Licence Committee - minutes

Centre 0327 (Boston Place)

Renewal Licence

Thursday, 2 May 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle Moya Berry Jennifer Rogerson Amanda Evans	Committee Secretary Committee Secretary (Observer) Research Manager (Staff Induction) Research Manager (Staff Induction)
Legal Adviser	Sarah Ellson	Fieldfisher LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

Papers enclosed:

- Executive update for 2 May 2019
- Executive Licensing Panel Minutes - 23 April 2019 – Special Directions
- Licence Committee Minutes - 7 March 2019 – Renewal Inspection
- Paper set for renewal application originally considered by the Licence Committee on 7 March 2019:
    - Executive update
    - Cover sheet
    - Renewal inspection report
    - Licence renewal application form
    - Email from PR confirming licence type applied for
    - Previous licensing minutes up to the last licence renewal:
        - Change of Person Responsible - 10 May 2018
        - Change of Licence Holder - 15 December 2017
        - Interim Inspection - 13 January 2017
        - Renewal Inspection - 27 February 2015

1. Background

1.1. Boston Place, centre 0327 is located in central London. The centre has held a licence with the HFEA since May 2013 and currently provides a full range of fertility services including embryo testing.

Licence Renewal

1.2. The centre's current licence was issued for a period of 4 years and is due to expire on 24 May 2019. A licence renewal inspection was carried out on 4 and 5 December 2018 and a number of non-compliances were identified including two critical, six major and nine 'other' areas of non-compliance. Due to the issues identified during the renewal inspection, the Executive held a management review meeting in accordance with the HFEA Compliance and Enforcement Policy on 20 December 2018, to evaluate the centre's performance and to decide a proportionate recommendation for the licence renewal application.

1.3. The Executive concluded that the non-compliances identified on inspection were significant and reflected direct and indirect risks to patients and to the centre's compliance with the HF&E Act 1990 (as amended) and other relevant legal requirements. As a result, the Executive considered recommending the renewal of the centre's treatment (including embryo testing) and storage licence for a period of three years, rather than the usual four, with a targeted interim inspection to be completed within one year of renewal.

1.4. A further meeting took place with the Person Responsible (PR) on 14 January 2019 to review the centre's action plans to address the non-compliances. The Executive considered that the proposed actions demonstrated the PR's commitment to attaining compliance and good governance and would thereby mitigate risks identified at the centre. The Executive planned to closely monitor the centre's performance. The PR had provided regular updates regarding corrective and preventative actions and has the support of the centre's Licence Holder, who is also the Chief Operating Officer for The Fertility Partnership group. Therefore, the Executive was assured that the PR will fully discharge his duties and strive to demonstrate better leadership.

Licence Committee Decision – 7 March 2019

1.5. The renewal inspection report was considered by the Licence Committee on 7 March 2019.

1.6. The Licence Committee had concerns about the number and nature of non-compliances identified at the renewal inspection. The committee noted that the Executive had considered adding a further non-compliance regarding poor leadership by the PR, but had decided that this was not necessary, given the level of engagement and commitment of the PR to ensure compliance at the centre since the inspection.

1.7. The committee acknowledged that the PR was engaging with the Executive and that since the renewal inspection the PR had committed to fully implementing all of the recommendations, providing evidence that actions have been taken, and where required, to audit the effectiveness of those actions within the set timescales.

1.8. The committee, on 7 March 2019, received an Executive update which confirmed that submissions were provided by the PR. However, they arrived outside of the set deadline, not allowing sufficient time for the Executive to review them in detail and make any further recommendations to the committee. Therefore, the committee agreed to adjourn its decision on the renewal of the centre's treatment (including embryo testing) and storage licence until the Executive had the opportunity to review, in detail, the evidence of progress in implementing the recommendations.

2. Consideration of application

Executive Update

2.1. The Executive has reviewed the submissions provided by the centre in detail. The committee noted the Executive update outlining the PR's progress on implementation of the recommendations to address two critical, six major and nine 'other' areas of non-compliance identified at the renewal inspection on 4 and 5 December 2018.

2.2. The committee noted that the PR has provided evidence that action has been taken to fully implement six major and nine 'other' areas of non-compliance. The PR has made a commitment to audit the effectiveness of changes within the required timescales. The inspectorate will continue to monitor the PR's progress.

2.3. Further actions remain to be completed in relation to the two critical areas of non-compliance.

Critical areas of non-compliance

Legal parenthood in surrogacy:

2.4. The committee noted that immediately after the inspection the PR suspended the provision of surrogacy treatments to new patients. The PR continues to provide treatment for surrogacy cases involving patients who had either stored gametes before January 2019 with intentions for use in surrogacy treatment, or patients who had already been seen at the centre before January 2019.

2.5. While the Executive remains concerned about the findings and corrective action taken in relation to consent forms following the centre's audit of consent to legal parenthood for surrogacy patients, it considers that there is no immediate risk to the safety of patients as the PR has provided his assurance that he is checking the documentation for all surrogacy cases currently taking place at the centre.

2.6. The committee noted that the inspectorate will focus on this area of practice at the next inspection.

Consent to storage:

2.7. An audit of samples received from another centre has been completed. The PR has confirmed that he has sought legal advice and is awaiting further legal guidance on further action to take.

2.8. The committee noted that the inspectorate will also focus on this area of practice at the next inspection.

Recommendation

2.9. The committee noted that the recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of three years remains the same.

2.10. However, given the findings on inspection and the concerns raised following the review of evidence provided by the PR since the time of the inspection, the Executive also made a further recommendation that the centre does not resume the provision of treatment for new surrogacy patients until such time that the Executive is satisfied that the centre's processes in this area of practice are robust. The PR should provide the Executive with evidence to demonstrate that the centre's processes for taking, checking and auditing consent to legal parenthood in surrogacy cases are robust, including staff training and competency assessments. It is also expected that the PR will address the Executive's concerns in relation to the centre's audit of surrogacy cases. The Executive will be able to confirm that it is safe and appropriate to resume the provision of surrogacy treatments once it is satisfied with the evidence of compliance provided by the PR.

