HFEA Licence Committee Meeting

15 January 2015

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 4

Centre 0070 (The Bridge Centre) – Investigation into the centre's medicines management procedure

Members of the Committee: Andy Greenfield (lay) (Chair) Debbie Barber (professional) Jane Dibblin (lay) Kate Brian (lay) Committee Secretary: Trent Fisher	Legal Adviser: Shelley Edwards, Fieldfisher Also in Attendance: Sam Hartley, Head of Governance and Licensing

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following **papers** were considered by the Committee:

- Additional report
- Correspondence between the previous Person Responsible (PR), Dr Kamal Ahuja and The Executive dated as follows:
  - 13 November 2014
  - 26 November 2014
  - 19 December 2014 (resent on 31 December 2014)
  - 23 December 2014
  - 6 January 2015
  - 7 January 2015
- Minutes from the last three years
  - 2014-10-07 Change of PR
  - 2014-06-07 Interim
  - 2013-11-07 Grade A incident follow up report
  - 2013-09-24 Grade A Incident
  - 2013-03-15 Change of PR
  - 2012-11-28 Change of Licence Holder
  - 2012-06-27 Renewal

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 8th edition of the HFEA Code of Practice

- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree); and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Bridge Centre has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services, including embryo testing.

2. The centre provided 1,730 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to February 2014. In relation to activity levels this is a large centre.

3. A change of Licence Holder to Dr Kamal Ahuja was approved by the Executive Licensing Panel (ELP) in November 2012. A change of PR to Ms Janine Elson was approved by the ELP in March 2013. A change of PR to Dr Kamal Ahuja was approved by the ELP in October 2014.

Discussion

4. The Committee noted that in July 2014 the Care Quality Commission (CQC) received an email detailing concerns about the actions of a nurse employed by The Bridge Centre. The email alleged that:
    - in June 2014 a nurse had remotely set up a treatment plan on the centre's electronic records system and had prescribed drugs under a consultant's name without their permission
    - the nurse subsequently dispensed the medication to a patient without the consultant's knowledge
    - the prescribed drugs contained lactose, to which the patient had a known allergy
    - the patient noticed the presence of lactose in the prescribed medication and made both informal and formal complaints to the centre
    - grievances and patient complaints relating to the same nurse had not been satisfactorily dealt with, and
    - the nurse had instructed other nurses to dispense drugs without prescriptions.

5. The Committee noted that a disciplinary hearing was held on 10 July 2014 and the nurse was given a formal written warning to be held on her personal file for 12 months. It noted that the incident was not reported to the HFEA.

6. The Committee noted that the CQC contacted the HFEA on the 29 July 2014 and it was agreed that the HFEA and the CQC should undertake a joint investigation of the allegation. An inspection was undertaken on the 28 August 2014 that revealed three 'critical', five 'major' and two 'other' areas of non-compliance or poor practice.

7. The Committee noted that the centre had placed the nurse on indefinite leave but received guidance from the NMC that the NMC considered that it did not need to restrict the nurse's practice whilst it concludes its investigation.

8. The Committee noted that the centre's disciplinary procedure will be reviewed and evidence of any corrective actions provided in the form of a summary report to the centre's inspector by the 30 January 2015. The centre is revising the medicines management policy with the assistance of OPUS Pharmacies and has been requested to provide a copy to the centre's inspector by 30 January 2015.

9. The Committee noted that 16 nurses have undertaken medicines management training and that the centre will conduct a medicines management audit providing a summary report to the Executive by 30 January 2015.

10. The Committee noted that even though the PR may have failed to discharge their duty at the time, there has since been a change of PR who has been working to address the areas of non-compliance or poor practice.

11. The Committee noted that the new PR has reviewed and improved the incident reporting system to make clear the direct responsibility of the PR and his accountability for reporting incidents within the prescribed timelines.

12. The Executive has recommended that an audit is undertaken to ensure that the changes of practice documented by the PR have been effective in ensuring that:
    - medicines are only prescribed and dispensed in line with the procedure described by the PR
    - all relevant incidents are reported to the HFEA, and
    - there is secure access to treatment plans

    A summary report of the audit findings should be provided to the Executive by 30 July 2015.

