Executive Licensing Panel - minutes

Centre 0070 (The Bridge Centre) Renewal Inspection Report - Update

Friday, 9 September 2016

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Paula Robinson (Chair) David Moysen Jessica Watkin	Head of Business Planning Head of IT Policy Manager
Members of the Executive	Dee Knoyle Ian Brown	Secretary Head of Corporate Governance
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 Bridge Centre, centre 0070 submitted two applications, one to vary the current treatment (including embryo testing) and storage licence to reflect a variation of licensed premises and the other to renew the licence. Both applications were considered by the Executive Licensing Panel on 12 August 2016. The panel approved the application for a variation of the centre's licensed premises, however the panel adjourned its decision to renew the centre's treatment and storage licence, in order to allow time to receive further information on the centre's progress in implementing the inspectorate's recommendations made in the renewal report.

1.2. The panel requested that the Executive provide a progress report for consideration by the Executive Licensing Panel in October 2016, once the deadline had passed for the centre to implement the recommendations made in the renewal inspection report.

1.3. The centre's current licence for treatment (including embryo testing) and storage expires on 30 September 2016. The panel recognised that the centre may need Special Directions to be issued on expiry of their current licence in order to continue licensed activities during the regulatory/licensing process and asked the Executive to consider an appropriate time to submit such an application to a licensing committee if necessary.

1.4. Further to this, the Executive has requested that the panel considers updates provided by the centre, in place of a later progress report, at this meeting.

2. Consideration of application

2.1. The panel considered the papers, which included a completed application form, inspection report, executive update, correspondence from the Person Responsible (PR) and licensing minutes for the last three years.

2.2. The panel noted that, after considering the PR's letter, other communications and evidence received since the Executive Licensing Panel meeting held on 12 August 2016, the inspectorate confirms that all recommendations have now been fully implemented with the following exceptions:

Storage Consent

2.3. The centre has gametes and embryos from a large number of patients in storage. An effective bring forward system will prevent samples being stored beyond their consented storage period and the PR has committed to work with the Executive to achieve this. The PR has committed to sending quarterly reports regarding samples stored without consent so that the Executive can continue to assess the effectiveness of the bring forward system.

2.4. The panel also noted that the PR had stated that no embryos were in store beyond their consented storage period in his response to the inspection report; however the PR had also stated in his update letter that two patients have embryos in this situation. This suggests a further failure of the centre's bring forward system has recently occurred. The inspectorate will consider whether further regulatory action is now necessary in accordance with the Compliance and Enforcement Policy.

2.5. The panel noted that the PR had reported that four patients have sperm samples stored beyond their consented storage period and that these patients have been contacted by the centre. At the time the report was considered by the Executive Licensing Panel on 12 August 2016, seven such patients were present. The inspectorate is therefore satisfied that progress is being made.

Register data reporting

2.6. The panel noted that the first outstanding action in relation to this recommendation was for the PR to provide an audit, due in October 2016, to evidence that corrective actions have prevented further errors occurring. However, reportable treatments have not taken place since the inspection and therefore such an audit is not possible by October 2016. In light of this practical obstacle, the inspectorate has requested that the audit be delayed until three months after the centre resumes reportable activities.

2.7. The second outstanding action relates to an unreported donor from 1994/95. The PR has confirmed that the centre will continue to work with the HFEA's register team to identify and correct this error. The inspectorate is satisfied that this observation does not represent a systemic failure, and considering when the treatment occurred, does not reflect the centre's current ability to comply with reporting requirements. The PR ran a register data validation report on 17 August 2016, and this demonstrated that there are no outstanding historical reporting or errors in the centre's current register data set.

2.8. The panel noted that reportable activity is no longer carried out or reported by centre 0070.

2.9. The panel noted that the inspectorate recommended the renewal of the centre's licence for a period of four years, to a treatment and storage licence with one additional condition.

3. Decision

3.1. The panel noted the inspection report, executive summary and letters from the PR in response to the inspectorate's update on the status of the implementation of the recommendations made in the renewal report.

3.2. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

3.3. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

3.4. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

3.5. The panel noted that all recommendations were completed with two exceptions relating to storage consent and Register data reporting.

3.6. The panel agreed that due to the PR's findings of further embryos in storage beyond their consented storage period, the inspectorate should consider whether further regulatory actions are now required in line with the Compliance and Enforcement Policy. However, the panel was pleased to see that the inspectorate will continue to work with the PR to ensure the outstanding recommendation in relation to storage consent is resolved and that the PR has committed to sending quarterly reports regarding samples stored without consent so that the inspectorate can continue to assess the effectiveness of the bring forward system.

3.7. The panel was encouraged to see that the PR will continue to work with HFEA's register team to identify the unreported donor from 1994/95 and make the necessary corrections.

3.8. The panel spent some time discussing the length of licence to be granted, due to the centre's history of non-compliance. However, on consideration of the new information provided by the PR and the extent to which further appropriate and timely action had been taken since the last

Executive Licensing Panel meeting, when the centre's renewal was first considered, the panel agreed, on balance, to grant a licence for four years.