2.11. The Executive also recommends that an interim inspection is completed within a year of the licence coming into effect, at which time the inspectorate will be able to evaluate the effectiveness of the changes that have been implemented since the time of the renewal inspection.

2.12. The centre's licence is due to expire on 24 May 2019, therefore, at the request of the Executive, the Executive Licensing Panel has issued Special Directions under Section 24 (5A) (b) of the HF&E Act 1990 (as amended), to permit the continuation of licensed activity, to allow time for completion of the licence administration process. These directions are to be in force from 25 May 2019 until 24 August 2019. The committee understands that if the licence is granted and accepted earlier than 24 August 2019, these directions will no longer be in force.

3. Decision

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

Administrative Requirements

Supporting Information under General Direction 0008

Application

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

Proposed Person responsible (PR) – Dr Antonios Vlismas

3.3. The committee was satisfied that the proposed PR possesses the required qualifications and experience and that the character of the proposed PR is such as is required for supervision of the licensed activities. It was further satisfied that the proposed PR will discharge his duties under section 17 of the HF&E Act 1990 (as amended).

Proposed Licence Holder (LH) – Ms Judith Fleming

3.4. The committee was satisfied that the proposed LH is suitable.

Activities

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

Premises – 16-20 Boston Place, London, NW1 6ER

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

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

Licence

3.8. The committee acknowledged that the PR is engaging with the Executive. The PR is making progress and has the support of the Licence Holder, who is also the Chief Operating Officer for The Fertility Partnership group. Mindful of the centre's licensing history, the committee carefully considered the duration of the licence it should offer with reference to the 'Guidance on licensing'. Weighing all factors in the balance, the committee agreed that a three-year licence, with no additional conditions, subject to the implementation of the recommendations outlined in the renewal inspection report, was appropriate.

3.9. The committee endorsed the inspectorate's recommendation that the centre does not resume the provision of treatment for new surrogacy patients until such time that the Executive is satisfied that the centre's processes in this area of practice are robust. The PR is to provide evidence of compliance.

3.10. The committee endorsed the inspectorate's recommendation to complete an interim inspection within a year of the licence coming into effect, to evaluate the effectiveness of the changes that have been implemented since the time of the renewal inspection. The committee noted that the Executive has concerns relating to legal parenthood in surrogacy and consent to storage at the centre and was pleased to see that the inspectorate will focus on these areas at the interim inspection. The committee also expressed grave concern about the non-compliance related to having available sufficient numbers of suitably trained staff, but were reassured that the Executive is expecting that action to address this will be completed by 5 June 2019.

3.11. The committee agreed that the inspectorate should continue to monitor the centre's performance and the implementation of the recommendations within the required timescales.

3.12. The committee agreed that the centre's future interim inspection report should be considered by the Licence Committee. The committee expect to see sustained improvement.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

9 May 2019

Executive Update for Licence Committee
2 May 2019

Centre number	0327
Centre name	Boston Place
Person Responsible	Dr Antonios Vlismas

Further update to progress report requested by Licence Committee

Background

1. Boston Place has held a treatment (including embryo testing) and storage licence with the HFEA since May 2013 and provides a full range of fertility services. The centre's current licence is due to expire on 24 May 2019.

2. The centre had a licence renewal inspection on 4 and 5 December 2018 and the report of that inspection was considered by Licence Committee on 7 March 2019.

3. The minutes of the Licence Committee meeting were provided on 5 April 2019 and recorded the committee's decision:

   '**3.4.** The committee agreed to adjourn its decision on the renewal of the centre's treatment (including embryo testing) and storage licence until the Executive has had the opportunity to review, in detail, the evidence of progress in implementing these recommendations and submitted a progress report to the Licence Committee.

   3.5. The committee requested an Executive update for consideration at the Licence Committee meeting scheduled in May 2019.'

4. This is the executive update requested by Licence Committee.

5. A summary of the PR's progress with implementing the recommendations in relation to two critical, six major and nine 'other' areas of non-compliance or poor practice identified during the inspection on 4 and 5 December 2018 is provided in the table below. These are noted in blue coloured text in the 'Executive Review' column under 'Progress update'.

6. The executive notes that further actions remain to be completed in relation to the two critical non-compliances identified at the time of the inspection.

   Legal parenthood in surrogacy:
   Immediately after the inspection the PR suspended the provision of surrogacy treatments to new patients and he has confirmed that this suspension remains in force. The centre continues to provide treatment to 'ongoing' surrogacy cases which are those patients who had either stored gametes before January 2019 with the intention to use these for surrogacy treatment, or that had already been seen at the centre before January 2019.
   As a result of the post-inspection monitoring carried out by the centre's inspector, the executive has become concerned about the findings and actions

taken following the centre's audit of consent to legal parenthood for surrogacy patients, as set out in the table below. The executive has made the PR aware of these concerns.
Whilst it remains concerned, the executive considers that there is no immediate risk to the safety of patients as the PR has provided his assurance that he is checking the documentation for all 'ongoing' surrogacy cases currently taking place at the centre.
This area of practice will be a focus of the centre's next inspection.

Consent to storage:
The centre has completed the audit of samples received from centre 0078 and the PR has confirmed that he has sought legal advice and is awaiting further legal guidance on further actions to take.
This area of practice will be a focus of the centre's next inspection.

7. The PR has provided evidence that actions have been taken to fully implement six major and nine 'other' areas of non-compliance or poor practice identified during the inspection. No further action is required in relation to nine areas of non-compliance and the PR has made a commitment to audit the effectiveness of changes made in relation to five areas of practice within the required timescales. Actions to be taken in relation to one 'other' area of non-compliance or poor practice is due by 5 May 2019. The centre's inspector will continue to monitor the PR's progress in fully implementing these actions.

8. The executive noted that the centre's licence is due to expire on 24 May 2019 and as this Licence Committee meeting is on 2 May 2019, there would not be enough time for the licensing administrative process to conclude prior to the expiry of the centre's licence. Therefore, the executive submitted a request that the Executive Licensing Panel issue Special Directions to the Person Responsible (PR) at centre 0327, under Section 24 (5A) (b) of the HF&E Act 1990 (as amended), to permit the continuation of licensed activity at the centre from 25 May 2019 to 24 August 2019. This is to be considered by Executive Licensing Panel on 23 April 2019 and a decision is awaited.

