Executive Licensing Panel - minutes

Centre 0333 (Harley Street Fertility Clinic)

Inspection to investigate whistle blower concerns

Friday, 6 October 2017

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Juliet Tizzard (Chair) Ian Peacock Anna Quinn	Director of Strategy and Corporate Affairs Systems Manager Scientific Policy Manager
Members of the Executive	Bernice Ash	Secretary
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. Consideration of application

1.1. The panel noted that Harley Street Fertility Clinic is located in central London and has held a treatment (including embryo testing) and storage licence with the HFEA since July 2014. The centre provides a full range of fertility services and is also registered with the Care Quality Commission (CQC).

1.2. The panel noted that between May and June 2017, the centre provided 274 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a small centre.

1.3. The panel noted that the centre was last inspected for the first renewal of its licence in February 2016. Under HFEA policy in place at the time, the February 2016 inspection would usually have been the first visit to a new centre after an initial two-year licence was granted. However, an unannounced inspection was conducted in June 2015 in response to a complaint to the CQC from a patient regarding the centre's medicines management procedures and patient feedback provided directly to the HFEA on the same subject.

1.4. The panel noted that a number of concerns were raised by the unannounced inspection, the most significant of which related to medicines management and sedation practices for surgical procedures at the centre. In accordance with the HFEA Compliance and Enforcement Policy, a management review was conducted at which the findings of the unannounced inspection were evaluated. It was considered appropriate to conduct an announced, full inspection of all the centre's activities to determine the current level of compliance in all areas. This was carried out in July 2015. Seven major areas of non-compliance were identified on these inspections. The Person Responsible (PR) and her team engaged fully with the HFEA; information requested and evidence of actions taken were provided in a comprehensive and timely manner.

1.5. The panel noted that the reports from both inspections were considered by the Executive Licensing Panel in October 2015, and due to concerns regarding non-compliances concerning consent, medicines management and sedation processes, an executive update was requested for January 2016.

1.6. The panel noted that the update provided in January 2016, The PR had provided evidence that the majority of the outstanding recommendations had been fully implemented. The centre's progress in addressing the non-compliances was noted and the PR was urged to address the remaining recommendations within the prescribed timescales. The PR fully implemented all outstanding recommendations.

1.7. The panel noted that the February 2016 renewal inspection focused on continuing compliance with the recommendations that were made in the previous inspection report. Two major and three 'other' areas of non-compliance were noted. These recommendations have since been implemented. The executive recommended renewal of the centre's licence for four years without additional conditions and this was agreed by the ELP. The executive noted the significant improvement in compliance since the inspection visits in June and July 2015.

1.8. The panel noted that on 8 June 2017, concerns about the centre were raised with the CQC anonymously, via their website and the allegations raised are as follows:

"disorganisation untrained clinical staff high turnover of staff no emergency procedure/policy/call bells for sick patients high number of complaints from patients some staff untrained in dispensing/checking/giving medication not well led uncaring and unresponsive to patients complaints/needs low morale/job satisfaction among staff, staff fear senior management, in particular the main clinician therefore numerous incidents not recorded poor hygiene/infection control if anaesthetist not available or late, untrained nurse will be asked to administer anaesthesia."

1.9. The concerns raised were shared with the Authority on 12 June 2017 and it was agreed, in discussion with the CQC, that it would be appropriate for this to be investigated further. The HFEA's whistle blowing policy was followed and, in accordance with the HFEA Compliance and Enforcement Policy, a management review was held on 14 June 2017 to consider the allegations raised. The allegations were deemed serious, if founded, and of a type that the executive was unable to give a fair consideration to without visiting the centre. It was decided that an unannounced inspection to the centre should be performed.

1.10. The panel noted that the inspection took place on 22 June 2017. The whistle blower's allegations were numerous and the subjective nature of some meant that assessment by the executive was difficult. The inspection team went to considerable lengths to ensure that the allegations made were discussed in full with the lead clinician, the management team and with individual members of staff in private. The inspection team has concluded that there is no evidence to support the allegations. There has been some fluctuation in staffing within the nursing team, which has had an impact on staff morale, but it was considered that this is being effectively managed by the senior team at the centre.

1.11. The panel noted that at the time of the inspection on 22 June 2017, a number of issues were identified that are not directly related to the whistler blower's comments. There were a number of areas of practice that required improvement in relation to one critical, two major and one 'other' area of non-compliance. The PR had provided evidence that actions had been taken to implement the recommendations concerning management of controlled drugs, infection control and safety and suitability of premises, and has committed, where required to audit the effectiveness of these actions within the prescribed timescales.

