Executive Licensing Panel - minutes

Centre 0109 (King's Fertility)

Executive Update

Friday, 16 February 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Helen Crutcher Anna Coundley	Head of Intelligence Risk & Business Planning Manager Information Access & Policy Manager
Members of the Executive	Bernice Ash Dan Howard Nana Gyamfi	Secretary Chief Information Officer (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 that King's Hewitt Fertility Centre is based in London and holds a treatment and storage licence. The centre provides a full range of fertility services and has two transport centres, Epsom and St Helier NHS Trust (centre 0259) and Kingston Hospital Associated Conception Unit (centre 0270).

1.2. The panel noted that the renewal inspection report for King's Fertility was considered by the Executive Licensing Panel on 16 June 2017. The panel noted that at the time of the inspection there was one critical and seven major areas of practice that required improvement and that the deadlines for the implementation of corrective actions were either 12 July 2017 or 12 October 2017. As such, the panel requested that the Executive submit a summary of all the required outcomes to a further meeting by the end of November 2017.

1.3. The panel noted that a report detailing the actions taken by the Person Responsible (PR) to implement the recommendations, was considered by the Executive Licensing Panel on 17 November 2017. The centre provided good evidence that it had fully implemented all but three of the recommendations. Work was on-going to address these three matters, including the critical area of compliance.

1.4. The 17 November 2017 Executive Licensing Panel requested that the inspectorate provides it with further assurances that all actions required to fully implement the outstanding recommendations have been completed, either through a further inspection report or an executive update by the end of February 2018.

2. Consideration of Progress Report

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

2.2. The panel noted that the centre has yet to change premises; the new premises are expected to be completed in Spring 2018, at which time they will be inspected. The panel noted that the additional information provided gave assurances that further actions have been taken towards fully implementing the renewal inspection report's outstanding recommendations.

2.3. The panel noted that the PR has continued to provide monthly updates regarding actions to address both the critical area of non-compliance, concerning consent to the storage of gametes and embryos, and the major non-compliance surrounding the Quality Management System (QMS).

2.4. The panel noted that the PR has engaged fully with the recommendations made in the renewal inspection report. Good progress has been made towards ensuring that all stored material is stored within the terms of the storage consent requirements and the faults within the QMS have been corrected.

3. Decision

3.1. The panel commended the new PR on their engagement with the inspectorate and the rapid establishment of practices leading to improvements for patients.

3.2. The panel thanked the inspectorate for their continued support and hard work with the centre.

4. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

21 February 2018

Executive Licensing Panel
16 February 2018

Centre number	0109
Centre name	King's Fertility
Person Responsible	Mr Ippokratis Sarris

Update to renewal inspection report

1. The renewal inspection report for King's Fertility was considered by the Executive Licensing Panel on 16 June 2017. The panel noted that at the time of the inspection there was one critical and seven major areas of practice that required improvement and that the deadlines for the implementation of corrective actions were either 12 July 2017 or 12 October 2017. As such, the panel requested that the Executive submit a summary of all the required outcomes to a further meeting by the end of November 2017.

2. A report detailing the actions taken by the PR to implement the recommendations was considered by the Executive Licensing Panel on 17 November 2017. The centre provided good evidence that it had fully implemented all but two of the recommendations, and work was on-going to address these two matters.

3. The panel requested that the inspectorate provides it with further assurances that all actions required to fully implement the outstanding recommendations have been completed, either through a further inspection report or an executive update by the end of February 2018.

4. The centre has yet to change premises as the new premises are expected to be completed in spring 2018, at which time they will be inspected. The executive update in Annex 1 has therefore been prepared, to provide the panel with information and assurances that further actions have been taken towards fully implementing the renewal inspection report's outstanding recommendations.

5. The PR has continued to provide monthly updates regarding actions to address the critical area of non-compliance relating to consent to the storage of gametes and embryos and the major non compliance in the quality management system.

6. Annex 1 provides an update on the implementation of the recommendations made in the renewal inspection report.

7. In summary, the PR has engaged fully with the recommendations made in the renewal inspection report. Good progress has been made towards ensuring that all stored material is stored within the terms of the storage consent and the faults within the quality management system have been corrected.