13. The Committee noted that the Executive recommends that the centre's licence should continue with no additional conditions subject to the remaining recommendations made in the inspection report being implemented within the prescribed timelines.

Decision

14. The Committee was concerned by the sequence of events presented to them, and the risk this incident may have posed to patient safety. It noted, however, that the actions taken since the inspection on 28 August were considered by the Executive to be appropriate in mitigating any risks to the safety of patients as a result of deficiencies in medicines management practices and procedures.

15. In relation to the allegation that the previous PR was prevented from discharging her duty; the Committee noted that the Executive found no evidence to substantiate this. However, the Committee also noted that the Executive concluded that a poor relationship with a senior member of the centre's management team may have been a contributory factor in her failure to discharge her duty. The Committee was reassured that the risk of any future conflict has been mitigated by the appointment of a new PR.

16. The Committee agreed to allow the continuation of the centre's licence with no additional conditions subject to the centre implementing the Executive's recommendations within the prescribed timelines. The Committee further noted that the new PR of the centre is also the Licence Holder. The Committee wishes to remind the PR of HFEA guidance which makes clear that the PR and the LH should be separate individuals.

17. The Committee requested that the progress inspection report should come before the Licence Committee at its meeting in March 2015, with updates on progress against the non-compliances outlined in the report.

Signed: Date: 29 January 2015

Andy Greenfield (Chair)

Additional Inspection Report

Purpose of the Inspection Report
This is a report of an additional 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.

Date of inspection: 28 August 2014

Purpose of inspection: Investigation of the centre's medicines management procedures

Inspection details: The report covers the findings from the inspection visit and communications received from centre staff.

Inspectors: Lisa Beaumont (HFEA), Mary Collier (Care Quality Commission, Regional Pharmacy Lead)

Date of Licence Committee: 15 January 2015

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, UK
Person Responsible	Dr Kamal Ahuja (from 07/10/2014) Ms Janine Elson (to 07/10/2014)
Licence Holder	Dr Kamal Ahuja
Date licence issued	01/10/2012
Licence expiry date	30/09/2016
Additional conditions applied to this licence	None

Section 1

Brief description of the centre and its licensing history:

The Bridge Centre is located in central London close to London Bridge and has held a licence with the HFEA since 1992.

The centre provides a full range of fertility services including embryo testing. The centre offers a UK based egg sharing programme offering treatment using donated eggs. The centre also has a network of satellite and transport centres.

The centre provided 1730 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to February 2014. In relation to activity levels this is a large centre.

A change of Licence Holder (LH) to Dr Kamal Ahuja was approved by the ELP in November 2012. A change of Person Responsible (PR) to Ms Janine Elson was approved by the ELP in March 2013. A change of PR to Dr Kamal Ahuja was approved by the ELP in October 2014.

Background to the additional inspection

1. On 24 July 2014 the CQC received an email detailing concerns about the actions of a nurse employed by The Bridge Centre. The email alleged that in June 2014, a nurse had remotely set up a treatment plan on the centre's electronic records system and prescribed drugs under a consultant's name without his permission, and then subsequently dispensed the medication to a patient without the consultant's knowledge. The prescribed drugs contained lactose, which the patient had a known allergy to: the patient noticed the presence of lactose in the prescribed medication and made both informal and formal complaints to the centre. The email also alleged that the nurse had instructed other nurses to dispense drugs without prescriptions, and that grievances and patient complaints relating to the same nurse had not been satisfactorily dealt with.

2. The CQC contacted the HFEA on 29 July 2014 and it was agreed that the HFEA and CQC should undertake a joint investigation of the allegation.

Activities undertaken to investigate the medicines incident

3. An inspection was undertaken on 28 August 2014.

4. The inspection team interviewed the Person Responsible (PR) and all the nurses on duty in the clinic on 28 August 2014 (including the nurse identified in the email) who handle drugs as part of their role. The HFEA inspector also undertook a telephone interview with the Quality Assurance Co-ordinator on 2 September 2014.