1.12. The panel noted that improvement was necessary in order for the centre to reflect good practice with respect to its management of controlled drugs, clinical waste and compressed gases. Although concerns over the centre's medicine management practices were raised at the 2015 inspection visit to this centre, these were predominantly around the management of non-controlled drugs and these non-compliances have been resolved. However, the panel noted that issues with the centre's management of controlled drugs were noted at both the 2015 and 2016 inspections and have since reoccurred.

1.13. The panel noted that the centre has performed a comprehensive review of its medicine management practices since the inspection and corrective action has been implemented. It is also noted that the non-compliance, although significant and serious, does not impact directly on patient safety.

1.14. The panel noted the inspectorate's recommendation to continue the centre's licence.

2. Decision

2.1. The panel noted that no evidence has been found to support the whistle blower's allegations. However, the panel noted the unrelated non-compliances identified at the time of the inspection, expressing particular concern regarding the management of controlled drugs, but acknowledging prompt action had been taken to rectify the issues.

2.2. The panel was satisfied the centre was fit to have its centre's treatment and storage licence continued.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

18 October 2017

Inspection Report

Date of inspection: 22 June 2017

Purpose of inspection:
This was an additional unannounced inspection conducted in response to concerns raised with the Care Quality Commission (CQC) by a whistle blower regarding practices at the centre. It is primarily written for the Authority's Executive Licensing Panel (ELP).

Inspectors: Sara Parlett and Gill Walsh

Date of Executive Licensing Panel: 6 October 2017

Centre name	Harley Street Fertility Clinic
Centre number	0333
Licence number	L/0333/2/a
Centre address	134, Harley Street, London, W1G 7JY
Person Responsible	Dr Geetha Venkataraman
Licence Holder	Mr Lawrence Ashford
Date licence issued	23 July 2016
Licence expiry date	22 July 2020
Additional conditions applied to this licence	None

Contents

Section 1: Summary report **3**
Section 2: Inspection findings **6**
Areas of practice requiring action **9**

Section 1: Summary report

Brief description of the centre and licensing history

Harley Street Fertility Clinic is located in central London and has held a treatment (including embryo testing) and storage licence with the HFEA since July 2014. This initial licence was granted for two years. The centre provides a full range of fertility services. The centre is also registered with the CQC.

Between June 2016 and May 2017, the centre provided 274 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small centre.

The centre was last inspected for the first renewal of its licence in February 2016. Under HFEA policy in place at the time, the February 2016 inspection would usually have been the first visit to a new centre after an initial two year licence was granted. However, an unannounced inspection was conducted in June 2015 in response to a complaint to the CQC from a patient regarding the centre's medicines management procedures and patient feedback provided directly to the HFEA on the same subject.

A number of concerns were raised by the unannounced inspection, the most significant of which related to medicines management and sedation practices for surgical procedures at the centre. In accordance with the HFEA Compliance and Enforcement Policy, a management review was conducted at which the findings of the unannounced inspection were evaluated. It was considered appropriate to conduct an announced, full inspection of all the centre's activities to determine the current level of compliance in all areas. This was carried out in July 2015. Seven major areas of non-compliance were identified on these inspections. The Person Responsible (PR) and her team engaged fully with the HFEA; information requested and evidence of actions taken were provided in a comprehensive and timely manner.

The report of both of these inspections was considered by ELP in October 2015. The panel was concerned about the non-compliances relating to consent, medicines management and sedation practices. The panel noted the progress the centre had made (four of nine recommendations had been fully implemented) but considered that the centre may not fully appreciate the serious consequences failing to take proper consent might have. Taking this into account, the panel requested that the executive provide an update in January 2016 regarding the centre's progress in implementing the outstanding recommendations.

This update was provided to ELP. The PR provided evidence that the majority of the outstanding recommendations had been fully implemented. The panel noted the centre's progress in addressing the non-compliances and urged the PR to address the remaining recommendations within the prescribed timescales. The PR fully implemented all outstanding recommendations.

In consideration of the inspection history of this centre, the level of engagement and commitment to achieving compliance demonstrated by the centre team and because a comprehensive inspection of all licensable activities had been performed in July 2015, a standard licence renewal inspection was not considered necessary. Instead, the February 2016 renewal inspection visit focused on continuing compliance with the recommendations that were made in the previous inspection report. Two major and three 'other' areas of non compliance were noted. These recommendations have since been implemented. The

executive recommended renewal of the centre's licence for four years without additional conditions. This was agreed by the ELP. The executive noted the significant improvement in compliance since the inspection visits in June and July 2015.