   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. Storage of gametes and embryos The centre does not have written effective consent for the storage of all cryopreserved sperm and embryos. Schedule 3, 8(1) HF&E Act 1990 (as amended). This area of practice was cited as a non compliance at the previous inspections.	The PR should ensure that there is effective written consent in place for all gametes and embryos that are in storage. The PR should establish an action plan for resolving the cases where sperm and embryos are in store beyond the consented storage period. A copy of the plan should be provided to the HFEA when responding to this report. The PR should provide monthly updates to the HFEA on progress in implementing the proposed actions.	It is acknowledged that there are a number of gametes and embryos in storage at King's in the absence of effective written consent. An action plan (Attachment 1.1) has been written to confirm how many samples are currently in storage without consent so that the scale of the non compliance can be established (attachmnet 1.2). A strict frozen sample management protocol will be implemented. This will encompass monthly administration duties to highlight all samples requiring annual review, all samples approaching consent expiry (bring forward policy trigger) and all samples where contact with the patient(s) has lapsed.	The PR has provided a suitable action plan to address this area of non compliance and a clear commitment to provide monthly updates on their progress. The centre's inspector will continue to closely monitor the centres progress. Further action is required. **Progress update, 13 July 2017:** The PR has provided an update on the number of samples currently in store without effective consent and has made significant progress. The PR is to continue to provide monthly updates to the centre's inspector. Further action is required.

	The PR is reminded of guidance issued by the HFEA in CH (03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.	Immediate actions will be identification of samples where consent has expired with actions to extend storage or discard as appropriate under guidance from Consultant Embryologist and PR. This will also include scanning and storing the most recent storage consents to the patient database (IDEAS) to allow more efficient future review. Action logs will be recorded in the form of electronic 'Medical record' events on each patient file. The summary plan(1.1) is attached as a document that includes a timetable of completion. Also included is the instruction of monthly progress reviews with the PR to allow updates to be forwarded to the HFEA inspection team.	**Progress update, 9 October 2017:** A further significant improvement has been made in reducing the number of samples currently in store without effective consent. After the inspection, the centre audited all stored material and the storage database, including donor sperm currently in storage, and identified a total of 11 sets of embryos and 111 sperm samples stored without effective consent. Corrective actions have been taken and remain on-going such that there are now no patient embryos in storage without effective consent but 27 sperm samples are so stored. The new PR has assured the centre's inspector that he is committed to correcting this situation. He will ensure that monthly updates are provided to the centre's inspector and that this recommendation is fully implemented in a timely manner.

			Progress update, 17 January 2018: At the time of the last update, a total of 27 sperm samples remained in storage without effective consent. This number has now been reduced to three and the PR has confirmed that for each of these remaining three cases there is a personalised plan of action to resolve each non compliance. The PR will continue to inform the centre's inspector of progress on a regular basis until these non compliances have been resolved.

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
2. Egg donor screening The inspection team reviewed two records of treatments involving egg donation. The following non compliances were observed: • One egg donor had not had a karyotype test performed prior to donating. • Blood samples taken from egg donors for screening purposes were not consistently obtained within a timeframe specified by the Authority, nor is an appropriate	The PR should ensure that egg donors are screened in accordance with regulatory requirements and professional body guidelines. The PR should provide the centre's inspector with confirmation of revised donor screening practices, evidence of relevant staff training and a summary of the changes made to the egg donation and any related SOPs when responding to this report. The PR should audit the treatments carried out with	Our donor screening practices have been revised. The screening check list for male and female donors have been ammended and are attached (Attachment 2.1 and 2.2). The tests recquired are listed. The tests will be requested at the first doctors consultation and the person taking the tests will sign and confirm that the test has been taken. The results will be entered on the sheet by the donor co-ordinator before the second doctor's consultation, the doctor will review the results at that consultation and virology screening will be repeated at the nurse consent appointment, this means that these blood test will	The Executive acknowledges the PR's response and commitment to ensuring that this area of non-compliance is fully addressed. The PR has provided the revised screening checklist and confirmation of staff training. The PR has confirmed that the audit of all treatments carried out with egg donors in the centre since the last renewal inspection in 2013 will be submitted by 12 July 2017 and the re-audit by 12 October 2017. Further action is required. **Progress update, 13 July 2017:** The PR has provided an audit of the treatments carried out with egg donors in the centre since the