5. The inspection team reviewed the following information and evidence in the course of the inspection:
    - a report of the centre's internal investigation into the incident referenced in the CQC email;
    - staff records in relation to medicines management training;

- the centre's policies on medicines management as follows:
    - Safe Handling of Medicines;
    - Safe Handling of Controlled Drugs;
    - Ordering of Medication;
    - Drug Dispensing Policy;
    - Medicines Policy;
- NMC registration status of all registered nurses;
- the centre's 'Disciplinary and Capability Procedure'.

Findings of the centre's internal investigation of the medicines incident

6. The incident took place on 20 May 2014 and was reported internally by the consultant on 2 June 2014. An internal investigation was undertaken by the centre on 8 June 2014 by the clinic's Quality Assurance Co-ordinator. The investigation appears to have followed the centre's 'Disciplinary and Capability Procedure'.

7. The centre's internal investigation found that:
    - the nurse admitted to having created the treatment plan under the consultant's name in order that the patient could commence treatment and 'to avoid inconveniencing the patient';
    - the nurse admitted to not being a qualified nurse practitioner;
    - the nurse admitted that she should not have asked a nurse colleague to dispense the medication from the treatment plan that she herself had set up;
    - the nurse stated that she understood the basis of the patient's complaint was about her lactose allergy having been overlooked;
    - the nurse stated that she did not see the incident as a non conformity.

8. A disciplinary hearing was held on 10 July 2014 and the nurse was given a formal written warning to be held on her personal file for 12 months.

Inspection Findings

9. During the inspection the nurse was on duty and continuing to undertake her normal duties included the handling of medications and having access to the centre's electronic records system (see recommendation 1).

10. The PR failed to report this incident to the HFEA (see recommendation 2).

11. The nurse's conduct was not reported to the NMC (see recommendation 3).

12. The majority (approximately 90%) of medications are dispensed from a treatment plan and not against a legal prescription (see recommendation 4).

13. Treatment plans generated using the centre's electronic record system are not secure and can be accessed and changed by members of staff other than individuals with prescribing rights: the inspection team consider that this poses a risk that other individuals without necessary authority could prescribe medication (see recommendation 5).

14. Discrepancies were found with the centre's medicines management policies (see recommendation 6).

15. Seven nurses were interviewed during the inspection visit, all of whom handle medications as part of their role. The majority of the nurses were unclear about the medicines management training they had undertaken and did not seem to be aware of the centre's medicines management policies. The nurses were not aware of any audits of medicines management practices having been undertaken (see recommendation 7).

16. On reviewing the centre's policies, the centre appears to operate at a lower standard than that set out in The Human Medicines Act 2012 (see recommendation 8).

17. Drugs in the clinic are dispensed by a single member of the nursing staff (see recommendation 9).

18. The Controlled Drugs Accountable Officer (CDAO) is not registered with the CQC (see recommendation 10).

19. The inspection team concluded that the nurse showed little insight with regard to the seriousness of her actions or that prescribing medication outside her professional authorisation may have impacted on patient safety. This, together with the centre appearing to have interpreted the nurse's actions as having been taken in the best interests of the patient gives cause for concern as to the robustness of the centre's attitude towards clinical governance and patient safety.

20. Whilst the centre undertook an internal investigation into this incident, it is the conclusion of the investigating team that the disciplinary action taken did not reflect the seriousness of the incident. The chair of the disciplinary hearing failed to report the nurse to the NMC as we suggest would be normal procedure for an incident of this nature.

21. Despite taking disciplinary action against the nurse for misconduct relating to drug prescribing, the inspection team questions the judgement of the chair of the disciplinary panel in suggesting that the nurse consider undertaking training to be a nurse prescriber.