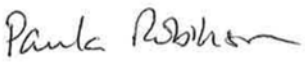
3.9. The panel noted that a treatment (without embryo testing) and storage licence includes all the activities which the PR has applied for, as well as some that are not included in the application. The panel noted that the HFEA does not provide a bespoke treatment and storage licence to fit the centre's desired activities. Therefore the panel agreed to grant the centre a standard treatment and storage licence, subject to the remaining recommendations made in the report being implemented within the prescribed timescales, with an additional licence condition to restrict the activities not applied for. The condition will state that the centre is not permitted to carry out the following activities which would otherwise be included in a standard licence:

- creation of embryos in vitro
- procuring embryos
- keeping embryos
- processing embryos
- placing any permitted embryo in a woman
- using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques.

4. Chair's signature

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

Signature



Name

Paula Robinson

Date

16 September 2016

Executive summary for Executive Licensing Panel 9 September 2016

Centre number	0070
Centre name	The Bridge Centre
Person Responsible	Dr Kamal Ahuja

Executive update regarding an application to renew a Treatment and Storage Licence

Background

1. On 12 August 2016, the Executive Licensing Panel (ELP) considered applications from centre 0070 to renew their licence for treatment and storage, and to vary their premises.

2. The ELP approved the application to vary the licensed premises.

3. The ELP adjourned its decision to renew the centre's licence, stating: '**2.10.** In light of the above, the panel agreed to adjourn its decision to grant a renewal licence in order to allow time to receive further information on the centre's progress in implementing the inspectorate's recommendations. The panel requested that the Executive provide a progress report to the Executive Licensing Panel at a meeting in October 2016, when the deadline has passed for the centre to implement all of the dated recommendations in the inspection report, or on completion of the recommendations, whichever is sooner. **2.11.** The panel recognised that the centre may need Special Directions to be issued on expiry of their current licence in order to continue licensed activities during the regulatory/licensing process. The Executive will consider an appropriate time to submit such an application to a licensing committee if needed.'

4. Minutes of the meeting were sent to the PR on 26 August 2016. The PR responded with a letter, included in the papers, detailing the centre's current status regarding the implementation of the inspectorate's recommendations.

5. The centre's current licence for treatment (including embryo testing) and storage (L0070/19/e) expires on 30 September 2016. The centre's licence will therefore expire before a progress report can be presented to the ELP in October 2016. The inspectorate therefore request the ELP consider the following update in place of the progress report due in October.

Progress report:

6. After considering the PR's letter, and other communications and evidence received since the ELP on 12 August 2016, the inspectorate can confirm that all recommendations have been fully implemented, except the following two:

Recommendation 1 – Critical – Storage Consent:

7. The PR states in his update: 'At the present time at the Bridge Centre there are two patients with embryos in storage that are out of their consent date.

We are in dialogue with the patients and waiting completed consent forms. We also have four patients with sperm samples out of their consented period. The patients have been contacted and I anticipate resolution within the month. As requested, 3 monthly reports will be provided to you until you are satisfied that our bring forward system is managed effectively. The next full report I believe is due in October.'

8. The PR has committed to send quarterly reports regarding samples stored without consent so that the inspectorate can continue to assess the effectiveness of the bring forward system.

9. The inspection team notes that in his response to the inspection report the PR had stated that no embryos were in store beyond their consented storage period, whereas the PR's update letter states that two patients have embryos in this situation. This suggests a further failure of the centre's bring forward system has recently occurred. This is of concern to the inspectorate and the centre's inspector will consider whether further regulatory action is now necessary in accordance with the Compliance and Enforcement Policy.

10. The PR reports that four patients have sperm samples stored beyond their consented storage period and that these patients have been contacted by the centre. At the time the report was considered by the ELP on 12 August 2016, seven such patients were present. The inspectorate is satisfied that progress is being made.

11. The inspection team notes that the centre has gametes and embryos from a large number of patients in storage. An effective bring forward system will prevent samples being stored beyond their consented storage period and the PR has committed to work with the Executive to achieve this.

Recommendation 8 – 'Other' – Register data reporting:

12. The PR states in his update: 'Register reporting data: This is due in October 2016. However, as discussed at the inspection reportable activity is no longer carried out or reported from the Bridge Centre. A validation report run from the clinic on 17th August 2016 showed no outstanding historical reporting's or errors. Of course we will continue to research the outstanding donor report from 20 years ago (1995) and we look forward to your continued support.'

13. The first outstanding action in relation to this recommendation is for the PR to provide an audit due in October 2016 to evidence that corrective actions have prevented further errors occurring. However, reportable treatments have not been provided since the inspection and therefore, such an audit is not possible by October 2016. Therefore, the inspectorate will request the audit is delayed until three months after the centre resume reportable activities.