timeframe for taking such blood samples stated in the centre's SOP for egg donation. • In addition to the above observations, there is no consideration of the risk of infection with Ebola based upon recent travel history. SLC T52, T52i and CoP Guidance 11.22 and T53.	egg donors in the centre since the last renewal inspection in 2013 to assess the number of recipients affected by the use of donors where screening has not been compliant. A summary of the findings of the audit should be provided to the centre's inspector by 12 July 2017. In view of the small number of treatments provided with egg donors, the PR should audit the effectiveness of changes introduced in this area of practice within six months. A copy of the audit should be provided to the centre's inspector by 12 October 2017.	be repeated within a few weeks of the donation. The doctors involved in seeing such patients and the egg donation coordinator have been made aware of these changes and have confirmed that they will follow the new process(attachment 2.3) We will audit all the egg donors seen at this centre since the last renewal inspection. the results will be provided to the inspector by 12 July 2017. An Ebola information sheet and consent form have been created and are attached (2.4). This will be given to patients at their first doctors visit to read and complete. they will have the opportunity to ask any questions when they see the doctor.	last renewal inspection in 2013. There was only one further patient and all screening tests had been performed. The PR has updated the centre's SOP for egg donation which includes repeat screening of egg donors at the nurse consultation. A follow up audit is due by 12 October 2017. Further action is required. **Progress update, 9 October 2017:** The PR has confirmed that since the inspection, there have been no egg donors recruited by the centre and therefore a follow up audit could not be performed. This will remain on the audit schedule. The centre's inspector will remain in close contact with the new PR to ensure that this recommendation is fully implemented. Further action is required.

			Progress update, 17 January 2018: The PR has stated 'we have been running an audit on a monthly basis, to check if there are any egg donors recruited at our centre. We have not recruited any egg donors as yet. However, we are at the preliminary stages of potentially accepting one which will then be included in our February/March audit if we indeed proceed'. This will be followed up by the executive as part of the post inspection monitoring process. Further action is required.
3. Import and exports The centre cannot provide evidence that they have complied with all the requirements of General Direction 0006. General Direction 0006; schedule 2b, c, e, f and g.	The PR should ensure that all imports and exports of gametes and embryos comply with the requirements of General Direction 0006. The PR should conduct a review against the requirements of General Direction 0006 of all gametes and embryos imported or exported by	The current SOP and documentation for national and international import / export of gametes / embryos will be reviewed and amended to ensure that it reflects all HFEA / EUTCD requirements. Namely, scrutiny of receiving centre to ensure that treaments that would not be permitted in the UK are intended, that they have traceability and QM systems in place, and also provision of full	The Executive acknowledges the PR's response and commitment to ensuring that this area of non-compliance is fully addressed and awaits the summary of the findings of the review and corrective actions by 12 July 2017. Further action is required. **Progress update, 13 July 2017:**

	the centre since the last inspection. A summary of the report should be sent to the centre's inspector by 12 July 2017. The PR should review the centre's processes for import and export to ensure compliance with regulatory requirements and General Direction 0006. A summary of the findings of the review and corrective actions taken should be provided to the centre's inspector by 12 July 2017.	information to patients prior to sample import / export. Consent and information forms will be reviewed and amended to reflect the necessary considerations from both patient and King's ACU prior to approving any import or export as well as ensuring that personnel are aware of the situations requiring submission of gamete in / out reports via EDI. A summary of the findings of the review and corrective actions will be submitted to the inspector by 12 July 2017	The PR has provided a summary of a review against the requirements of General Direction 0006 of all gametes and embryos imported or exported by the centre since the last inspection. The centre's processes for import and export to ensure regulatory compliance have also been reviewed with corrective actions. The SOP, patient information leaflets and patient consents have been amended to ensure compliance with regulatory requirements and General Direction 0006. No further action is required.
4. Quality Management System The following was noted regarding the centre's audits: • whilst the centre had audited some aspects of the counselling service as part of a broad audit of consent, the inspectors	The PR should ensure that the centre's QMS and auditing processes are effective, that they include an audit against regulatory requirements and professional guidance, and that audits, including proposed corrective actions, are consistently documented.	Our QMS will be reviewed to ensure that all required audits are scheduled to be performed and reviewed within the suggested time frames or more frequently as results suggest. These will be recorded on Q Pulse with any corrective action logged. All processes will be audited aginst regulatory requirments to ensure that comprehensive and	The Executive acknowledges the PR's response and commitment to ensuring that this area of non-compliance is fully addressed. The PR has confirmed that a copy of the action plan and audits identified in this report will be submitted by 12 July 2017 and further audits and SOPS by 12 October 2017. Further action is required.