9. The executive confirms that there is no change to the recommendation made by the inspection team in the renewal inspection report - that the centre's treatment (with embryo testing) and storage licence is renewed for a period of three years. However, given the findings on inspection and the concerns raised following the review of evidence provided by the PR since the time of the inspection, the executive also seeks to make a further recommendation that the centre does not resume the provision of treatment for new surrogacy patients until such time that it is satisfied that the centre's processes in this area of practice are robust. The PR should provide the executive with evidence to demonstrate that the centre's processes for taking, checking and auditing consent to legal parenthood in surrogacy cases are robust, including staff training and competency assessments. It is also expected that the PR will address the executive's concerns in relation to the centre's audit of surrogacy cases. The executive will be able to confirm that it is safe and appropriate to resume the provision of surrogacy treatments once it is satisfied with the evidence of compliance provided by the PR.

10. The executive recommended that an interim inspection takes place within a year of the licence coming into effect, at which time the inspection team will be able to evaluate the effectiveness of the changes that have been implemented since the time of the renewal inspection.

11. The Licence Committee is invited to make findings in this regard.

Karen Conyers
Inspector

Critical area of non-compliance

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

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Legal parenthood in surrogacy A number of issues related to consent to legal parenthood in surrogacy were noted by the inspection team. These are described in the body of the report. Human Fertilisation and Embryology Act 2008.	The PR should ensure that proper consent to legal parenthood is obtained. The PR should provide a summary of immediate actions to be taken to ensure that proper consent to legal parenthood is obtained for all patients when responding to this report. The PR should review the centre's processes for taking consent to legal parenthood, in particular for surrogates and couples commissioning a surrogacy arrangement to consider why the issues	A full audit of all surrogacy cases since 2016 will be undertaken by 31st January 2019. This will then be reviewed by the PR and Grp Head of Quality to ensure that any remedial actions are appropiate and implemented. A summary report of the review findings, including remedial actions taken will be sent to our inspector by 5 March 2019. No new surrogacy patients are being accepted at Boston Place until the unified TFP surrogacy programme has been launched.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update on this issue to the centre's inspector. The PR has confirmed that no new surrogacy patients are currently being accepted at the centre. The PR has also confirmed that staff training was provided on 22 January 2019, that assessment of competencies

	identified during the inspection arose. A summary report of the findings of the review including corrective actions and timescales for implementation should be provided to the centre's inspector by 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 5 June 2019.	Our TFP Lawyer will provide direct training to the team on all areas of legal parenthood and surrogacy on 22nd Jan 2019, for which staff attendance records will be available. There are also current plans, at HR Group-level, to review and refresh staff competency reviews as part of their annual performance review/appraisal process. We are aiming to launch the on-line consenting programme by end of March. The on-line programme provides patients with informative videos of the treatment they are expected to consent to, clearly explains the processes and also ensures the patients understand what they are consenting to, before they have the opportunity to attend a nurse consultation in the clinic. A summary report of the review of the effectiveness of the changes introduced will be	has been undertaken for relevant staff, and that a full audit of surrogacy cases has been completed. A summary of the findings of this audit and the requested review of the centre's processes for taking consent to legal parenthood due by 5 March 2019 is awaited. An audit to evaluate the effectiveness of changes in this area of practice due by 5 June 2019 is awaited. **Further action is required**. **Progress update:** On 6 March 2019 the PR provided a summary of the findings of the centre's audit of all surrogacy cases undertaken between 2016 and 2018. The PR confirmed that legal advice would be sought in relation to cases where issues have been identified. On 20 March 2019, the PR informed the centre's inspector that the centre has

		sent to our inspector by 5 June 2019.	adopted the first stage of the group-wide review of surrogacy practices and that staff training on surrogacy would also be provided as part of this unified process On 2 April 2019, the PR provided further details on the findings of the centre's audit and confirmed that he 'continues to check all documentation for ongoing surrogacy cases'. The PR also confirmed that he has provided training to the nursing staff. The executive was concerned with some of the findings and corrective actions recorded in this audit report and contacted the PR on 10 April 2019 for further clarification. The PR replied to advise the centre's inspector that he was on leave and that he will respond fully on his return on 16 April 2019. An issue of concern to the executive was that in one case where there was an error in a

			legal parenthood consent form, the corrective action was to complete a new form. However, the executive noted that the surrogate is pregnant therefore any errors cannot be rectified by completing a new consent form retrospectively, i.e. after treatment. The PR was asked to clarify why this corrective action was considered appropriate, and on 16 April 2019 he confirmed that this corrective action documented in the audit was incorrect and should not have been recorded. Following further correspondence with the PR, on 17 April 2019 he advised the centre's inspector that a member of staff had informed the surrogate of the error in her consent form and had 'provided her with a copy of the paperwork to show her'. A few days later the surrogate returned the form to the centre. She had corrected the error and had initialled and dated the amendment but had

			backdated this to the date that she had originally signed the consent form. The PR states 'This was not under advice from the clinic.' The PR acknowledges that this amendment is not valid and that there remains an anomaly in the surrogate's legal parenthood consent form. He confirmed that he will be contacting the intended parents to inform them of this anomaly and to discuss the options available to them. It is expected that the PR will act in accordance with HFEA guidance in support of the couple affected by this anomaly in consent to legal parenthood. The centre's inspector will follow up progress with this action with the PR. The executive remains concerned that the surrogate amended the form and has advised the PR that he must investigate why this happened. The PR was also

			reminded that he must ensure that all staff are aware that these forms cannot be amended retrospectively. The centre's inspector will follow up progress with this action with the PR. In addition, the audit noted corrective actions in relation to granting of Parental Orders, that were made on the assumption that it is more than six months since the birth of the child therefore no further actions were deemed appropriate. The executive is concerned about the appropriateness of the corrective action recorded ('no further action') based on such an assumption. The executive would have expected that the patients had been contacted to confirm there were no issues in the granting their Parental Orders, and sought confirmation of this from the PR. On 17 April 2019 the PR informed the centre's