14. The second outstanding action relates to an unreported donor from 1994/95. The PR continues to work with HFEA's register team to identify and correct this error. The inspectorate is satisfied that this observation

does not represent a systemic failure, and considering when the treatment occurred, does not reflect the centre's current ability to comply with reporting requirements. Furthermore, the PR has run a register data validation report which shows no errors in the centre's current register data set.

Summary:

15. In summary, the PR has fully implemented all but two recommendations.

16. The centre's inspector will continue to work with the PR to ensure the outstanding recommendation in relation to storage consent is resolved. In response to the PR's findings of further embryos in storage beyond their consented storage period, the inspectorate will consider whether further regulatory actions are now required in line with the Compliance and Enforcement Policy.

17. In consideration of the HFEA's Guide to Licensing, the inspectorate notes that there is a history of non compliance, particularly in relation to storage consent. The inspectorate is however satisfied that the PR is taking appropriate and timely action in relation to the non-compliances identified and that he has given a commitment to implement all the required recommendations in relation to critical and major non compliances.

18. The inspectorate therefore considers a recommendation to renew the centre's licence for a period of four years remains appropriate.

Recommendation:

19. The inspection team notes that the centre's licence expires on 30 September 2016 and recommends that the ELP reviews the letter from the PR and this executive summary, and considers them as the update requested by the ELP on 12 August 2016.

20. The inspection team recommends that the ELP consider whether they have sufficient information to renew the centre's licence for a period of four years, as recommended in the inspection report.

21. If the ELP decide they do not yet have sufficient information, the inspection team recommends that Special Directions are issued under Section 24 (5A) (b) of the HF&E Act 1990 (as amended) to permit the continuation of the centre's current treatment (including embryo testing) and storage licence from 1 October 2016 until 1 January 2017.

22. The inspection team asks that the reasons for the decision taken are provided clearly in the minutes and that the ELP also considers responding to the concerns outlined in the PR's letter.

Janet Kirkland MacHattie
HFEA inspector

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's applications for a renewal of its licence and a variation to its existing premises. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 12 and 13 April 2016

Purpose of inspection: Renewal of a licence to carry out treatment and storage and variation to existing premises.

The centre has applied to reduce the licensed activities: To those necessary to carry out insemination with partner or donor sperm, and sperm and embryo storage

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Janet Kirkland, Grace Lyndon, Andrew Leonard, Neil McComb

Date of Executive Licensing Panel: 12 August 2016

Centre details:

Centre name	The Bridge Centre
Centre number	0070
Licence number	L/0070/19/d
Centre address	1, St Thomas Street, London Bridge, London, SE1 9RY, United Kingdom
Person Responsible (PR)	Dr Kamal Ahuja
Licence Holder (LH)	Dr Kamal Ahuja
Date licence issued	1 October 2012
Licence expiry date	30 September 2016
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

The Bridge Centre is located in central London and currently holds a treatment and storage (with embryo testing) licence. The centre has been licensed by the HFEA since 1992.

Until January 2015 the centre provided a full range of fertility services including embryo testing. The centre also provided a UK based egg sharing programme, offering treatment using donated eggs, and was the primary centre for a large network of satellite and transport centres.

An interim inspection of the centre was performed in April 2014. Recommendations were made to address one critical, one major and three 'other' non compliances. These were addressed by the centre to the satisfaction of the Executive.

An additional inspection visit was performed by a joint HFEA/CQC inspection team in August 2014 to investigate medicines management practices at the centre. The report made recommendations to address three critical, five major and two 'other' areas of non compliance or poor practice. These recommendations were implemented by the centre to the satisfaction of the Executive. A progress report was considered by Licence Committee in March 2015: all issues have been addressed.

From January 2015, egg collections and treatments with fresh gametes and embryos were suspended at the centre. Frozen embryo transfers continued until April 2015, after which all licensed activity was suspended except for the storage of gametes and embryos already in store. Stored gametes and embryos are transferred to the London's Women's Clinic (centre 0105) if required for use in treatment. The suspension of licensed treatment activities was because the ownership of the centre changed and the new owner planned to renovate the premises and develop the service, focusing on recruiting sperm donors, providing insemination treatment with donor or partner sperm, and on storing gametes and embryos. The centre will not be carrying out IVF, ICSI or embryo testing treatment in future.

The centre has continued to function as a satellite to centre 0105 during the activity suspension, patients being prepared at centre 0070 for treatment - including ultrasound monitoring of their ovarian stimulation - before transferring to centre 0105 for egg collection, the laboratory processing of their gametes and embryos, and embryo transfer.

The current licence has been varied to reflect:

- A change of LH from Paul Williams to Dr Kamal Ahuja was approved by the ELP in November 2012.
- A change of Person Responsible (PR) from Alan Thornhill to Janine Elson was approved by the ELP in March 2013
- A change of PR from Janine Elson to Dr Kamal Ahuja was approved by the ELP in October 2014.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data confirm that the centre was inactive after April 2015, and activity before this was negligible. The centre's success rates therefore cannot be reported.

In 2015, the centre reported no cycles of partner insemination.