considered the scope was too narrow and did not for example review if the offer of counselling had been made prior to consent; • the centre has not audited records of manual witnessing steps; • the centre has not completed an adequate audit of legal parenthood since 2014; • the centre has not audited its transport service within the last two years; • audits that have identified and documented non-conformances do not consistently record corrective actions and the implementation of those actions. • the centre has not effectively audited processes against	The PR should develop an action plan to ensure that all the centre's processes are reviewed against regulatory requirements and provide a copy of the plan to the centre's inspector by 12 July 2017. The PR should review the centre's audit programme to ensure that it is compliant in the range of audits performed, the methodology used and the documentation of corrective and preventative actions and their implementation. The PR should provide the centre's inspector with a copy of the review and an action plan for the implementation of this recommendation by 12 July 2017. The PR should provide copies of the audits and SOPs identified in this	current SOPs and guidance documents (including patient information) are in place and accessible via Q Pulse. This will required extensive planning and team delegation. The plan for this will be formalised by the PR and submitted to the inspection team by 12 July 2017. Areas of audit that were not deemed broad enough will be expanded to be more comprehensive with an audit schedule confirmed and submitted to the inspection team by 12 july 2017. Audits and SOPs identified as non compliant at inspection will be reviewed and updated or completed by 12 October 2017. The transport centre at kingston Hospital was inspected in 2015 and the report is attached (Attachment 4.1). A further inspection is planned for 30 June 2017 the PR will submit an inspection repert by 12 July 2017.	**Progress update, 13 July 2017:** The PR has informed the centre's inspector that a full-time Quality Manager is to be employed to refine and improve the current quality management system. The manual witnessing audit has been submitted and the remaining audits and SOPs identified in this report are due to be submitted by 12 October 2017. Further action is required. **Progress update, 9 October 2017:** The PR has stated 'this is an ongoing issue that requires the appointment of a quality manager and design of a QMS. *This is something that will need to be addressed by the new management'.* The Executive is aware that a new Quality Manager is currently being appointed and that the development of the QMS remains a priority. The centre's inspector will remain in close contact with the new PR to ensure that Quality

regulatory requirements. The following was noted regarding the centre's SOPs: • some SOPs had passed their review dates without review. • some SOPs and patient information, for example 'embryos for use in training and research', contain regulatory requirements and other information which has been superseded, suggesting the audit of SOPs against the regulatory requirements is not effective; • SOPs to direct the use of embryos in training and research do not state the training activities that embryos can be used for, that embryos used in training must	report as non-compliant, by 12 October 2017.	The other transport centre at St Hellier Hospital now has it's own laboratory and we are currently seeing very few referrals from them, it is expected that this will stop completely in due course. The PR will arrange a visit to inspect the facilities and provide the inspector with a report of the findings by 12 October 2017.	Management System is fully compliant. Further action is required. **Progress update, 17 January 2018:** The PR has stated 'following a change of management and PR in November 2017, the new PR made the development of the QMS a priority. The PR and the centre's inspector have remained in close contact to ensure that the Quality Management System is fully compliant. Specifically: - A new quality manager (QM) and quality officer have been appointed. - Each area within the clinic has a nominated quality representative. - The new QM and PR have audited the previous QMS according to the HFEA's Guidance Note 23 and highlighted the areas for improvement. - As a result of the above audit, we have reviewed

not be used in treatment or to ensure there is no conflict of interest; • the SOP to direct vitrification and/or warming does not fully reflect practices observed during the inspection. SLC T32, T33b and T36.			the unit's pre-existing SOPs including those for performing audits and reporting incidents. Where required, the SOPs have been updated and new SOPs have been written. - We have amended the quality manual accordingly and we have reviewed our aims and objectives. - We have created a new audit calendar in keeping with the HFEA's Guidance Note 23. - Based on the above, we have already performed several audits in line with the new QMS. - Relevant staff have attended a course and/or workshop on quality management and implementation in an IVF unit. - We have procured a new licence for the updated version of the Q-Pulse software, which will be reinstalled in such a way as to incorporate the new QMS's disciplines of