22. The PR in post at the time of the incident resigned from her post on 29 September 2014. In her letter of resignation she alleged that she had been prevented from discharging her duties as PR (as required by Section 17 of the Human Fertilisation and Embryology Act 1990, as amended) by a senior member of the management team. Specifically, it was alleged that she had been prevented from taking further appropriate action to secure the suitability of staff members and from reporting the medicines incident to the HFEA. The Executive reviewed information provided by the PR in post at the time of the incident (Janine Elson) and from Kamal Ahuja (Licence Holder at the time of the incident, and PR from the time of Ms Elson's resignation). This information demonstrated a possible breakdown in the relationship between these individuals but was not considered to provide conclusive evidence that the PR was prevented from discharging her duties as PR.

Recommendation to the Licence Committee

23. The PR, in failing to ensure that staff were suitable; that the centre had suitable practices for medicines management, and; to report the medicines incident to the HFEA, may have failed to discharge her duty as PR as required by S.17 of the 1990 Human Fertilisation and Embryology Act (as amended). It is acknowledged that the PR felt she was prevented from discharging her duty. The HFEA Executive did not see evidence to substantiate the allegation that the PR was prevented from discharging her duty but concluded that a poor relationship with a senior member of the centre's management team may have been a contributory factor in her failure to discharge her duty.

24. It is noted that under Section 18(2) of the Act, the Authority may revoke a licence if it is satisfied that the person responsible has failed to discharge their duty under section 17. However since the investigation was completed there has been a change of PR at the centre. The Executive also considers that the actions taken following the inspection on 28 August were appropriate in securing the mitigation of any risks to the safety of patients as a result of deficiencies in medicines management practices and procedures.

25. The Executive considers that the risks of any future conflict between centre management and a PR have been reduced by the appointment of a member of the centre's senior management team to the role of PR.

26. As a result of the actions detailed above, the Executive recommend that regulatory sanctions should not be imposed and that the centre's licence should continue without additional conditions subject to the remaining recommendations for improvement made in this report being implemented within the prescribed timescales: this is important to ensure that the centre's staff and practices are suitable and to provide evidence that the newly appointed PR is discharging his duty under S.17. The centre's inspector will continue to monitor performance and failure to implement the recommendations of this report within the prescribed timescales or incidences of further non-compliance brought to the attention of the HFEA Executive will result in the submission of a further report to the LC with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

Annex 1

Areas of practice that require the attention of the Person Responsible

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, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

‘Critical’ area of non-compliance

A ‘critical’ area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. 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 response to the PR’s statement
1. On the day of the inspection the nurse was found to be on duty and still undertaking her full clinical duties. Human Fertilisation and Embryology (HFE) Act 1990	The PR should review the working arrangements of the nurse and provide evidence to the HFEA that patients are not at risk from the nurse pending the outcome any resulting NMC investigation. The PR should ensure that the nurse is placed on indefinite leave until the centre has received advice and guidance from the NMC as to what, if any, restrictions	The working arrangements have been fully reviewed and the inspection team informed of the steps taken. The nurse was on indefinite leave; however, following further advice and guidance from the NMC, who assured us that they did not consider that her practice required restrictions, she is working under supervision at	29 August 2014: The PR confirmed that the nurse has been placed on indefinite leave until the outcome of this and any resulting NMC investigation has been completed. 5 September 2014: The centre has confirmed that the nurse’s IT access, including remote access had been withdrawn.

(as amended) 17(1)(a)	or conditions should be placed on her practice pending their investigation. **This action should be implemented immediately.**	another clinic in the group. This will be further reviewed following the NMC investigation and outcome. The PR will follow the guidance of the NMC investigation recommendations.	9 October 2014. The Centre has received guidance from the NMC that the nurse does not require any restrictions in her duties whilst the NMC conclude their investigation. No further action required
2. The PR failed to report this incident to the HFEA. General Directions 0011 Human Fertilisation and Embryology (HFE) Act 1990 (as amended) 17(1)(g)	The PR should report the incident immediately and undertake a review of the centre's procedure for adverse event reporting to ensure all adverse incidents are reported to the HFEA within the required timeframes. This action to report the incident should be taken **immediately**. A summary report of the findings of the review of the adverse incident reporting procedure and any corrective actions or amendments should be provided to the HFEA by 30 November 2014.	The incident reporting system has been reviewed and improved to be clearer about the direct responsibility of the PR and his accountability for reporting incidents within the defined time frames. Incident reporting is audited via the Quality Management Review meeting each month. The PR will sign off each individual NCO and Adverse Incident report which will in turn be reported to the JDH Executive Committee.	The centre reported this incident to the HFEA. Although brief, the PR's comments are accepted in lieu of a summary report of the findings of the incident reporting system review. It is further recommended that an audit is undertaken to ensure that the changes of practice documented here by the PR have been effective in ensuring that all relevant incidents are reported to the HFEA, The Executive would be happy to review the centre's incidents log as part of this exercise to provide advice on reportable incidents. A summary report of the audit findings should