Multiple births[2]

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

The centre has been inactive since April 2015 and had only performed frozen embryo transfers between January and April 2015. A statistically valid multiple pregnancy rate cannot therefore be provided.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision:

The PR has applied to renew the centre's licence using a 'new Treatment (IUI/DI) Licence' application form. The PR has confirmed that the centre will not be performing all activities authorised by their current 'treatment (with embryo testing) and storage' licence. However the centre will be undertaking embryo storage and distribution, i.e. activities not included on an IUI/DI licence, and has stated as such in the additional information area of the application form. For reasons discussed below, the inspection team suggests that this application is considered by the ELP as an application to renew the centre's licence as a 'Treatment and Storage' licence.

The PR has also submitted an application to vary the existing licensed premises, reflecting the changes resulting from the renovation activities.

This report has considered the centre's compliance with regards to both applications and it is suggested that the ELP consider both applications together, given the interaction between the premises and the licensed activities undertaken.

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

- the applications are submitted in the form required;
- the applications have designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the applications contain the supporting information required by General Direction 0008, in application for renewal of their licence and to vary the existing licensed premises;

- the centre has paid the application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one critical, three major and four 'other' areas of non-compliance which have resulted in the following recommendations:

Since the inspection visit the PR has confirmed that the following recommendations have been fully implemented.

Major areas of non compliance:

- The PR should immediately ensure that screening tests are carried out by laboratories which are appropriately accredited.
- The PR should ensure that the centre's premises support the maintenance of patient privacy and confidentiality and are safe to use. The PR should also ensure the resuscitation trolley contents and the frequency of checking the trolley are as required by the Resuscitation Council guidelines.

'Other' areas that requires improvement:

- The PR should ensure that all staff are provided with refresher training, including in the areas of consent taking, legal parenthood and needle stick injury, at an appropriate frequency.
- The PR should ensure staff, where required, are registered with an appropriate professional body.
- The PR should ensure the process to direct the response to a clinical emergency is documented.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Since the inspection visit the PR has given a commitment to fully implementing all remaining actions relating to the following recommendations in the prescribed timescales:

Critical areas of non compliance:

- **The PR should ensure that gametes and embryos are stored within the terms of the consents provided by the gamete providers.**

Major areas of non compliance:

- The PR should ensure that the floor and furnishings within the ultrasound and main phlebotomy rooms are suitable from an infection control perspective.

Recommendation to the Executive Licensing Panel:

The centre has one critical area of concern and three major areas of concern.

Improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided. The inspector will continue to monitor the centre's performance to ensure recommendations are implemented.

The inspection team recommends the approval of the centre's application to vary its licensed premises.

The inspection team recommends the renewal of the centre's licence for a period of four years subject to the recommendations made in this report being implemented within the stated timescales.

The ELP will need to consider what licence type best suits the range of activities applied for by the PR, these being;

- procuring gametes
- keeping gametes
- processing gametes
- using gametes
- distributing gametes
- storage of gametes
- storage of embryos
- distributing embryos

It is the Executive's understanding that HFEA licence templates cannot be varied to reflect a bespoke range of activities. The ELP should be mindful that whilst a HFEA 'Treatment (inseminating using partner/donor sperm) and Storage' licence covers most activities applied for, it does not allow the storage and distribution of embryos.

The Executive suggests therefore that a 'Treatment and Storage' licence could be issued (without embryo testing), which includes all the activities which the PR has applied, as well as some relating to embryos not included in the application. In which case, the ELP could consider the application of an additional licence condition preventing such activities which are not required from being undertaken, these being: Creation of embryos in vitro; Procuring embryos; Keeping embryos; Processing embryos; Placing any permitted embryo in a woman; Using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques.

Section 2: Inspection findings

The inspection focus

This inspection focussed on centre 0070's compliance, or likely future compliance, with requirements relevant to the proposed activities after licence renewal, these being: procuring gametes; keeping gametes; processing gametes; using gametes; storage of gametes; distributing embryos and storage of embryos. Other activities besides these, related to the provision of a full IVF/ICSI service with embryo testing, were not reviewed. Such activities are currently licensed, but they have not been undertaken for 12 months or more, will not be undertaken in future after licence renewal, and are not included in the application form as proposed activities. As such they were considered irrelevant to the renewal of the licence and so were not reviewed.

The premises have been changed significantly since the suspension of treatments and this inspection also focussed on the suitability of the modified premises for the proposed activities. A summary of the modifications made to the premises and their suitability are described in the 'premises' section of this report.

Activities undertaken in relation to the centre's satellite service with centre 0105 were reviewed at this inspection where they were relevant to the activities to be undertaken in future under the licence at centre 0070.