			quality, safety and risk management to deliver compliance, anticipation of problems, and operating efficiency. - We are organising further training for the new version of Q-Pulse directly from the manufacturers. - We have a new clinic meeting structure and calendar, with attendances and minutes recorded, to ensure that all changes are implemented effectively. As a consequence, we feel that King's Fertility has progressed towards an effective Quality Management System to address this area of non-compliance. No further action is required.
5. Equipment and materials The centre was unable to provide documented evidence of the validation of the suction pump(s) used during egg collection.	The PR should ensure that all critical equipment is validated and that only CE marked medical devices are used. It is expected that validation of this item will	The equipment of note was a Cook aspiration pump used for TVOR. Service / calibration reports will be obtained from the Trust medical engineering department and filed electronically on the Q Pulse asset register log. In addition the	The Executive acknowledges the PR's response and awaits the validation documentation and confirmation of their intentions regarding CE marking by 12 July 2017. The PR is reminded of relevant CE marking guidance

SLC T24. The centre supplement CE marked culture media with CE marked human serum albumin for use when culturing vitrified embryos after they have been removed from storage. This is against the manufacturer's instructions and invalidates the CE mark of the media. SLC T30.	be complete by 12 July 2017. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this, the PR should identify a suitable CE marked alternative product by 12 July 2017. It is expected that all medical devices should be CE marked by 12 October 2017.	relevant SOPs will be amended to ensure pre use checks are performed, the equipment will be labelled to clearly indicate acceptable pressure range for use during TVOR (to safeguard against potential oocyte damage) and a validation report will be generated to demonstrate that the device is fit for purpose. This will comprise of retrospective KPI analysis as well as suggested prospective KPI analysis / service frequency. This will be summarised and submitted to the PR by 12 July 2017 and fowarded to the inspection team. With respect to off label use of G-TL culture medium for embryo culture post warming, a validation report will be generated to suppport this process. This will comprise of potential risks vs benefits and will be supported by media supplier information as well as KPI analysis relating to FET success rates prior to and post change to the Vit -warming SOP. A decision will be made as	issued in the September 2016 issue of Clinic Focus. Further action is required. **Progress update, 13 July 2017:** The PR has provided evidence that the suction pumps used for egg collected are validated and that the culture media is appropriately CE marked. No further action is required.

		to suspending supplementation of G-TL with additional serum, continuing the practice or sourcing an alternative CE product by 12 July 2017. The report and recommendations will be reviewed by the PR and submitted to the inspection team by 12 October 2017.	
6. Process validation The centre introduced a new culture procedure for warming vitrified embryos after they have been removed from storage, but this had not been validated or documented in a SOP. SLC T72.	The PR should ensure that this procedure is validated. It is expected that validation will be complete by 12 July 2017.	With respect to off label use of G-TL culture medium for embryo culture post warming, a validation report will be generated to suppport this process. This will comprise of potential risks vs benefits and will be supported by media supplier information as well as KPI analysis relating to FET success rates prior to and post change to the Vit -warming SOP. This validation will be completed and submitted to the PR and subsequently the inspection team by 12 July 2017.	The Executive acknowledges the PR's response and awaits the validation documentation to be submitted by 12 July 2017. Further action is required. **Progress update, 13 July 2017:** Confirmation that this process has been validated has been received. No further action is required.
7. Record keeping The centre does not maintain a record containing	The PR should ensure that the identity of a patient is reliably confirmed and documented.	An SOP will be created to confirm responsibilities and actions when confirming patient identity. This will include staff	The Executive acknowledges the PR's response and awaits a summary of the review by 12 July

how, and by whom, the patient/donor has been reliably identified. SLC T46b and T47.	The PR should undertake a review of the centre's processes for establishing the identity of patients. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 12 July 2017. Within three months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 12 October 2017.	responsible for this event as will as documnentation and record retention to ensure accessibiliyt to all staff who may be required to verifiy patient identitiy prior to, during and post treatment. Staff will be advised of the process and trained appropriately. A summary review and changes implemented will be provided by 12 July 2017. An audit of the of records will be compolted within three months to ensure that corrective actions are effective. Audit findings to be submitted by 12 October 2017.	2017 and a summary of the follow up audit by 12 October 2017. Further action is required. **Progress update, 13 July 2017:** The PR has provided a summary of the review of the centre's processes for establishing the identity of patients and corrective actions. A follow up audit is due by 12 October 2017. Further action is required. **Progress update, 9 October 2017:** The PR has provided the follow up audit. No further action is required.
8. Payment of HFEA fees The centre has a historic issue with the late payment of HFEA fees. Invoices over the last year have been paid on average of 54 days. The	The PR should take appropriate action to ensure that all HFEA invoices are paid within the timescales specified by the Authority.	We recognise that the trust has been slow in making these payments despite the PR's request efforts to speed up the process. The trust has assured me that payments will be made on time. As the PR I will	The Executive acknowledges the PR's response and commitment to ensuring that this area of non-compliance is fully addressed. The Executive will continue to monitor this issue closely.