			be provided to the HFEA by 30 July 2015.
3. The centre's disciplinary procedures were not considered adequate to ensure the suitability of staff. Human Fertilisation and Embryology (HFE) Act 1990 (as amended) 17(1)(a)	The conduct of the nurse should be reported to the NMC and evidence of this should be provided to the HFEA. **This action is to be implemented immediately.** The PR should update the HFEA of the outcome of the NMC investigation and any recommended action the centre is required to take. On the basis of the NMC's recommendations, the PR should reconsider whether the nurse should be nominated to undertake nurse prescribing training. The PR should seek documented advice from relevant professional bodies on circumstances that would warrant referral of staff members. The Centre's disciplinary procedures should be reviewed in	The nurse was reported to the NMC. Evidence has been provided to the inspector. The nurse will not be recommended for the nurse prescribing course The PR will update the HFEA of the outcome of the NMC investigation immediately on conclusion. The disciplinary procedure will be reviewed and evidence of any corrective actions provided to the HFEA in the form of a summary report by the 30th January 2015	11 September 2014 The centre provided evidence from the NMC that the nurse was referred on 5 September 2014. Further action is required by the PR to provide a summary report of the findings of the review of the centre's disciplinary procedures. by 30 January 2014. This will be monitored by the centre's inspector.

	consideration of this advice and a summary report of the findings of the review and any corrective actions or amendments should be provided to the HFEA by 30 January 2014.		

‘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 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[I]	Executive response to the PR’s statement
4. Nurses are dispensing drugs against a treatment plan produced on the centre’s electronic records system and not against a legally signed drug prescription. (The Human Medicines Act 2012)	The PR should review the current drugs dispensing process and ensure that medication is dispensed against a legal prescription at all times. These actions should be implemented by 30 November 2014. Actions taken with respect to this recommendation should be provided in responding to this report.	The PR has taken independent advice from OPUS Pharmacy Services http://www.opuspharmserve .com/ regarding all areas of medicines management including prescribing, dispensing and storage. Nurses have already received update training and have had their competencies independently assessed. The PR and Nurse Manager have instituted the following procedures with immediate effect. Medications are only dispensed from the clinic if the	No further action required in relation to this recommendation. It is further recommended that an audit is undertaken to ensure that the changes of practice documented by the PR have been effective in ensuring that medicines are only prescribed and dispensed in line with the procedure described by the PR. A summary report of the audit findings should be provided to the HFEA by 30

		following are in place for each individual patient: a: Written prescriptions signed by consultant b: Prescription entered into the drug sales on IDEAS c: Double check of dispensing with 2 nurses d: Written in the daily stock folder removal of medications from the daily log book. To reduce the number of drugs being dispensed at the clinic, routine patient prescriptions for treatment drugs are outsourced to a home delivery company. All patients requiring supplementary drugs will still be able to get medications from the clinic as a basic stock will be available. Drug packages for treatment can be purchased and delivered to the patient in advance of the cycle taking place.	July 2015.
5. Treatment plans are generated by doctors on the centre's electronic records system access to which is not restricted.. SLC T 44 a	The PR should review how patient treatment plans can be secured to prevent unauthorised personnel amending and / or creating treatment plans that include prescriptions for	Treatment plans are set by clinicians and then secured by electronic signatures on IDEAS. The treatment plan is password protected with access only by the clinician of record who set the treatment plan. Prescriptions for treatment	No further action required in relation to this recommendation. It is further recommended that an audit is undertaken to ensure that the changes

