licence to recommend.

In considering the length of licence to recommend, the inspection team has consulted the 'Guidelines on Licensing' used by HFEA licensing committees. 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.

The inspection team, in line with these guidelines, recommends the renewal of the centre's Treatment (with embryo testing) and Storage licence for a period of three years (rather than the usual four), with an interim inspection being conducted within 12 months of the renewed licence coming into force. This will allow an inspection team to observe directly whether there are improvements in practices, processes and the centre's overall compliance.

The inspection team recommends the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of three years. The additional condition on the current licence should be included on the new licence, i.e.:

> 'a) 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.'

The centre's current licence is due to expire on 28 February 2018. If the ELP approves the renewal of the centre's licence, the ELP may need to consider issuing Special Directions under Section 24 (5A) (b) of the HF&E Act 1990 (as amended) to permit the continuation

of the centre’s current treatment and storage activities if a renewed licence cannot be issued in time.

Section 2: Inspection findings

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

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

1. Protection of the patient and children born following treatment

▶ **Witnessing and assuring patient and donor identification**
What the centre does well **Witnessing (Guidance note 18)** The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.
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 **Screening of donors (Guidance note 11)** The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos. **Payments for donors (Guidance note 13; General Direction 0001)** The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused. **Donor assisted conception (Guidance note 20)** The centre's procedures are compliant with HFEA requirements to ensure the donor-conceived and their parents will be able to receive all required donor-related information. It is important that centres use donated gametes or embryos from identifiable donors and

keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non-identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

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 and/or embryos are suitable. However, an assessment of the premises of the centre's satellite and transport facilities could not be made (see recommendation 5).

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third-party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or

any material removed from them, are compliant with HFEA requirements to be accredited by CPA (UK) Ltd or another body 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 compliant with guidance.

Medicines management (Guidance note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable.

Written information provided to patients offered intralipid therapy is compliant with guidance.

Pre-operative assessment and the surgical pathway (Guidance note 25)
The centre has policies and procedures in place that are broadly compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and

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

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

- document the justification for the use of the patient's gametes (or embryos created with their 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 and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes/embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are broadly compliant with HFEA requirements.

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

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is partially compliant with HFEA requirements. 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 has systems in place to manage transport and satellite activities that are partially compliant with HFEA requirements. This is important to ensure that activities performed by transport and satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are partially compliant with HFEA requirements. The centre reports most adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates adverse incidents that have occurred, however, the centre does not investigate all 'near misses'. Reporting and investigation of adverse incidents, including 'near misses', 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

Medicines management (Guidance note 25)
In three out of eight patient records reviewed on inspection there was no record of a controlled drug being provided on the patient's prescription sheet, yet for each of the three patients, a controlled drug was recorded in the controlled drug book in theatre as having been given to them. Therefore, it was not possible to see clearly in the patient's record the time and dose of administration, some staff were recording administration of the controlled drugs in the anaesthetic record, the centre SOP for 'Safe handling of controlled drugs' is specific about how to record a controlled drug in the register, but does not identify how and where to record the administration of a controlled drug in the patients record. This is important for staff in the post procedure area to be able to identify quickly the amount of controlled drugs and time given should an emergency arise. The Misuse of Drugs Regulations 2001 section 15 (SLC T2).

See recommendation 9.

Pre-operative assessment and the surgical pathway (Guidance note 25)
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).

See recommendation 10.

Imports and exports (Guidance note 16; General Direction 0006)
The centre received a bulk shipment of donor eggs from a Ukrainian donor egg bank even though the import had not been arranged. The centre had been in correspondence with the egg bank to discuss the development of an agreement between the centres but this had not been finalised, one reason being that the PR was not satisfied that all requirements of General Direction 0006 could be fulfilled. The donor eggs were stored at the centre in a quarantine storage tank until export back to the Ukrainian clinic was arranged. The export was undertaken but the centre did not then submit Embryo and Gamete Movement – Out (GO) forms to the HFEA via the Electronic Data Interchange (EDI) system, as should happen within 10 working days of a gamete or embryo export taking place (General Direction 0006).