HFEA payment terms is 28 days. This was an issue identified during the previous two inspections. SLC T09(d).	An action plan to address this should be sent to the centre's inspector when responding to this report.	continue to monitor this and and exert any influence I have.	Further action is required. **Progress update, 13 July 2017:** The centre will have new management in October 2017. The PR has confirmed that this new structure which will be effective from 2 October 2017, will allow payments to be made on time. The Executive will continue to monitor this issue closely. No further action is required.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
9. Safety and suitability of premises and facilities During the inspection, two members of staff were observed carrying a tray with liquid nitrogen without the use of personal protective equipment (for example safety goggles and gloves). CoP guidance 25.17.	The PR should ensure that staff are aware of health and safety requirements when using liquid nitrogen. The procedure used for the transfer of liquid nitrogen between laboratories must be reviewed and risk assessed and precautions put in place to minimise potential hazards to laboratory staff. A summary of this review including confirmation of staff training should be sent to the centre's inspector by 12 July 2017.	Laboratory staff have all been enrolled on a liquid nitrogen safety training course. Renewal date will be reviewed and the course will be repeated if necessary. Initial action proposed is to raise the importance of using appriate PPE at a team meeting and also to confirm suitable PPE is available and accessible. The lab manager will be reposnsible for monitoring compliance when decanting and moving LN2. If further non compliance is obsvered then remedial training and ultimatley disciplinary action may be taken. It will be sytressed that this is for individual as well as Trust protection.A summary of the review and actions taken will be provided by 12 July2017	The Executive acknowledges the PR's response and awaits a summary of the review by 12 July 2017. Further action is required. **Progress update, 13 July 2017:** The PR has confirmed that all staff are enrolled on a liquid nitrogen safety training course and all have been provided with the SOP for filling of liquid nitrogen dewars which includes safe use of liquid nitrogen. No further action is required.

10. Medicine management A review of the controlled drugs register identified that in at least three instances the amount of controlled drug administered had not been recorded. SLC T2, Misuse of Drugs Regulations 2001, Schedule 19(b).	The PR should ensure that the procedures for the management of medicines are compliant with all regulatory requirements and guidance. The PR should review the centre's procedures to ensure that the amount of controlled drug administered is recorded in the controlled drugs register A summary of the review should be sent to the centre's inspector by 12 July 2017. Within three months of having implemented any corrective actions, the centre should audit the record of administration of controlled drugs in the controlled drugs register to ensure that actions taken are effective. A summary of the report of the audit should be sent to the centre's inspector by 12 October 2017.	We will review our procedures for the management of medicines to ensure that that we are compliant with regulations and guidance. Once the review is complete we will implement corrective actions as required. A summary of the review findings an dcorrective action taken will be privided to the inspector by 12 July 2017. An audit will then be carried to ensure that the steps taken have resuilted in th erequired changes. A summary of the audit will be submitted by 12 October 2017	The Executive acknowledges the PR's response and awaits a summary of the review including corrective actions by 12 July 2017 and a summary of the follow up audit by 12 October 2017. Further action is required. **Progress update, 13 July 2017:** The PR has confirmed that the centre's controlled drug procedures have been reviewed, all staff have been provided with the King's College Hospital controlled drugs policy and this has been signed to confirm that they understand and will comply with this policy. A follow up audit is due by 12 October 2017. Further action is required. **Progress update, 9 October 2017:** The PR has provided the follow up audit.