	medication. These actions should be implemented by 17 December 2014. Actions taken with respect to this recommendation should be provided in responding to this report.	medications are prescribed in advance of the treatment taking place and ordered from Healthcare at Home for direct dispensing to the patient. Prescriptions for medications needed during the cycle not prescribed in the original treatment prescription are dispensed from the clinic only with a signed prescription in place: the prescription is only filled when double checked by 2 nurses: added to the IDEAS database and with batch and serial numbers on the patients file. Record of the dispensing is added to the daily log book for each drug held at the clinic this record is signed by 2 nurses.	of practice documented by the PR have been effective in ensuring secure access to treatment plans. A summary report of the audit findings should be provided to the HFEA by 30 July 2015.
6. The following areas of concern were identified in medicines management policies: a. the policies are generic and are not personalised to represent practice at the Bridge Centre; b. storage requirements are not clear i.e. for	The PR should review the policies to ensure they reflect practice at the Bridge Centre, and submit the revised policies, highlighting where this has been done, to the HFEA. This should be completed by 30 January 2014. The PR should nominate another senior member of	The PR and the new Nurse Manager have instituted the following policies with immediate effect: a: Opus pharmacies were resourced to ensure that the medications policy at the Bridge Centre reflected a specific working practice at the centre. Following an onsite visit on the 30th September to look at the current working practices and to ensure that the SOP's are specific to the units daily function	Further action required to provide a copy of the revised medicines management policy by 30 January 2015. This will be monitored by the centre's inspector

secure fridge storage; c. the Controlled Drugs Accountable Officer (CDAO) is referred to as the Nurse Manager. This is acceptable if the Nurse Manager is not handling controlled drugs routinely, however the nurse is the Nurse Manager and she is handling medicines; d. the 'Ordering of Medication' policy is noted to be 'under review'. SLC T2	staff who does not handle medication as the CDAO and provide evidence that this has been done to the HFEA by 30 November 2014.	b: The individual refrigerators at the centre have locks fitted and the keys stored in a secure wall mounted lock box. Access is protected through a coded entry mechanism. c: The CDAO will be the new Director of Operations starting on the 1st December 2014- her application is already in process with the CQC. d: See (a)- The policy will be finalised following review by Opus and input from the clinical/nursing team.	
7. Members of the nursing team were unable to articulate a clear understanding of the centre's medicines management procedures and the centre has not undertaken any medicines	The PR should ensure that all staff who handle medicines undertake medicines management training at regular intervals and that this training is embedded in every day practice. Evidence of	All nurses, will receive mandatory repeat training on medicines management on completion of the new SOP's and practice review. All nurses will receive annual update training as part of the mandatory training schedule.	9 October 2014 The PR has reported that 16 nurses had medicines management training on 1 October 2014. Further action is required by the PR to provide a

management audits. SLC T12 and SLC T36	actions taken to implement this recommendation should be provided to the HFEA by 30 January 2014. The PR should ensure that an audit to assess compliance against the centre's medicines management policies is undertaken. A summary report of the audit findings should be provided to the HFEA by 30 January 2014.	All nurses will have their competencies assessed annually in order assess compliance against the centre's medicines management policies. All the nurses have completed their competency testing. A summary report will be provided to the HFEA by the 30th of January 2015.	summary report of the findings of the medicines management audit by 30 January 2014. This will be monitored by the centre's inspector.
8. The Human Medicines Act 2012 sets out the legislation regarding prescribing and dispensing of medicines. The centre appears to operate at a lower standard that that required by this legislation.	The PR should provide assurance of the standard to which the centre operates and what action / mitigation is needed to ensure that best practice in relation to medicines management is in place. This action should be implemented by 30 November 2014.	It is submitted that the information provided in 4-7,9 would be reassuring to fulfil this requirement.	No 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 response to the PR’s statement
9. Drugs in the clinic are dispensed by a single member of the nursing staff. NMC Standards for Medicines Management – Standard 4	The PR should provide evidence to the HFEA, as to how he is assured that nurses are practicing safely and in line with NMC Standards for Medicine -Standard 4, if nurses continue to dispense drugs alone. Evidence should be provided to the HFEA by 17 December 2014.	The new Nurse Manager has instituted the following protocols with immediate effect: All medications dispensed from the clinic are signed off by 2 nurses as standard. Prescriptions are generated from IDEAS database and signed by clinicians; the prescription is dispensed by 2 nurses- the data from the prescription is added to IDEAS in the patient file and the scanned signed prescription also in patient documents- The batch number and expiry dates are added via pharmacy sales on IDEAS. Stock log book has the details of the dispensing to the patient and is signed off by 2 nurses.	No further action required in relation to this recommendation. It is further recommended that an audit is undertaken to ensure that the changes of practice documented by the PR have been effective in ensuring that dispensing is carried out as described. A summary report of the audit findings should be provided to the HFEA by 30 July 2015.
10. The Controlled Drugs	The PR should ensure	The newly appointed Director of	The HFEA has been provided with