Whistle blower concerns

On 8 June 2017, concerns about the centre were raised with the CQC anonymously, via their website.

The allegations raised are as follows:
"disorganisation untrained clinical staff high turnover of staff no emergency procedure/policy/call bells for sick patients high number of complaints from patients some staff untrained in dispensing/checking/giving medication not well led uncaring and unresponsive to patients complaints/needs low morale/job satisfaction among staff staff fear senior management, in particular the main clinician therefore numerous incidents not recorded poor hygiene/infection control if anaesthetist not available or late, untrained nurse will be asked to administer anaesthesia."

These concerns were shared with the HFEA on 12 June 2017 and in discussion with the CQC it was agreed that it would be appropriate for the HFEA to investigate and then share its findings. The HFEA's whistle blowing policy was followed and, in accordance with the HFEA Compliance and Enforcement Policy, a management review was held on 14 June 2017 to consider the allegations raised. The allegations were deemed serious, if founded, and of a type that the executive was unable to give a fair consideration to without visiting the centre. It was decided that an unannounced inspection to the centre should be performed. This is a report of the findings of this visit.

Summary for licensing decision

The whistle blower's allegations are numerous and the subjective nature of some meant that assessment by the executive was difficult. The inspection team went to considerable lengths to ensure that the allegations made were discussed in full with the lead clinician, the management team and with individual members of staff in private. The inspection team has concluded that there is no evidence to support the allegations. There has been some fluctuation in staffing within the nursing team, which has had an impact on staff morale, but it was considered that this is being effectively managed by the senior team at the centre.

However, whilst investigating these concerns during the inspection, a number of issues were noted that are not directly related to the whistle blower's comments.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement in relation to one critical, two major and one 'other' areas of non-compliance.

The PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of these actions within the required timescales:

Critical areas of non-compliance:

- **The PR should review procedures to ensure that the management of controlled drugs is compliant with legal requirements and professional best practice.**

Major areas of non-compliance:

- The PR should ensure that staff are aware of and comply with requirements to ensure that clinical waste is traceable and that the clinical waste skip is secure at all times.
- The PR should ensure that all compressed gas cylinders are stored in accordance with compressed gas safe handling and storage requirements.

'Other' areas of non-compliance:

- The PR should ensure that the checks of the anaesthetic equipment and resuscitation trolley contents is recorded in accordance with clinic policy.

Recommendation to the Executive Licensing Panel

This additional inspection identified one critical and two major areas of non compliance. Improvement was necessary in order for the centre to reflect good practice with respect to its management of controlled drugs, clinical waste and compressed gases.

Although concerns over the centre's medicine management practices were raised at the 2015 inspection visit to this centre, these were predominantly around the management of non controlled drugs and these non compliances have been resolved. However, it is of concern that issues with the centre's management of controlled drugs were noted at both the 2015 and 2016 inspections and have since reoccurred.

This reoccurrence gave the executive pause in considering if the recommendation made in this report will be appropriately implemented this time. However, the ELP is asked to note that the centre has performed a comprehensive review of its medicine management practices since the inspection and corrective action has been implemented. It is also noted that the non compliance, although significant and serious, does not impact directly on patient safety.

The executive therefore recommends continuation of the centre's licence.

Section 2: Inspection findings

On 8 June 2017, concerns were raised with the CQC by a whistle blower about this centre. These concerns were numerous and have been grouped into themes and are considered in turn, below:

Details of inspection findings

1) Disorganisation

No further details were provided by the whistle blower and it is unclear what this was specifically referring to. No concerns were noted by the inspection team.

2) Untrained clinical staff; some staff untrained in dispensing/checking/giving medication; high turnover of staff; low morale/job satisfaction among staff

A full review of staffing with respect to doctors, nurses and health care assistants was performed on inspection. A sample of induction and training records for nursing staff was also reviewed and the inspection team interviewed a number of members of staff.

There has recently been a higher rate of staff turnover in the nursing and health care assistant team. Some members of staff confirmed that this has, understandably, had an impact on staff morale. However, a review of the reasons for staff leaving demonstrates there is no single factor responsible and the inspection team considered that this is being effectively managed by the senior team.

The process for checking and dispensing medication against that prescribed was discussed with staff responsible for this task and their training records were reviewed. Evidence of training and the assessment of competence of relevant staff to perform these tasks was available. A sample review of dispensing records did not indicate any cause of concern.

In summary, the centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services.

3) Staff fear senior management, in particular the main clinician therefore numerous incidents not recorded; not well led

There is no evidence to support these allegations although it is acknowledged that it is not straightforward to assess the many aspects of leadership.