See recommendation 11.

Traceability (Guidance note 19)
The centre does not keep a record for traceability purposes of the centrifuge used to process sperm for use in treatment or of the equipment used to perform ICSI (SLC T99).

An audit of six batches of materials in use in the laboratory was carried out on inspection. The batch number of one item did not match that recorded as being in use on the centre's traceability database (SLC T99).

See recommendation 3.

QMS (Guidance note 23)
Audits conducted by the centre that identified non conformances did not consistently detail the corrective and preventative actions (CAPA) or have due dates and closure dates for the CAPA. It was therefore unclear if actions had been taken in response to the audit findings (SLC T36).

The centre undertakes a stand-alone rolling patient consent 'audit' which had identified missing consent forms. On further inspection, this consisted of a checklist with no documented action plan to correct the non-conformances, and no system to investigate the reasons for the missing consents or to prevent a recurrence. The centre had also completed an audit of FET consent on 4 July 2017 which identified several instances of missing signatures on consent forms and absent consent forms in the patient records prior to treatment. At the time of the inspection no action had been taken to investigate or correct these issues

The centre had audited the presence of legal parenthood consents in patient records, but this was part of a general consent audit and did not specifically look at whether the consent forms had been signed correctly before treatment, and if counselling had been offered prior to the consent forms being signed. Also see Legal Parenthood section.

See recommendation 4.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has not audited the suitability and compliance of services provided by their transport and satellite centres (SLC T36).

See recommendation 5.

Equipment and materials (Guidance note 26)
The vitrification media used by the centre is not currently CE marked to the appropriate standard. This issue was noted at the previous inspection. It is acknowledged that the centre has attempted to introduce an alternative and appropriately CE marked vitrification media, but they have found this does not work as well. Correspondence from the company producing the media, shows that they are working towards and expecting to achieve the appropriate CE mark by March 2018. The use of this vitrification kit without the appropriate CE mark and any associated risks is not discussed with patients (SLC T30).

See recommendation 6.

Adverse incidents (Guidance note 27)
On inspection it was found that the centre had not reported or investigated a 'near miss' incident to the HFEA that occurred in December 2016. The near miss involved a donor sperm sample that was thawed in error. Fortunately, replacement donor sperm was available and the patient's treatment was not affected. This near miss was not reported to the quality manager and was not investigated at the time. In May 2017, the centre reported an incident to the HFEA involving donor sperm that was thawed in error. The patient affected is currently going through the centre's complaint procedure. Had the near miss in December 2016 been investigated at the time, corrective and preventative actions could have been put in place which may have prevented the incident in May 2017 (General Direction 0011; Guidance 27.6).

Non-reporting of a 'near miss' incident to the HFEA was a non compliance noted at the centre's last renewal inspection in 2013.

The centre did not report a legal parenthood consent anomaly as an incident. Also see Legal Parenthood section.

See recommendation 7.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of nursing 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. However, see Consent section.

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's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA;
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons;
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.
What the centre could do better Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well
During the inspection visit, an inspector spoke to three patients who provided feedback on their experiences. This feedback was positive and the patients complimented the centre on the care received. One patient however raised concerns that she was able to view other patient names on a monitor following a scan procedure (see confidentiality and privacy section). The centre did not have their own patient feedback to review. However, the counselling team does independently seek feedback on the counselling service. They have a good response rate for services and the counsellors are to be commended on the positive feedback.

What the centre could do better
The centre does not effectively collect or analyse patient feedback. The centre has received only two patient questionnaires in the last 12 months. This is unacceptably low when the centre has performed 2,927 cycles in the last year (SLC T32 and CoP guidance 23.17).