			inspector that they have now confirmed that two of the couples have been granted their Parental Orders and that he will continue to try to contact the other two couples. The PR also assured the centre's inspector that if these couples have had issues with the granting of their Parental Orders he will seek legal advice and support them in finding a resolution. Again it is expected that the PR will act in accordance with HFEA guidance in support of the couple(s) if necessary. The centre's inspector will follow up progress with this action with the PR. A report of the centre's audit of the surrogacy cases carried out since January 2019 should be provided by 5 June 2019. **Further action is required**. **The centre's inspector will continue to monitor the PR's progress in fully**

			implementing this recommendation.
2. Consent to storage A number of non-compliances in relation to the storage of cryopreserved samples were noted on inspection, as discussed in detail in the body of the report. These are related to: the apparent storage of gametes and embryos without consent; inadequate audit of records related to stored material; inadequate understanding amongst relevant staff of the regulations and requirements governing statutory storage periods and their extension; inadequate actions to address non-conformances in the storage records; inadequate records of storage consent and of decisions related to the discard of material at the end of storage. The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991.	The PR should ensure that there is effective written consent in place for all stored gametes and embryos. The PR should undertake a systematic and detailed audit of the storage consent forms in place for all stored samples received from centre 0078, to clarify what anomalies or issues there are in relation to the consent to storage of all these samples. This audit should also review the accuracy of the records (e.g. storage consent expiry dates) held within the centre's database which is used to manage the 'bring forward' system. The PR should ensure that relevant staff are provided with training in the regulations and requirements governing gamete and embryo statutory storage periods and their	A new audit has been designed to fully audit all stored samples and their relevant consents. The audit is designed to check all items from the original clinic records through to the computerised version in Boston Place. Full training on what to check and the importance of each of the points will be provided and signed-off prior to commencing. We plan to use support form our sister clinics to provide the resources to ensure this can be completed accurately and thoroughly within a reasonable time period. The "standard" bring-forward system is being refined with input from our Group, and use of the Patient Portal should help to simplify the process for the clinic and also help patients.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update on this issue to the centre's inspector. The PR has confirmed that a new methodology for the audit of stored samples has been designed and approved, and that full training has been provided to the staff who are performing the audit. The findings of this audit of storage consent forms in place for all stored samples received from centre 0078 to clarify what anomalies or issues there are in relation to the consent to storage of all these samples due by 5 March 2019 is awaited.

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. SLCs T12, SLCT36, SLC T79, SLC T80, SLC T81 and SLC T82. Chief Executive's letter CE(16)02.	extension, prior to undertaking this audit. This should ensure that all anomalies in storage consent are correctly identified by the audit, but also that the bring forward system and extension of storage consent are, in future, carried out in a compliant manner. When responding to this report the PR should provide the centre's inspector with a plan, with timelines, by which this staff training, and the storage consent audit will be completed. To allow a robust audit to be undertaken, it is expected that all actions will be completed by 5 March 2019 rather than immediately. A summary report of the audit, including corrective and preventative actions and timelines for their implementation, should be provided to the centre's inspector by 5 March 2019. The PR should ensure that once a stored sample has been identified as requiring	The Cryo-storage Administrator (reporting to the Patient Support Manager) will be responsible for ensuring that letters regarding storage are sent out in a timely manner, and that every effort is made to contact patients in advance. The Lab Manager will be responsible for ensuring the tank contents and the records are compliant, and discards are undertaken in a timely manner. Destruction records will be monitored to ensure they are being done within reasonable timeframes to ensure that storage remains lawful. The timeline will be: - training provided to auditors from 17th January - audit will begin from 18th January and will be completed by 5th March.	The PR has also confirmed that the cryo-storage administrator has been re-trained on his responsibilities relating to the 'bring forward' system and that processes to manage the timely discard of material at the end of storage have been implemented. The findings of the PR's review of both the centre's 'bring forward' system and the centre's procedures for auditing cryopreserved materials, to determine why they did not prevent the significant non-compliances detailed in this inspection report due by 5 March 2019 is awaited. An audit to evaluate the effectiveness of changes in this area of practice due by 5 June 2019 is awaited. **Further action is required**. **Progress update:** The PR has provided the findings of the audit of stored

	discard, this action is undertaken in a timely manner. A summary of changes made to implement this recommendation should be provided to the centre's inspector by 5 March 2019. The PR is reminded of HFEA guidance in relation to the timely disposal of cryopreserved material (see Chair's letter CH(03)03). The PR should review both the centre's 'bring forward' system and the centre's procedures for auditing cryopreserved materials, to determine why they did not prevent the significant non-compliances detailed in this inspection report. Summary reports of the findings of both reviews, including corrective actions with timescales for their implementation, should be provided to the centre's inspector by 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of		gametes and embryos received from centre 0078. The auditors reviewed the records of all 700 patients whose samples remained in storage at the centre since the time they were received from centre 0078 in 2017. The centre reports that 64 issues affecting 25 sets of gametes, 22 sets of embryos and one set of gametes stored prior to 1991 were identified. This affects 47 patients. The PR confirmed he has sought legal advice and is awaiting further legal guidance on further actions to take. In addition, the PR has also commenced a further audit of consent forms for samples either stored at his centre (0327) or that were imported from clinics other than 0078. The findings of the PR's review of both the centre's 'bring forward' system and the centre's procedures for auditing cryopreserved materials has also been

	practice within three months of their introduction. A summary report of the findings of the audit should be provided to the centre's inspector by 5 June 2019.		provided. The PR confirmed that the centre has already implemented a number of changes to practices in the bring-forward system and auditing of stored materials such as; ensuring that all anomalies are brought to the attention of the PR or lead embryologist in his absence, that samples reaching their 10 year storage limit must be reviewed 12 months prior to expiry, and improvements to the way the data is handled so that expiry dates can be checked more easily. A report of the centre's audit to evaluate the effectiveness of these changes due by 5 June 2019 is awaited **Further action is required**. **The centre's inspector will continue to monitor the PR's progress in fully implementing this recommendation.**

Major area of non-compliance

A major area of non-compliance is a non-critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several 'other' areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