			No further action is required.
11. Patient feedback The centre was unable to provide assurance of appropriate mechanisms to respond to and act upon patient feedback. SLC T32 and CoP guidance 23.17.	The PR should ensure there is an appropriate mechanism in place to review and act upon patient feedback. The PR should inform the centre's inspector of the actions taken to comply with this recommendation by 12 July 2017.	This has been highlighted internally. Although there is a Trust patient feedback mechanism, this is not highly visible to ACU staff or even patients. The intention is to generate a short but useful patient feedback questionnaire that will be distributed and collected regularly from patients in the waiting areas / post TVOR and post ET. The results will be collated and presented at QM meetings and team meeting as appropriate. A summary of the changes will be provided by 12 July.	The Executive acknowledges the PR's response and awaits a summary of the actions taken by 12 July 2017. **Progress update, 13 July 2017:** The PR has provided an updated feedback questionnaire. This will be given out to all patients following treatment. A large sign is also in reception advising patients where to deposit completed questionnaires. The results will be collated and presented at Quality Management and team meetings. No further action is required.
12. Website Success rates on the centre's website are not presented in accordance with HFEA guidance.	The PR should review the contents of the centre's website to ensure success rates are presented in accordance with guidance.	The success rates on the web site are out of date. We will provide corporate communications with more recent data so that the website can be amended. We aim for	The Executive acknowledges the PR's response and awaits confirmation that the website is compliant within four weeks. Further action is required.

Code of Practice, Guidance Note 4.5. This was also identified during the previous inspection.	The PR should audit the centre's website against the regulatory requirements and promptly arrange for any amendments required. The PR should inform the centre's inspector of actions that have been taken when responding to this report.	these changes to be completed within 4 weeks.	**Progress update, 13 July 2017:** The PR has confirmed that recent success rates have been provided to the King's College Hospital communications team to enable the website to be updated. A new website will be designed under the new ownership in October 2017. No further action is required.
13. Disclosure of information, held on the HFEA Register, for use in research Seven discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. CH(10)05 and General Direction 0005.	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register. The PR should correct the submissions that have been identified as being incorrect and confirm this has been completed when responding to this report. The PR should review the centre's procedures to ensure that the disclosure consent information supplied to the HFEA accurately reflects that	We have corrected the submissions that have been identified. The procedure for obtaining consent to disclosure has been reviewed and a summary of the findings and corrective actions taken will provided by 12 July. The leaflet entitled " How to fill WOC and CD forms" has been revised to give the patient /partner clearer information on how to complete these forms (attached). This instruction leaflet will be given to patients	The Executive acknowledges the PR's response and awaits the summary of the review by 12 July 2017 and a summary of the follow up audit by 12 October 2017. Further action is required. **Progress update, 13 July 2017:** The PR has confirmed that submissions that have been identified as being incorrect have now been corrected. A summary of the review of the centre's procedures to ensure that the disclosure consent

	given and recorded on patient's consent forms. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 12 July 2017. Within six months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 12 October 2017.	when they arrive for the first doctors visit. Patients will be asked to complete these forms and will have the oppurtunity to ask the doctor for any clarification. At this point the doctor will ensure that the forms have been completed correctly. An audit will be undertaken to ensure that the corrective actions taken are effective and the findings will be provided by 12 October 2017.	information supplied to the HFEA accurately reflects that given and recorded on patient's consent form has been submitted including corrective actions. A follow up audit is due by 12 October 2017. Further action is required. **Progress update, 9 October 2017:** The PR has provided the follow up audit. No further action is required.
14. Obligations and reporting requirements 26% (35/134) of the IVF and 34% (24/70) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005. General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the HFEA within the timeframe required by General Direction 0005. The PR should review the centre's procedures used to submit licensed treatment data to identify and address the reasons for poor quality submissions. A summary of the	The memebrs of staff involved in the submission of data met to review our processes. The following challenges were identified: 1. Delays in returning notes from the lab after completion of treatment sometimes means the admin staff are delayed in sumbitting data	The Executive acknowledges the PR's response and awaits a summary of the follow up audit by 12 October 2017. Further action is required. **Progress update, 13 July 2017:** The PR has confirmed that changes have been made to the process of submitting data

	findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector when responding to this report. Within six months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 12 October 2017.	2. Outcome data is sometimes late from transport centres. 3 Some staff were not aware of time frames for data submission. Corrective actions: The team has been reminded of the HFEA time frames as detailed in Direcion 0005. The laboratory staff have been advsied of the need to return notes to the admin team as soon as a treatment is completed. The Transport partners have been reminded of the need to communicate treatment outomes speedily. It is anticipated that this will improve the data entry and submission via EDI. This will be audited within 6 months and the results forwarded to the PR and inspection team.	to ensure that licensed treatment activity is reported within the required timeframe. A follow up audit is due by 12 October 2017. Further action is required. **Progress update, 9 October 2017:** The PR has provided the follow up audit. No further action is required.