The inspection findings

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

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

1. Protection of the patient and children born following treatment

▶ **Witnessing and assuring patient and donor identification**
What the centre does well **Witnessing (Guidance note 18)** The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.
What the centre could do better Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment. Therefore it is important that centres use donated gametes from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

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

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre has undergone considerable renovation since the suspension of activities in April 2015. These changes are the subject of a licence variation application to be considered with the renewal application. These changes comprise:

- The basement has been upgraded with patient comfort facilities and plans are underway to convert the operating theatre, which is currently being used for storage.
- The ground floor has received a complete make-over of the entrance and reception/waiting area so that it is now a functional and patient friendly environment.
- On the first floor, the embryology laboratory has been closed and a dedicated andrology laboratory, consulting rooms and upgraded production rooms for gamete donors have been commissioned.
- On the second floor, the space has been reorganised to create a comfortable and dedicated waiting area adjacent to an enlarged nurses' office and scanning room.
- The third floor has been upgraded and cleared to produce offices for administrative staff, a meeting room and a staff room.
- Systems have also been upgraded, for example telephony, air-conditioning, electric circuits, the lift and the IT system.

Confirmation that the refurbished premises are safe and suitable, including confirmation of a fire safety inspection and refurbishment completion certification/sign off, has been provided to the executive, with one exception noted below. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are partially compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable. The centre no longer operates any transport services.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, are partially compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are partially compliant with guidance.

Medicines management
The proposed activities after renewal will not require the use of controlled drugs. The centre has arrangements in place for obtaining, recording, handling, using, keeping,

dispensing, administering and disposing of medicines that are compliant with guidance.

Pre-operative assessment and the surgical pathway
The proposed activities after renewal will not require egg collections or other operative procedures. The procedure room is currently used for storage and recovery area has been converted into office space. Requirements related to pre-operative assessment and the surgical pathway were therefore not reviewed at this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre will be providing only insemination treatments, but such treatments still expose patients to the risks of multiple pregnancies and births. The single biggest risk of fertility treatment is a multiple pregnancy and birth. Thus it is important for centres providing such treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

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

- document the justification for the use of the patient's gametes in treatment, based on the patient's medical history and therapeutic indications;
- if sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

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

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

Receipt of gametes (Guidance note15)
The centre's procedures for the receipt of gametes are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes from other centres if the gametes are appropriately labelled and have enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

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

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These

requirements are important to ensure that the centre has the ability:

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

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre provides a satellite service to London Women's Clinic (centre 0105) and has no transport centres.

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

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
The inspection team was concerned that the ground floor consulting rooms had walls and doors through which conversations could be heard, which represented a risk to patient privacy and confidentiality (SLC T43). These rooms are part of the original centre and are due for renovation. The premises have also not been risk assessed since renovation (SLC T17). See recommendation 2.

The resuscitation trolley did not contain a mobile suction generator and the checks of the trolley contents were not performed at the frequency specified by the centre (Resuscitation Council guidelines; SLCs T2 and T17). See recommendation 2.

Laboratory accreditation (Guidance note 25)
See 'screening of patients' in section 3: The safety of gametes and embryos, and also recommendation 3.

Infection control
The floor and furnishings in the ultrasound and main phlebotomy rooms were not suitable from an infection control perspective (SLC T17). See recommendation 4.

Quality management system (QMS) (Guidance note 23)
There is no SOP to direct the response to a clinical emergency at the centre (SLC T33b). See recommendation 5.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements. The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (T/1043/7).

Staff (Guidance note 2)
The centre is broadly compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner, within the UK, to advise on and oversee medical activities respectively.

What the centre could do better

Staff (Guidance note 2)
Evidence could not be provided that nursing staff have had recent training regarding consenting and legal parenthood. Nursing staff were also inconsistent in their descriptions of the actions to be taken in the event of a needle stick injury, suggesting that training in this area is necessary (SLC T12 and T15a). See recommendation 6.

The proposed individual who will be responsible for the andrology laboratory is not registered with the Health and Care Professions Council (HCPC) (SLC T14). See recommendation 7.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before treatment is provided, the welfare of any child who may be born as a result of licensed treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well
The centre will not be providing embryo testing services in future and the activity of embryo testing is not included in the application as an activity to be licensed. Therefore requirements related to embryo testing were not considered at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

On the day of the inspection no patients agreed to speak with the inspection team regarding their experience at the centre. In the period 15 January -14 April 2016, the HFEA received feedback from five patients: three stated that they had compliments about the centre and four that they had complaints.

What the centre could do better

The HFEA receives a higher than normal number of complaints regarding this centre, with eight being received in 2015. The centre also reported that they had received 20 complaints since January 2015. The complaints relate to the satellite and storage activities, and to the embryo transfer activities undertaken up until April 2015. The complaints were discussed with the quality manager. She confirmed that the centre team are concerned regarding this level of dissatisfaction and are actively seeking to address it, however they have not identified a consistent theme.

The renovation of the centre and the reduction in licensed activities is recognised by the centre as an opportunity to focus on patient satisfaction. Due to the changes to the centre's activities and premises, the centre's continued concern and focus on patient satisfaction, and the actions taken, the inspection team considered a recommendation in this area was not necessary. The centre team are strongly encouraged to keep patient satisfaction under constant review.