See recommendation 12

Treating patients fairly

Counselling
Egg 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 and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consents and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind;

- egg providers are fully assessed and medically suitable; and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are partially compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints (see patient feedback section). 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 broadly compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Confidentiality and privacy (Guidance note 30)
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 contained the names of other patients already booked (SLC T43).

See recommendation 13.

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 and/or donors are compliant with HFEA requirements with the exception of that patients are not informed about the use of a non CE marked vitrification kit (see equipment and materials section and recommendation 6). This ensures that the centre gives prospective and current patients and donors 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 is important to ensure that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about its effectiveness and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that in total 15 couples were affected by legal parenthood consent anomalies. Several attempts have been made to contact all of the couples affected but only one couple came forward to seek a declaration of parenthood through the family courts, this was awarded and the case is now closed. It has been made clear to the other couples that should they wish to seek a declaration of parenthood through the family courts in the future, the centre will cover all legal costs.

At the inspection on 27 October 2015, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

To provide some assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood with a prior offer of counselling was seen to be in place before treatment in all cases.

However, significant concerns have been raised in relation to a recent audit performed by the centre (detailed below). In summary, the inspection team considers that the centre's current processes for obtaining effective consent to legal parenthood are partially compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better

Legal parenthood (Guidance note 6)
During this inspection, it was noted that the centre had not undertaken an adequate audit of consent to legal parenthood since the audit requested by the HFEA in 2014. The centre has audited the presence of legal parenthood consent forms in patient records but this was part of a general consent audit and it was not clear if it specifically looked at whether the consent forms were signed before treatment and that counselling had been offered prior to signing the consent forms. This undermines the PR's reassurance, provided in October 2015, that 'effective audit procedures are in place to ensure on-going compliance with consent taking requirements'. It also leaves the centre exposed to a risk that consenting processes may not have been robust at times since 2014 and further cases of anomalous consent to legal parenthood may be present.

The centre's consent audit conducted on 4 July 2017 identified a missing signature in one of the page declarations in a PP consent form. The couple have previously had a live birth following treatment at the centre using donor sperm in 2012, and correctly completed legal parenthood consent forms were present in the patient records from this treatment cycle. The couple attended the centre earlier this year for further treatment and completed new consent forms, but omitted a signature in one of the page declarations in the new PP form. The patient is currently pregnant. The PR confirmed that she has contacted the couple to ask if they have completed consent forms at home but at the time of this inspection, there had been no response and no other actions appear to have been taken by the PR. The inspectors were concerned that over three months have passed since the anomaly was discovered and the PR has not reported this as an incident or initiated an investigation. It is not clear how the PR can currently be assured that the centre's legal parenthood procedures are robust. This also casts doubts on the PR's understanding of the serious consequences of anomalies in legal parenthood consent, especially as the centre has previously been involved in supporting patients through the family courts to attain a declaration of legal parenthood (Section 44(1) of Part 2 of the HF&E Act 2008).

See recommendation 2.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman; and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

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, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Storage of gametes and embryos (Guidance note 17)

On review of the centre's 'bring forward system', it was noted that the storage consent of one set of embryos had recently expired on 5 October 2017. The couple provided storage consent for two years but are no longer together. The female patient has confirmed that she does not want to keep the embryos but the centre cannot contact the male partner. The centre has incorrectly applied a year's cooling off period until October 2018, storing

beyond the consented storage period. Therefore, these embryos are currently being stored without effective consent (HF&E Act 1990 (as amended); Schedule 3, 8 (2), CoP 'interpretation of mandatory requirements 5H).

See recommendation 8.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are partially compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

What the centre could do better
In one out of four patient records reviewed on inspection, it was observed that the centre had used embryos for training in embryo biopsy without the consent of the egg provider (SLC T94).

The centre's SOP for the use of embryos in staff training does not include information on: 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 (SLC T92, T93 and T95).