A major area of non-compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
3. Medicines management A number of issues with medicines management practices and the centre's audit of controlled drugs were noted by the inspection team. These are described in the body of the report. SLC T2. 'Controlled Drugs in Perioperative Care' 2006. NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'	The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice guidance. The PR should review medicines management practice including, but not exclusively, the issues identified in this report. This review should also include staff training requirements. A summary report of the findings of the review including corrective actions and	Since 9th January the Theatre Lead is responsible for ensuring that any page changes are correctly noted and the requirement has been added to the Daily Theatre Task Checklist. Anaesthetists will continue to be reminded of the need to record all use of controlled drugs in the patient record and the Theatre Lead is now required to check this is completed after every case.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of the findings of his review of medicines management practices including corrective actions and timescales for implementation. An audit to evaluate the effectiveness of changes in

DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' CoP Guidance 25.23	timescales for implementation should be provided to the centre's inspector by 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 5 June 2019.	This item is on the Daily Theatre Checklist and is also a required field in the patient management database. The Nurse Manager has reviewed the relevant SOP and has made the changes as listed above. The centre's QM has created an audit plan for 2019, for the follow-up and timelines for corrective actions. Audit compliance, and remedial actions will be reviewed as a standing agenda item at the clinic's monthy Quality Meeting, which is attended by the PR and Group Head of Quality. A summary report of the above will be sent to our inspector by 5 June 2019.	this area of practice due by 5 June 2019 is awaited. **Further action is required**. **Progress update** Actions are not yet due therefore there is nothing further to update. A report of the centre's audit to evaluate the effectiveness of these changes due by 5 June 2019 is awaited. **Further action is required**. **The centre's inspector will continue to monitor the PR's progress in fully implementing this recommendation.**
4. Third party agreements The following issues were noted with regard to the centre's third party agreements: • The centre's most recent agreement with	The PR should ensure written agreements with all third parties who provide goods or services that influence the quality and safety of gametes	The genetic testing TPA is in place and compliant with regul atory requirements. Due to the company ownership changing they have had some name	The executive acknowledges the PR's response. The executive notes that a third party agreement with the genetic testing laboratory was

'InVitro Genetics Ltd.' the laboratory that undertakes genetic testing, expired in April 2018, and a current version was not seen in the centre's records. Typographical errors in the expired document had not been identified by centre staff. • The centre did not have an up-to-date agreement on file with the company that removes and destroys their confidential waste. SLC T114.	and embryos are compliant with requirements. The PR should provide an updated third party agreement with the service provider identified and confirm this has been completed when responding to the report. The PR should establish an agreement with the company that removes and destroys their confidential waste and confirm the actions taken to address this when responding to the report.	changes, but a compliant and correct TPA was in place. A current customer agreement for confidential waste is in place. We have been receiving weekly certificates of destruction each time confidential waste is removed from the premises. However, we have further enhanced the wording in our agreement in relation to waste security and confidentiality in particular, which is the provider's specialist area, and are awaiting a signed response from the provider.	in place at the time of the inspection but had not been provided to the inspectors therefore this was noted as a non-compliance. This has now been provided. The PR has confirmed that an agreement with the company that removes and destroys their confidential waste is now in place. **No further action is required.** **No further action was required.**
5. Satellite agreements The centre's agreement in relation to satellite activities carried out at Spire Hospitals was not compliant with General Direction 0010. The centre has not evaluated the ability of their satellite services to meet the required standards.	The PR should ensure that written agreements with satellite services are compliant with requirements and that the satellite activities are audited against the specifications detailed in the satellite agreements.	An updated Satellite Agreement has been provided to Spire Hospitals, who have been very attentive and plan to return the final copy by 18/01/19. The final agreement will be provided to the HFEA as soon as it is available.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The finalised written agreement for the satellite services undertaken at Spire Hospitals has been provided.

General Direction 0010 paragraph 2 and SLC T112.	The finalised written agreement for the satellite service should be provided to the centre's inspector when responding to this report. The PR should undertake an audit of all the centre's satellite activities to assess compliance with General Direction 0010. A summary report of this audit should be provided to the centre's inspector by 5 March 2019.	The satellite audit will be undertaken in February 2019, the report will be provided to the inspector on completion, within the required timescale.	The audit of satellite activities due by 5 March 2019 is awaited. **Further action is required.** **Progress update** A summary report of the findings of the audit of the centre's satellite activities was provided. **No further action is required.**
6. Staff The inspection team had a number of concerns in relation to nursing and clinical staffing, as described in the body of the report. HF&E Act 1990 (as amended), SLC T12, SLC T15 and CoP Guidance 2.11	The PR should ensure that staff are available in sufficient number and are suitably trained and assessed as competent to undertake their roles. The PR should review the centre's process for staff induction, assessment of competency and re-assessment of competencies. The review should include, but not be limited to, consideration of the issues identified by the	We review our staffing levels on a regular basis and compare the requirements and staff levels with the 9 other clinics in our Group to ensure that they are appropriate. Being part of a Group also provides the protection of providing each other with staff cover during any sickness or jury service requirements. Boston Place also has 3 nurses available and trained	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of the findings of his review and the plans in place to ensure that staff are available in sufficient number and are suitably trained and assessed as competent to undertake their roles.