Treating patients fairly

Counselling
Sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

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

- care is taken when selecting sperm providers donating for benefits in kind;
- sperm providers are fully assessed and medically suitable, and;
- the benefit offered is the most suitable for the sperm provider and recipient(s) (where relevant).

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

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

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

Information

What the centre does well
The centre's procedures for providing information to patients and donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

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

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit indicated that six couples may have been affected by legal parenthood consent anomalies.

As the impact of legal parenthood consent failures came to light, the HFEA wrote again to centres in October 2015 requiring that, by 17 November 2015, PRs should provide the HFEA with assurance that their initial audit process was comprehensive and that the centre's processes for staff training and ongoing audit of consent to legal parenthood processes are robust. The PR did not respond to this request within the required timescales, however in a subsequent meeting and by letter, the Executive was provided with the assurances required about the quality of the original audit and staff training, albeit licensed activity at the centre was suspended so on-going audit was not relevant at centre 0070. The number of couples affected increased to eight due to the inclusion of two couples whose parenthood consent forms were anomalous in small details only, which had originally been considered to have little impact.

At this inspection, the PR and quality manager explained that each partner has been sent a registered letter outlining the problems associated with their parenthood consent, its potential consequences, and the support available from the centre including free counselling and independent legal advice. Patients have also been provided with dedicated telephone line and email points of contact to the centre. Corrective actions to address the anomalous parenthood consents are on-going and the centre continues to support the patients affected.

The PR of centre 0105, where satellite patients at centre 0070 receive licensed treatment, was present on inspection. She confirmed that prior to treatment, she personally checks every patient's record for effective and accurate records of consent to legal parenthood from the patient and partner, where required. Refresher training for staff with regards to legal parenthood was provided soon after inspection from an external expert.

The inspection team are assured that legal parenthood consenting process will be robust when licensed activity recommences under the licence at centre 0070.

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

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

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre will no longer create embryos during treatment, but it does have embryos in storage which will remain at the centre for some time. These embryos will not be used to provide treatment at the centre but may be transported to other centres, e.g. centre 0105, for use in treatment.

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities:

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

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

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are partially compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre should only store gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Screening of patients (Guidance note 17)
A review of patient records and discussions with staff showed that in some cases the centre has not assessed whether screening tests were carried out by a laboratory which had suitable accreditation (SLC T50). In addition, blood samples for screening of

individuals providing gametes for partner treatment are not always obtained within three months of the gametes first being provided (SLC T51). See recommendation 3.

Storage of gametes and embryos (Guidance note 17)
On the day of the inspection the centre did not have written effective consent for the storage of gametes from 22 providers and embryos from six patient couples (HF&E Act 1990 as amended, Schedule 3, 8(1) (2)). See recommendation 1.

Use of embryos for training staff

What the centre does well
The centre will no longer create embryos for treatment, but embryos are maintained in storage which will remain at the centre for some time. These embryos will not be used to provide treatment at the centre, nor will they be used in training staff. Therefore requirements related to the use of embryos in training were not considered further at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
1% (1/96) of the IVF treatments reviewed at inspection had not been reported to the HFEA. At the time of the visit there was one treatment using an unregistered donor (SLC T41; General Direction 0005). See recommendation 8.

Section 3: Monitoring of the centre's performance

An interim inspection of the centre was performed in April 2014. Recommendations were made to address one critical, one major and three 'other' non compliances. These were addressed by the centre to the satisfaction of the Executive. However it is noted that one of the non compliances described in this report has reoccurred (recommendation 1). Storage of gametes and embryos beyond their consented period has been a non compliance at every inspection since at least 2010.

An additional inspection visit was performed by a joint HFEA/CQC inspection team in August 2014 to investigate medicines management practices at the centre. The report made recommendations to address three critical, five major and two 'other' areas of non compliance or poor practice. These recommendations were implemented by the centre to the satisfaction of the Executive. A progress report was considered by Licence Committee on 12 March 2015: all issues have been addressed.

On-going monitoring of centre success rates

In 2015 the centre did not receive any performance related alerts.

Areas of practice requiring action

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

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Storage consent On the day of the inspection the centre did not have written effective consent for the storage of gametes from 22 providers and embryos from six patient couples (HF&E Act 1990 as amended, Schedule 3, 8(1)(2)). **This has been a non compliance**	The PR should ensure that gametes and embryos are stored within the terms of the consents provided by the gamete providers. The PR should provide the HFEA with an update on the number of patients for whom gametes and embryos remain in store without effective consent by the time this report is considered by a licensing committee. At the same time, the PR should provide plans, with timelines, detailing the actions to be taken to resolve unlawful gamete and embryo storage. The PR should thereafter provide monthly updates to the HFEA on progress in implementing the proposed actions.	All embryos stored at the Bridge Centre are within the consented storage period. (1st June 2016) The bring forward system has identified sperm samples from 12 patients out of the consent period as of 1st of June 2016. These are being processed through the bring forward system. We anticiapte that this will be completed by the end of July 2016 The PR has reviewed the	The Executive acknowledges the PR's response however noted the discrepancy between the numbers of samples without effective consent noted on inspection and those detailed in the inspection response Following further communication with the centre the Executive has received clarification from the centre regarding the samples: • embryos for the six couples have been removed from storage;