(supervision and management of use) Regulations 2013 require the CDAO to be registered with the CQC. The inspection team note that the Bridge Centre has attempted to register the CDAO but due to technical difficulties beyond their control the application was not completed. SLC T14	that the CDAO is registered with the CQC and provide evidence to the HFEA that this has been done by 17 December 2014.	Operations is our new CDAO. Her application is currently with CQC receiving consideration to become effective from 1st December 2014 when she takes up her new post.	confirmation of the appointment of the CDAO. No further action.

The PR is invited to reflect, below, on the circumstances set out in this report and in particular how his leadership and status as PR will combine to ensure higher standards of care in the future such that patients continue to be safe; the treatment they receive is effective; and the essential requirements of the HFEA are met.

Additional information from the Person Responsible
The Bridge Centre is part way through a 3 and 5 year strategic plan which will ensure it is a vibrant , successful and compliant HFEA licenced fertility clinic. The HFEA has already been provided with a number of documents detailing our achievements so far and plans in the coming months and years. Briefly, the clinic has reached financial stability, secured the site on a long-term basis, and significantly reduced its activity by proactively managing our working partnerships and third party arrangements More detail is available in documents previously provided to the HFEA. I have been Person Responsible at a number of other HFEA regulated clinics and take the duties of the PR very seriously. In my role as managing director I will provide full personal and corporate commitment to the further development of The Bridge Centre and provide reassurance to the HFEA in relation to our regulatory compliance. As you are aware, we have made a number of new appointments and restructured our existing team. The newly appointed but experienced senior clinician lead will provide onsite leadership to the medical team; the recently appointed nurse manager is providing leadership to the nursing team; a complete restructure of laboratory services and staffing will ensure the safe delivery of licensed activity including gamete and embryo storage. In the short term, some of the laboratory services may become shared with the established and successful laboratory structures at the London Women's Clinic The Bridge Centre will be the main focus of the newly appointed Director of Operations for our group who will also oversee all Quality Management functions, including regulatory compliance, as well as daily operations. Along with this very senior and experienced team, I will provide full support and leadership to all members of the team in order to maintain safe patient care and effective, successful treatment.

Additional responses from the Person Responsible in post at the time of the incident and the current PR
The PR at the time of the incident requested an opportunity to comment on the content of this report and submitted the following observations through her solicitor: My client would only wish to make two observations: 1. At no time did my client have the belief that she had sufficient basis to make a report – for example, she was not privy to any information or outcomes following disciplinary investigations into the nurse's practice. Absent any evidenced conclusion that there had been a definite notifiable event, then it seems difficult to make a report to you. 2. Post the HFEA inspection on 28.08.14, the measures put in place were initiated by my client and that should be reflected in the Investigation Report. In response to these comments the current PR submitted further comments in correspondence provided for consideration by the Licence Committee.

[i] *The PR responses were provided to the HFEA in pdf format with the content of this file transferred to this document to facilitate addition of the Executive response.*