	inspection team. A summary report of the findings of the review including corrective actions and timescales for implementation should be provided to the centre's inspector by 5 March 2019. It is expected that any corrective actions identified will have been implemented by 5 June 2019 and the PR should provide confirmation of this to the centre's inspector by 5 June 2019.	on a bank nurse schedule, which we feel is sufficient. Some additional training is being provided to reinforce the training that has already been provided. We have provided evidence of the induction training we provide, and hope it reassures the inspectors that a full and robust induction is followed. The General Manager will work with the group HR team to ensure that the annual appraisal process includes re-assessment of competencies.	The PR should provide the centre's inspector with updates on progress with implementing these actions which are expected to be completed by 5 June 2019. **Further action is required.** **Progress update** On 5 March 2019 the PR provided a summary of the changes to be implemented, including training, competency assessments and external training. On 20 March 2019 the PR confirmed that these actions had all been completed. **No further action is required.**
7. Welfare of the child A number of issues related to the welfare of the child assessments were noted by the inspection team and are described in the body of the report. These related to ensuring that such an	The PR should ensure that a woman is not provided with treatment services unless account has been taken of the welfare of the child.	All staff will be provided with WoC training from our TFP Lawyer on 22nd January 2019. A new process will be used: WoC (& CD) consent forms	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update

assessment is completed prior to provision of treatment services and that competencies of staff undertaking these activities has been evaluated. HF&E Act 1990 (as amended), SLC T56 and CoP Guidance 14.1.	The PR should provide a summary of immediate actions to be taken to address the issues identified during the inspection when responding to this report. The PR should review welfare of the child practices and processes including, but not limited to, the issues identified in this report. A summary report of the findings of the review including corrective actions and timescales for implementation should be provided to the centre's inspector by 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 5 June 2019.	will be completed prior to initial consultation, allowing for doctors to review the paperwork at the initial consultation. A nursing Post-consenting Checklist will ensure that all the consent forms have been signed and countersigned correctly prior to issuing a prescription. This will ensure that all assessments are completed prior to the provision of treatment. The new SOP which details the new process will be provided to the inspector by 5th March 2019.	on this issue to the centre's inspector. The PR has provided a summary of the immediate actions taken to address the issues identified during the inspection including training in welfare of the child assessments completed on 22 January 2019. The PR has also confirmed that all relevant staff are aware of the new processes in place for reviewing and checking these assessments prior to provision of treatment. The findings of the PR's review of welfare of the child practices and processes including, but not limited to, the issues identified in this report, due by 5 March 2019 is awaited. An audit to evaluate the effectiveness of changes in this area of practice due by 5 June 2019 is awaited. **Further action is required**.

			Progress update The findings of the PR's review of the centre's review of welfare of the child practices and processes has been provided. The centre has implemented actions to ensure that these assessments are completed and reviewed before treatment is provided. A report of the centre's audit to evaluate the effectiveness of these changes due by 5 June 2019 is awaited. **Further action is required**. **The centre's inspector will continue to monitor the PR's progress in fully implementing this recommendation.**
8. Counselling A number of issues related to the offer and provision of counselling, and the auditing of this critical activity were noted by the inspection team.	The PR should ensure that patients and donors are provided with a suitable opportunity to receive proper counselling and that this offer is documented.	Regarding proof of offering of counselling: A tick box has been added to the patient management system to record the clinician offer and recommendation for	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the

These are described in the body of the report. HF&E Act 1990 (as amended), Schedule 3, paragraph 3(1)(a), SLC T35 and SLC T36.	The PR should provide a summary of immediate actions to be taken to address the issues identified during the inspection when responding to this report. The PR should review the centre's practices for offering patients and donors a suitable opportunity to receive counselling and what actions are to be taken to address the issues identified during the inspection. A summary report of the findings of the review including corrective actions and timescales for implementation should be provided to the centre's inspector by 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of practice within three months. A summary report of the findings of the audit should be provided to the centre's inspector by 5 June 2019.	counselling (at intial consultation). A Checklist has been introduced for the patients to complete and sign to ensure that they know and understand the importance of the counselling that is offered/provided. Regarding the timing of implications counselling: The SOP has been re-written to insist that counselling should be offered and delivered prior to patients consenting to treatment. An audit of patients using donor gametes during the last 12 months will be undertaken to check the timing of counselling appointments. The report and corrective actions will be provided to the inspector by 5th March 2019. This audit will be repeated after 2 months of its implementation, to measure the effectiveness and compliance of the changes	requested fortnightly update on this issue to the centre's inspector. The PR has provided a summary of the immediate actions taken to address the issues identified during the inspection including the implementation of additional record keeping and checking processes. The findings of the PR's review of centre's practices for offering patients and donors a suitable opportunity to receive counselling including, but not limited to, the issues identified in this report, due by 5 March 2019 is awaited. The PR reports that an audit of the records of patients who have used donor gametes is underway and an update will be provided to the centre's inspector on 15 February 2019. Following further discussion, the PR has confirmed that this audit will also include gamete donors. A

		made. The updated report will be provided to the inspector by 5th June 2019.	summary report of the findings of the audit should be provided to the centre's inspector by 5 March 2019. An audit to evaluate the effectiveness of changes in this area of practice due by 5 June 2019 is awaited. **Further action is required**. **Progress update:** The findings of the PR's review of the centre's review of practices for offering patients and donors a suitable opportunity to receive counselling has been provided. The centre has implemented the corrective actions identified to ensure that all patients and donors are offered counselling and that this offer is documented. A report of the centre's audit to evaluate the effectiveness of these changes due by 5 June 2019 is awaited. **Further action is required**.

			The centre's inspector will continue to monitor the PR's progress in fully implementing this recommendation.

Other areas of practice that requires improvement

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

An 'other' area of non-compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
9. Safety and suitability of premises and facilities The centre's cryostore room has an alarm to alert staff when the oxygen levels decrease below a safe limit. Although this alarm sounds immediately outside of the cryostore this room is located in a quiet area of the clinic, on a separate floor, and the inspection team was concerned that if a member of staff is working alone in this room no-one else would be aware of an alarm triggered by low oxygen and would not be able to assist. In one of the consultation and scan rooms, there was a privacy screen, but because of the position of the bed, when a	The PR should ensure that the centre's facilities are suitable for patients and staff. The PR should ensure that the cryostore is sufficiently alarmed so that any potential risks to staff working in this area are minimised. The PR should provide a summary of the actions taken to address this finding when responding to the report. The PR should review the usage of the consulting room discussed during the inspection to consider what actions can be taken to ensure that the patients privacy and dignity are	The SOP states that entry is not permitted into the Cryostore room when working alone to remove any risk. However a quote has been approved to add an alarm repeater into the main admin office and its installation is now being organised. The privacy screen will be replaced by a curtain rail attached to the ceiling rails, which will reduce the floor space requirements. We would like to reinforce that in addition to the door entry system requiring a staff pass to enter the room, there is also a manual lock on the door	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of actions taken to minimise the risks to staff using the cryostore and to ensure that the patients privacy and dignity are maintained. The executive is assured that these actions will be completed by 5 March 2019. **No further action is required.**