Patients are not given written information but are given information verbally at the nurse's consultation appointment about the use of embryos in training of staff, before the patients give consent. However, this information does not include details of whether any information will be available following the training and if this information will be fed back to the patients (SLC T97b).

See recommendation 1.

4. Information management

Record keeping and obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information about licensed activities to the Authority are compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

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

Section 3: Monitoring of the centre's performance

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

The PR provided information and evidence that all the recommendations were fully implemented within the prescribed timescales. It was noted however during this inspection that the centre has continued to use a non-CE marked vitrification media; see recommendation 6.

On-going monitoring of centre success rates

The centre has received one risk tool alert in the last six months relating to the IVF pregnancy rate in patients aged 38 years and over. Success rates were discussed with the PR and Quality Manager during this inspection. The inspectors were provided with evidence to show that the centre evaluates its success rates monthly and discusses them during multidisciplinary team meetings. The PR and Quality Manager provided a commitment to keep success rates in all groups of patients under review.

Areas of practice requiring action

This section sets out matters which the inspection team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, General Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
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 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.	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 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

the use of embryos in training of staff does not include details of whether any information will be available following the training and if this information will be fed back to the patients. SLC T97b.	A retrospective audit of all embryos used in training since this licence was issued on 1 March 2014 should be performed, to determine if 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	The medical records of the patient identified at inspection were reviewed. It was noted that although a check box (5.2) 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.	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 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.**

	audit should be submitted to the centre's inspector by 25 July 2018.		
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 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.	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 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	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 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	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 root cause analysis and legal parenthood audit is to be provided to the centre's inspector by 25 January 2018. **Further action is required.**

	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 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	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 addressed the issue of legal parenthood and consent.	

	findings including corrective actions, such as staff re-training, to the centre's inspector by 25 January 2018.		

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, should be submitted to the	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 laboratory. This audit	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.**

	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.	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.	
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 centre's inspector by 25 January 2018.	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.**

	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 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 vitrification media used by the centre is not currently CE marked to the appropriate standard, albeit appropriate	The PR should ensure that CE marked medical devices are used where available. It is acknowledged that the centre has attempted to introduce an	Attached is the most recent correspondence from the vitrification manufacturer.	The Executive acknowledges the PR's response and her commitment to fully implement the recommendation.

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.	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 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	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 amended patient information is to be provided to the centre's inspector by 25 January 2018. **Further action is required.**

	copy of the amended patient information should be provided to the centre's inspector by 25 January 2018.		
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. Guidance Note 27.6; General Direction 0011.	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 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	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. 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.	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. **Further action is required**.

	the centre's inspector by 25 January 2018.		
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 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	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.**

	centre's inspector by 25 January 2018.		

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require 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.**
10. Pre-operative assessment and the surgical pathway	The PR should complete a risk assessment for the six-bed recovery area,	Work has been done to identify suitable equipment to provide an emergency call bell	The Executive acknowledges the PR’s response and her

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.	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 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.	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 long-term improvement plans for the recovery area.	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.**
11. Imports and exports The centre exported donor eggs back to the Ukraine but did not submit GO forms to the HFEA within the required timeframe. General Direction 0006.	The PR should ensure that GO forms are completed and submitted to the HFEA within 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	The EDI GO form for the return of eggs to the Ukraine has now been submitted. 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	The Executive acknowledges the PR's response and her commitment to fully implement the recommendation. A summary of the audit is to be submitted by 25 April 2018.

	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.	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	
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 be presented to all patients at consultation.	The Executive acknowledges the PR's response. No further action is required.
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	The PR must ensure that all information is kept confidential and only disclosed in circumstances permitted by law.	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 Executive acknowledges the PR's response and her commitment to fully implement the recommendation.

patients already booked in for appointments. SLC T43.	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.	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. 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.	A summary of the review is to be provided to the centre's inspector by 25 April 2018. **Further action is required.**

		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.	

Responses from the Person Responsible to this inspection report