at previous inspections.	The PR should review the bring-forward system and procedures for auditing stored gametes and embryos to ensure they are effective. Summary reports of both reviews, including corrective actions with timescales for implementation, should be submitted to the HFEA by 13 July 2016. Within three months of the implementation of corrective actions, the centre should conduct an audit of consent to storage and a summary report of the findings of the audit should be provided to the HFEA. The PR is reminded of the guidance 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 disposal.	bring-forward system and procedures for auditing gametes and embryos. Improvements are included in Section 6 of the Bridge Centre Laboratory Manual. The PR will provide a further report by the 13th of July 2016.	• of the 22 sets of sperm samples 15 have been removed from storage; discarded; • the centre team are awaiting the return of consent forms from the remaining seven sets of sperm. The inspector is satisfied with the response and requests an update regarding the seven sets of sperm which remain in storage pending the return of the consent forms. In consideration of the recurrence of this non compliance the PR should provide the Executive with an update every three months of gametes and embryos which are in storage beyond their consented storage period. This should continue until the Executive is satisfied that the centre's bring forward system is being managed effectively. Further action required.

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Premises and facilities The inspection team was concerned that the ground floor consulting rooms had walls and doors through which conversations could be heard (SLC T43). The premises have also not been risk assessed since renovation (SLC T17). The resuscitation trolley did not contain a mobile suction generator	The PR should ensure that the centre's premises support the maintenance of patient privacy and confidentiality and are safe to use. The PR should assess the confidentiality of the consulting room area and should take appropriate action to protect patient privacy and confidentiality. A summary of the assessment, with appropriate corrective actions and implementation timelines, should be submitted to the HFEA with the response to this report. Actions should be implemented by 13 October 2016 and the HFEA advised. The PR should ensure that the premises are risk assessed and that any risks identified are effectively controlled so the premises are safe to use. A list of	A risk assessment of the confidentiality of the consulting rooms area has been carried out and will be supplied to the HFEA along with this response. The PR has put in place an action plan for corrective actions. Actions will be implimented by the 13th of October and the HFEA advised. Risk assessments from the building contractors are in place and will be provided on request by the inspection	The Executive acknowledges the PR's response and receipt of the risk assessment of the confidentiality of the consulting room area and the corrective actions implemented. On the 12 July 2016 the centre's inspector received the additional risk assessment regarding the hazards to patients and staff in addition to a list of related risk assessments. The inspector has received evidence of documentation of weekly checks of the resuscitation trolley and its contents

(SLCs T12, T17 and the Resuscitation Council (UK) 2013 Quality Standards Section 3) and the checks of the trolley contents were not performed at the frequency designated by the centre (Resuscitation Council (UK) 2013 Quality Standards 2 (8)).	the risk assessments performed should be provided by 13 July 2016. A sample will then be requested by the inspection team to ensure they are robust. The PR should ensure the resuscitation trolley contents and the frequency of checking the contents of the trolley are functional and/or within date, are as required by the Resuscitation Council guidelines. The actions taken to implement this recommendation should be notified to the HFEA by 13 July 2016.	team. The PR has reviewed the resusitation trolley contents and the required frequency for checking the equipment. All medications are in date and will be checked weekly.The PR will provide a further report by the 13th July 2016.	No further action.
3. Patient screening In some cases the centre has not assessed whether screening tests were carried out by a laboratory which has suitable accreditation (SLC T50). Blood samples for screening of individuals providing gametes for partner treatment are not obtained within three	The PR should immediately ensure that screening tests are carried out by laboratories which are appropriately accredited. The PR should advise the HFEA of the actions taken to implement this recommendation when responding to this inspection report. It is noted that further guidance on the matter of patient and partner screening is being prepared by the HFEA so the inspection team make no specific recommendation at this time on this matter, except to recommend that the PR reviews HFEA communications	All screening tests will be carried out by an established national provider. Results provided by GP's or alternate laboratories, although accredited, often do not have the necessery paperwork to demonstrate accreditation and will therefore not be accepted. Affordable screening price packages will be introduced for all patients. This change will be implimented on the 1st of July 2016 and patients informed accordingly. An audit to	The Executive acknowledges the PR's response and actions taken towards compliance with this recommendation. Audit to be received by 13 October 2016. Further actions required.