patient is being scanned there is no space to position the screen to protect the patient's privacy and dignity from anyone entering the room. SLC T17 and CoP 25.9.	maintained at all times. A summary of the actions to be taken should be provided to the centre's inspector by 5 March 2019.	which is used when a patient is being scanned so that it is not possible for anyone to enter the room during a scan. Immediately after the inspections we also provided photographic evidence to the inspector of "vacant/engaged" signs that have been put onto each door. We will update the inspector when the other changes are made, this will be before 5th March.	**No further action was required.**
10. Infection control The seal that closes the join between the flooring and the wall was detached from the wall along a significant length in both men's sample production rooms. SLC T17 and DH Health Building Note 00- 09: 'Infection control in the built environment' 2013.	The PR should ensure that all clinical areas of the centre meet the requirements of infection prevention and control regulations. The PR should ensure repairs to the faulty seal are carried out and provide confirmation that this has been completed when responding to this report.	The flooring issue was fixed in the week of the inspection. Photos showing the repairs have been provided to the inspector with this report. The remaining clinic areas have been checked for this issue. There will be weekly "environment checks" by each department.	The executive acknowledges the PR's response. The PR has confirmed that the flooring has been repaired. **No further action is required.** **No further action was required.**

11. QMS A number of issues related to the centre's QMS were noted and are described in the body of the report. These related to the centre's quality indicators, a lack of robustness of some audits of critical activities, and inconsistent recording of audit findings and corrective and preventative actions taken in response to issues identified. SLC T32, SLC T35 and SLC T36.	The PR should ensure that the centre's QMS and auditing processes are effective in identifying and implementing appropriate corrective actions in response to audit findings. The PR should ensure that the all quality indicators are reviewed so that they are appropriate to the relevant critical activity and that suitable audits of compliance with regulatory requirements can be performed. A revised list of quality indicators should be provided to the centre's inspector by 5 March 2019. The PR should review the centre's auditing methodology to ensure that all audits evaluate compliance with the regulatory requirements, the centre's approved protocols and quality indicators, that findings are recorded consistently, and that any corrective and preventative actions identified are documented and fully	The entire audit process is currently under revision across the Group. The audit schedule is being made much more robust; mandatory audits of each of the licensed activities and processes will be scheduled more frequently e.g. biannually. As part of this review Group audit and action plan templates will be rolled out for all clinics to use in 2019. The clinic's 2019 audit plan has already been drafted, and is due for approval at the Quality Meeting due to be held 24th January, 2019. Audit is also a standing agenda item at this meeting. Implementation and progress with the plan will be followed up by the Group Head of Quality. TFP have already implemented regular (monthly/bi-monthly) QM meetings, with a standing agenda which includes follow	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. The PR has provided a summary of the review of the QMS that is taking place as part of a wider project reviewing the system across the entire across the 'The Fertility Partnership' group. A further update on progress with these changes together with a revised list of quality indicators due by 5 March 2019 is awaited. **Further action is required.** **Progress update** The PR has provided the requested updates and revised list of quality indicators. **No further action is required.**

	implemented. A summary report of the review including corrective actions and the timescale for implementation of corrective actions should be provided to the centre's inspector by 5 March 2019.	up of quality items e.g. incidents, audits etc, and all clinics also hold regular meetings, where these quality matters are discussed as standing agenda items. The group audit reporting and action plan templates will form part of the revised audit process which all TFP clinics will follow this year.	
12. Equipment The inspection team noted that the fridge used to store drugs is subject to temperature monitoring but there is no record of the acceptable temperature parameters. The temperatures are not monitored out of working hours and there are no processes in place to note out-of-range values or initiate action if the temperature is not within the specified range. On the second day of inspection, centre staff informed the inspection team that the fridge was now connected to the centre's	The PR should ensure that all critical equipment is subject to ongoing monitoring. The drugs fridge has now been connected to the centre's equipment monitoring systems. The PR should review the centre's processes for recording and monitoring the temperature of the drugs fridge to ensure that acceptable ranges are established, and staff are aware of the actions to be taken if any out-of-range values are noted.	As noted the fridge is now not only monitored out of hours, but is also has a "dial-out" alarm system. The SOP will be updated to detail the required actions if there are issues with the fridge temperature. This will be completed by 5th March.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Confirmation that the relevant SOP has been updated by 5 March 2019 is awaited. **Further action is required.** **Progress update** The PR provided the requested confirmation. **No further action is required.**

systems for monitoring critical equipment. SLC T24.	The PR should confirm that this recommendation has been implemented by 5 March 2019.		
13. Safeguarding The inspection team was concerned that there could be a risk that effective safeguarding processes are not in place at the centre for the reasons set out in the body of the report. CoP Guidance 25.33(a) and 25.35. This non-compliance has been graded as 'other' because although the inspection team considers there is a risk that robust safeguarding practices are not in place, there is no evidence that there has been a failure in these processes.	The PR should ensure that appropriate safeguarding processes are in place. The PR should ensure that staff are fully aware of their roles and responsibilities in relation to safeguarding practices and should provide a summary of immediate actions to be taken to address the issues identified during the inspection when responding to this report. The PR should review the centre's processes for implementing safeguarding practices including staff training in this area to address the issues identified during the inspection. A summary report of the findings of the review including corrective actions and timescales for implementation should be	We can confirm that Safeguarding training has been completed but the course has a different name and we believe the differing terminology has caused some confusion. However to be certain, we are providing additional training and checking that all staff are aware of the required actions if they have any concerns. A summary of the training outcomes will be provided to the inspector by 5th March.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update on this issue to the centre's inspector. The PR has provided a summary of his review of the centre's processes in this area of practice and that additional 'Safeguarding' training is due to take place on 4 March 2019. **No further action is required.** **No further action was required.**

	provided to the centre's inspector by 5 March 2019.		
14. Website The centre's website is not compliant with guidance as it does not provide live birth rates, nor does it provide a like-for-like comparison to national outcomes. CoP 4.12.	The PR should take appropriate action to ensure that the centre's website is compliant with requirements. The PR should ensure that the centre's website is compliant with requirements when responding to this report.	The website has been corrected to include live birth data (compared to national average) as well as the pregnancy rates.	The executive acknowledges the PR's response. The centre's website 'success rate' information has been updated. **No further action is required.** **No further action was required.**
15. Disclosure of information, held on the HFEA Register, for use in research Two discrepancies were found between completed patient/partner disclosure consents in 10 patient files audited and the related consent data submitted for inclusion on the register. Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of	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 confirm that the incorrect submissions identified have been corrected	The clinic will audit 20% of the cycles from 2018. Any inaccuracies identified will be corrected and if more than 5% of cases have issues then the remaining 80% of cases will be audited. In addition to historical audit, we will conduct a weekly audit of submissions (2 cases per	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update on this issue to the centre's inspector.