The centre's procedures for reporting adverse incidents were reviewed and are considered 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 that have occurred and the centre's investigation reports are of a high standard. From interviews with staff, there was no evidence to suggest incidents would not be reported and acted upon.

There appears to be an open culture at the centre where staff can make suggestions for change and improvement and these are listened to by senior management. For example, nursing staff recently proposed a significant change to their shift patterns to the lead nurse. This proposal was taken to senior management and they agreed to it on a trial basis. The

centre's appraisal system also includes a 360-degree feedback process for all staff to provide feedback on their peers and management. Staff surveys are also conducted.

4) Uncaring and unresponsive to patient complaints/needs; high number of complaints

The centre's complaint process and patient feedback mechanism was reviewed and the inspection team interviewed a number of members of staff. There is no evidence to support these concerns. The inspection team considers that the centre's procedures are compliant with requirements to seek patient feedback and to be responsive to patient complaints.

Patient feedback is sought from all patients at the time of embryo transfer and responses are highly complementary. Where patients had provided constructive feedback, evidence was available that this feedback had been acted upon. Centre staff engage effectively with patient complaints, in a timely fashion and giving comprehensive responses. There was no evidence that there is a 'high' number of complaints about services at this centre.

5) No emergency procedure/policy/call bells for sick patients; if anaesthetist not available or late, untrained nurse will be asked to administer anaesthesia.

The centre's emergency procedures and sedation practices were reviewed. There is no evidence to support these concerns.

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

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

The PR confirmed that on three occasions this year, the anaesthetist had been late arriving for an egg collection. The timing of egg collection is critical for patients having IVF as once ovulation is 'triggered' there is a finite time in which to harvest the woman's eggs before she ovulates and therefore the eggs cannot be collected. In consideration of this, on these occasions the PR did administer the conscious sedation drugs and was supported by a nurse and the doctor performing the procedure. One of these occasions occurred the day before inspection; the patient's notes were reviewed and demonstrated that the patient had been safely cared for. The inspection team was assured that an untrained nurse would never be put in a position of being asked to administer anaesthesia to a patient.

6) Poor hygiene/infection control

The centre's infection control procedures were reviewed and the centre's premises were toured during the inspection. The centre has systems in place to manage and monitor the prevention and control of infection that are broadly compliant with guidance:

- the clinic's waste sharps bins are not dated or signed by the person who assembles them. This is necessary to ensure full traceability.
- the skip for clinical waste located on the lower ground floor was unlocked on the day of inspection and was potentially accessible by the public.

Recommendation 2.

Compliance with HFEA standard licence conditions

To effectively investigate the whistle blower's concerns, the inspection team observed an egg collection being performed on the day of inspection and performed a tour of the centre. Although not directly related to the whistle blower's concerns, these observations demonstrated non compliance with the following HFEA requirements:

- Management of controlled drugs (CD):
  - During a routine CD check on the day of the inspection, there was a discrepancy between the number of ampoules of one drug recorded in the CD register (15) against the actual number in the CD cupboard (14) when the physical check was performed. No CDs had been used on the day of inspection and the CD check conducted by two members of staff the previous evening had recorded that all drugs had been checked and were correct. Further investigation accounted for the 'lost' ampoule, in that the total number of ampoules used had not been correctly 'counted down' in the CD register. A review of the relevant patient records for that day confirmed that the 'missing' ampoule had been used in a patient's treatment.
  - The CD register in use at the centre has been changed since the last inspection and does not conform to regulatory requirements. For example, it is comprised of a series of linked, loose leaf pre-printed sheets rather than being fully bound. It appears to be for the use of a pharmacy supplying controlled drugs in the community and is not an appropriate register for use in this setting.
  - The name, strength, volume and form of each drug is not listed at the top of each page of the register (this non compliance was noted at the previous inspection).
  - The waste portion of a controlled drug drawn up but not used is witnessed but not recorded in the CD register (this non compliance was noted at the previous inspection).
  - Disposal of expired controlled drugs is not recorded correctly in the CD register or witnessed by the authorised person.
  - The CD keys are stored securely when not in use. However, when access to controlled drugs is required, the registered nurse in charge may not always be aware of their whereabouts if she is not allocated to work in theatre or recovery.

Recommendation 1.

- Large compressed gas cylinders are stored in an outside area, without being secured or within a secure designated compressed gas storage area (recommendation 3).

- The centre employs a check list mechanism to record when both the anaesthetic equipment and the resuscitation trolley contents have been checked. On the day of inspection this had not been completed for a number of weeks (recommendation 4).