months of the gametes first being provided (SLC T51).	going forward and implements guidance on the timing of patient and partner screening when it is released. Six months after licensed treatment activity commences, the PR should audit records to ensure patient and partner screening is being performed in a compliant manner. A summary of this audit, including corrective actions with timescales for implementation, should be provided to the HFEA inspector as soon as it is completed.	confirm compliance will be supplied to the HFEA by 13th October 2016 The PR will review all HFEA communications regarding this matter and impliment any changes as required. An audit will be performed and provided to the HFEA as required.	
4. Infection control The floor and furnishings in the ultrasound and main phlebotomy rooms were not suitable from an infection control perspective (SLC T17).	The PR should ensure that the floor and furnishings within the ultrasound and main phlebotomy rooms are suitable from an infection control perspective. The PR should assess the suitability of the ultrasound and main phlebotomy rooms against infection control requirements. A summary of the assessment, with appropriate corrective actions and implementation timelines, should be submitted to the HFEA with the response to this report. Actions should be implemented by 13 July 2016 and the HFEA advised.	An infecton control risk assessment and clinical audit have been carried out and instructions provided to adapt the necessery rooms. The risk assessment and audit will be supplied to the HFEA along with this response The HFEA will be provided with an improvement update by the 13th July 2016.	The Executive acknowledges the PR's response and receipt of the risk assessment. The PR proved an update on 12 July 2016 which stated that appropriate taps and wash basins had been installed in the phlebotomy and scanning rooms and that suitable flooring had been ordered. Further action 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
5. QMS There is no SOP to direct the response to a clinical emergency at the centre (SLC T33b).	The PR should ensure a SOP to direct the response to a clinical emergency is documented. A copy of the SOP should be provided to the HFEA by 13 July 2016.	A relevent SOP has been attached to this report.	The Executive acknowledges the PR's response and has received the relevant SOP. No further action.
6. Staff training Evidence could not be provided that nursing staff had had recent training regarding consenting and legal parenthood. Staff were also inconsistent in their descriptions of their actions in the event of a needle stick injury, suggesting that training in this area is necessary (SLC T12 and T15a).	The PR should ensure that all staff are provided with refresher training, including in the areas of consent taking, legal parenthood and needle stick injury, at an appropriate frequency. The PR should provide the HFEA with a report documenting for all centre staff, the training requirements relevant to each staff member, and the anticipated date for completion of any training requirements which are currently outstanding. This report should be provided by 13 July 2016. The PR should provide monthly updates to the HFEA thereafter	All staff have received refresher training in the areas of consent and legal parenthood. (12th May LWC and 17th May at the Bridge Centre) A list of all staff attending the training is attached to this report. A copy of the certificate supplied to staff CPD folders is also attached. Training in the management of needle stick injuries will be conducted by 1st July 2016. The contents and a list of attendees will be submitted to the HFEA by 13th July 2016.	The Executive acknowledges the PR's response and actions taken towards compliance with this recommendation. Evidence has been provided of staff training in actions to be taken in the unfortunate event of a needle stick injury. No further action.

	regarding training undertaken and remaining outstanding. The inspection team anticipates the provision of training to be prioritised on the basis of risk and that all training requirements should be satisfied by 13 October 2016.		
7. Staffing The proposed individual who will be responsible for the andrology laboratory is not registered with the HCPC (SLC T14; CoP 2.19).	The PR should ensure all staff are registered with an appropriate professional body. The PR should review the skills and experience of the proposed individual responsible for the andrology laboratory and document either: how that individual's skills are equivalent to those conferred by HCPC registration; or a plan to ensure that the proposed individual attains HCPC registration and, while this happens, a HCPC registered andrologist is available to act as the nominated scientist for the centre. This information should be provided to the HFEA with the response to this report.	The PR (who is HCPC registered) has reviewed the skills and experience of the proposed individual responsible for the andrology laboratory and has judged that the proposed scientist skills are equivalent to those confered by HCPC and will register under the international section of the HCPC. An HCPC registered scientist (Laboratory Manager) is available to act as the nominated scientist for the centre.	The Executive acknowledges the PR's response and the actions that he has taken towards compliance with this recommendation. No further action.
8. Register data reporting At the time of the visit there was one treatment using an unregistered donor. In	The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.	An audit of the timely reporting of required HFEA treatment forms will be completed and supplied to the HFEA by 13th July 2016.	The Executive acknowledges the PR's response. It is noted that he states in his response that an audit of the timely reporting of treatment forms will be supplied to the HFEA

addition, one of the IVF treatments reviewed had not been reported to the HFEA (SLC T41; General Direction 0005).	The unregistered donor should be immediately registered. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for non-reporting. These recommendations should be implemented by the time the PR responds to the inspection report. The centre's inspector should also be informed of the results of the procedural review and actions taken. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the Authority.	The details of the donor from 1994/5 and the related patient have yet to be located. The Bridge Centre archive and the previous patient data base have been interrogated. The PR has asked the HFEA for further information (email 26th May 2016). Every effort will be made to locate the donor and patient and immediately registered with the HFEA.	by 13th July 2016. The Executive has not received this report however the recommendation was for this audit report to be provided six months after the implementation of corrective actions which would be October 2016. The PR has been in dialogue with the registry team at the HFEA however has not at the time of presentation of this report to a licensing committee been successful in locating notes/details of the donor. This situation will be monitored closely. Further action required.

Reponses from the Person Responsible to this inspection report
I would like to thank the inspection team for a very professional and helpful inspection. I am grateful for the willingness of the team to adapt the licensing process to accommodate the clinics novel requirements.