consents to disclosure to researchers. The inspection team noted that in one case the discrepancy could pose a risk that the HFEA may inadvertently release patient identifying information to researchers against the patient's wishes. The other error was not one that could pose such a risk. Chair's Letter (10)05 and General Direction 0005. *NB. The Centre's designated HFEA form returnee has been provided with the relevant patient and partner numbers so that the incorrect data can be reviewed and corrected.*	when responding to this report. The PR should review the centre's systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the Authority accurately reflects that given and recorded on completed disclosure 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 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of practice within six months. A summary report of the findings of the audit should be provided to the centre's inspector by 5 September 2019.	week) to ensure that live data entry is correct. If any discrepancies are noted, then all cases that week will be checked. This audit will run until 100% compliance is noted for 6 weeks in a row, then we will revert to the annual audit. These audit reports will be provided in the timescales requested.	The PR has confirmed that the incorrect submissions identified have been corrected. The executive notes that an audit of 20% of treatments from 2018 has been completed and errors of 5.88% were noted and corrected. As a result, all remaining cycles from 2018 are now being audited. In addition, the PR reports that a weekly audit of records was completed and subsequently all records for January 2019 were checked (73 cases). A total of 17 errors were noted and these are being corrected. The PR has confirmed that this weekly audit will continue until 100% compliance for 6 consecutive weeks is noted. Given the number of discrepancies identified, the PR should ensure that a thorough review of the centre's systems and processes for recording and

			submitting patient and partner disclosure of consent information to the Authority is undertaken to establish why there are so many errors. It is expected that this review will include a root cause analysis. A summary of the findings of the review due by 5 March 2019 is awaited. An audit to evaluate the effectiveness of changes in this area of practice due by 5 September 2019 is awaited. **Further action is required**. **Progress update** The PR provided a copy of his review of centre's systems and processes for recording and submitting patient and partner disclosure of consent information to the Authority and the requested root cause analysis. The centre has implemented actions to ensure that these submissions are accurate. The actions taken include recruitment of an additional staff member,

			developing new processes, providing training, and completing competency assessments. A report of the centre's audit to evaluate the effectiveness of these changes due by 5 September 2019 is awaited. **Further action is required**. **The centre's inspector will continue to monitor the PR's progress in fully implementing this recommendation.**
16. Document control The inspection team noted that a number of documents were past their review date. The centre's quality manager was aware of this and had plans in place to address it, however due to the number of documents out of date the inspection team considered that further action was needed to address this issue. SLC T34.	The PR should ensure that the centre's document control procedures are effective. The PR should review the documents that are past their review date and provide an action plan with a timescale by which the documents can be reviewed when responding to this report.	The Group Head of Quality will work with the clinic Quality Manager to ensure that there is a schedule in place to ensure that all out of date documents are reviewed and that the future process ensures timely review.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. Confirmation that all documents are up to date by 5 May 2019 is awaited. **Further action is required.** **Progress update**

	It is expected that all documents will be up to date by 5 May 2019.		Actions are not yet due therefore there is nothing further to update. Confirmation that all documents are up to date by 5 May 2019 is awaited. **Further action is required**. **The centre's inspector will continue to monitor the PR's progress in fully implementing this recommendation.**
17. Obligations and reporting requirements The DI data provided by the clinic for our audit was incomplete (i.e. it recorded significantly less DI treatments during the sample period than recorded on the register as having taken place at the clinic). 3% (4/135) of the IVF and 24% (5/21) of the DI treatments reviewed post inspection had not been reported to the HFEA in	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005. The PR should review the systems and processes used for licensed treatment data submission to identify and address the reasons for non-reporting and delayed submissions. A summary of the findings of the review including corrective actions	Weekly review of submissions started by 14th January. Updated SOP to ensure that DI forms are submitted by the embryologist that thaws the straw (on the day of the thaw). We will have an automatic weekly report from the patient database to ensure that all required reports are submitted and the timescales are being met.	The executive acknowledges the PR's response and his commitment to fully implementing this recommendation. In addition, the PR has provided the requested fortnightly update on this issue to the centre's inspector. The PR has provided a summary of the findings of his review into this area of practice, and the corrective actions in place to address the

accordance with General Direction 0005. 91% (119/131) of the IVF but only 31% (5/16) of the DI treatments reported had been reported to the HFEA within the 10 working days period required by General Direction 0005. General Direction 0005 and SLC T41. *NB. The Centre's designated HFEA form returnee has been provided with the relevant patient and partner numbers so that the incorrect data can be reviewed and corrected.*	and the timescales for implementation should be provided to the centre's inspector by 5 March 2019. The PR should audit the effectiveness of changes introduced in this area of practice within six months. A summary report of the findings of the audit should be provided to the centre's inspector by 5 September 2019.	The follow-up audit and report will be sent to the inspector by 5th September 2019.	issues identified which includes weekly checks of submitted data. An audit to evaluate the effectiveness of changes in this area of practice due by 5 September 2019 is awaited. **Further action is required**. **Progress update** Actions are not yet due therefore there is nothing further to update. A report of the centre's audit to evaluate the effectiveness of these changes due by 5 September 2019 is awaited. **Further action is required**. **The centre's inspector will continue to monitor the PR's progress in fully implementing this recommendation.**