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

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Management of controlled drugs • A number of concerns related to the management of controlled drugs at the centre were noted, as detailed within the report. **Some of these issues are a repeat of non compliances noted at previous inspections.**	• The PR should review the centre's procedures to ensure that the management of controlled drugs is compliant with legal requirements and professional best practice. The PR should provide a summary of the review, including details of the resulting corrective actions when responding to this report. The review should	A review of the Clinic's controlled drugs management procedures has been performed The report of that review is enclosed with this report. Corrective action has been proposed based on the findings of that review. We can confirm the review includes investigation of why some non-compliances have reoccured since the last inspection.	The PR has provided a comprehensive review of the centre's medicine management procedures and a detailed incident investigation report. Corrective actions have been implemented, including obtaining a new fit for purpose CD register. Refresher training in CD management by an authorised third party has also been arranged and will be completed within three months. Quarterly audits of CD management will continue and

• During a routine controlled drugs check on the day of the inspection, according to the CD register one ampoule of a controlled drug had gone missing since the last check had been performed. Further investigation accounted for the 'lost' ampoule, demonstrating that the previous check had not been performed properly. SLC T2, Misuse of Drugs Act 1972, Misuse of Drugs Regulations 2001 and NMC Standards for medicines management.	include an investigation of why some of these non compliances have reoccurred since the last inspection. • The implications of this finding are significant and serious. The PR should investigate this incident and provide a copy of the investigation report, including details of any corrective actions and what learning may be made from this report.	An investigation into that adverse incident relating to controlled drugs has been performed. The report of that investigation is enclosed with this report. Corrective action has been advised and learning objectives have been detailed based on that investigation.	will include the areas of non compliance noted in this report. The executive acknowledges the actions taken and requests that the report of the next CD audit is provided to the centre's inspector, along with confirmation that the refresher training has been provided, by 22 January 2018.

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Infection control • The clinic's waste sharps bins are not dated or signed by the person who assembled them. • The skip for clinical waste located on the lower ground floor was unlocked and was potentially accessible by the public. SLC T2. HTM 07-01 Safe Management of Healthcare Waste.	The PR should ensure that staff are aware of and comply with requirements to ensure that all clinical waste is traceable and that the clinical waste skip is secure at all times. The PR should provide details of the actions taken to ensure this when responding to this report.	The Clinic's senior nurse has raised both of these matters of non-compliance with the entire nursing team. Fortnightly spot checks for compliance with these requirements will be performed by the Senior Nurse during the period September to November 2017 to ensure compliance.	The executive acknowledges the PR's response and commitment to performing spot checks to ensure continued compliance. No further action is required.
3. Safety and suitability of premises	The PR should ensure that all compressed gas cylinders are stored in accordance with	A safe and secure solution for the storage of compressed gas cylinders has been requested from the Clinic's architects and	The executive acknowledges the PR's response and additional information provided that temporary measures have

Large compressed gas cylinders are stored in an outside area, without being secured or within a secure designated compressed gas storage area. SLC T2, Health Technical Memorandum 02-01: Medical gas pipeline systems, Part B: Operational management.	compressed gas safe handling and storage requirements. When responding to this report, the PR should provide details of the action taken to ensure that health and safety requirements are met.	contractors. Since the premises are Grade II listed, the Clinic is the process for obtaining listed building consent for these works. Remedial works will be completed upon receipt of listed building consent. In the event of refusal of consent, the Clinic will ensure an alternative solution is in place.	been put in place to ensure the safe storage of gas cylinders until a permanent solution can be arranged. No further monitoring is required.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. Equipment The centre employs a check list mechanism to record when both the anaesthetic equipment and the resuscitation trolley contents have been checked. On the day of inspection this had not been completed for a number of weeks.	The PR should ensure that the checks of the anaesthetic equipment and resuscitation trolley contents is recorded in accordance with clinic policy. Confirmation of this should be provided when responding to this report. An audit should be performed in three months to ensure adherence to the centre's policy. The report of the audit should be provided to the centre's inspector by 22 October 2017.	Per the Clinic's SOPs, the anaesthetic equipment and resuscitation trolley should be checked each day that the theatre suite is in use. This requirement was raised at the Clinical Staff Meeting in August 2017. As requested, we will perform an audit in three months to ensure adherence to this policy. The report of the audit will be provided to the HFEA by 22 October 2017.	The executive acknowledges the PR's response and commitment to fully implement this recommendation. The audit due by 22 October 2017 is awaited.

Reponses from the Person Responsible to this inspection report