Licence Committee - minutes

Centre 0035 (Oxford Fertility)
Grade A Incident Report

Thursday, 7 May 2020

Teleconference

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Gudrun Moore Jonathan Herring	
Members of the Executive	Dee Knoyle Karen Conyers (Observing)	Committee Secretary Inspector
Legal Adviser	Darryn Hale	DAC Beachcroft LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

Papers enclosed:

- HFEA Serious Grade A Incident Investigation Report
- Centre's Incident Investigation Report
- Licensing minutes from the past three years:
  - 2019-09-03 Executive Licensing Panel Minutes – Interim inspection
  - 2019-07-22 Licensing Officer Record of Consideration - Variation of Licence Holder (LH)
  - 2017-07-14 Executive Licensing Panel Minutes – Renewal Inspection

1. Background

1.1. Oxford Fertility, centre 0035 has been licensed by the HFEA since 1992. The centre provides a full range of fertility services including embryo testing.

1.2. The centre's licence was varied in July 2019 to reflect a change of Licence Holder (LH).

2. Consideration of application

Grade A Incident

2.1. The committee noted that when a licensed centre reports a grade 'A' incident (a serious adverse reaction or event) to the HFEA, the Executive immediately contacts the centre to obtain further information and agree what further action needs to be taken. The Executive also carries out an incident inspection visit to find out why the incident occurred, and the action needed to minimise the risk of a similar incident reoccurring in the future.

2.2. The committee considered the reports, together with the centre's response.

Patient's Medical History Since 2018

2.3. The patient had a previous history of OHSS, deep vein thrombosis (DVT) and necrotising fasciitis following her egg collection cycle in 2018. The HFEA was informed.

First IVF Cycle – Planned Fresh Embryo Transfer – June 2018

2.4. The committee noted that the patient attempted her first fresh IVF cycle in June 2018. Following this cycle, the patient was admitted to hospital with severe OHSS. No embryo transfer took place and all of the embryos created from that cycle were frozen. This information was reported to the HFEA in June 2018.

2.5. Following the patient's hospital admission for OHSS, she developed further complications of pelvic sepsis, pneumonia, DVT and became seriously ill with necrotising fasciitis, for which she had a very poor prognosis of survival. The HFEA was informed by the Person Responsible (PR) in July 2018. After intensive medical and several surgical interventions, the patient recovered from the necrotising fasciitis, and notified the centre of her intention to commence fertility treatment.

Consultation - September 2018

2.6. On 10 September 2018, the patient attended a consultation with a Senior Consultant at Oxford Fertility Centre with a view to undergoing treatment using her frozen embryos. Due to the patient's previous medical history, the Senior Consultant arranged for the patient to see an external Obstetric Physician for a medical opinion on her suitability for treatment.

2.7. The Obstetric Physician provided written advice to the Senior Consultant at Oxford Fertility Centre stating that the Royal College of Obstetrician and Gynaecologists would recommend antenatal prophylaxis from a positive pregnancy test and this would be in the order of 7500 units of Fragmin daily throughout pregnancy and for six weeks postnatal.

2.8. On 4 December 2018, the Senior Consultant at Oxford Fertility Centre documented this recommendation on the patient's electronic patient record (IDEAS) as a medical progress note and created a high priority alert visible to all centre staff, which stated 'Fragmin from positive test (prev DVT)'.

IDEAS

2.9. IDEAS is a medical database management software that is used by fertility centres to store patient records and treatment information.

First Frozen Embryo Transfer Cycle – January 2019

2.10. The patient attended Oxford Fertility Centre for her first frozen embryo transfer cycle in January 2019.

2.11. Fragmin was not started during this cycle.

2.12. The patient had a biochemical pregnancy (miscarriage) at 5 weeks.

Second Frozen Embryo Transfer Cycle – December 2019

2.13. The patient had her second frozen embryo transfer cycle in December 2019.

2.14. The patient did not have a medical review before starting this cycle which resulted in a positive pregnancy. At this time, a medical review was not mandatory at the centre until a patient had undergone three failed cycles.

2.15. On 17 January 2020, the centre was informed by John Radcliffe Hospital, Oxford, that the patient had been admitted to the neurological intensive care unit with a severe cerebral infarction (a blood vessel blockage in the brain affecting the supply of blood and oxygen, commonly referred to as a stroke). The centre reported this as an incident to the HFEA on the same day.

2.16. The centre immediately began an investigation and it was discovered that Fragmin had not been prescribed to the patient and there was no documentation of any discussion with the patient regarding the requirement for her to be given this drug with a positive pregnancy test in either of her frozen embryo transfer cycles.

2.17. The patient had to be fully ventilated and the hormone replacement therapy supporting her pregnancy had to be removed. On 20 January 2020, the patient sadly miscarried her pregnancy.

2.18. The patient has now been discharged from hospital and is making a surprise recovery, able to walk and hold conversations. In March 2020, the patient informed the centre that she is doing well, driving and returning to work. The PR is keeping in regular contact with the family.

HFEA Executive's findings and observations

2.19. The committee noted the findings and observations in the Executive's report:

IDEAS Alert System - over-used

2.20. The alert function on IDEAS was over-used for non-critical information. This meant that the alert to prescribe Fragmin for this patient was overlooked at various points of the patient's treatment cycle. Other non-critical information in relation to the patient's treatment cycle such as general billing and storage billing information was also added as an alert. This non-critical information, which could also be classed as 'high priority', could have masked the importance of the Fragmin alert. At the time of the patient's positive pregnancy result, there were seven high priority alerts on the patient's record.

Medical Review - not completed

2.21. The errors that occurred during the patient's first frozen embryo transfer cycle were not picked up as the patient did not have a medical review before commencing her second cycle. A medical review is not mandatory at the centre until a patient has had three failed cycles, however a consultation is always strongly advised. The lack of medical review following the patients first frozen embryo cycle was a missed opportunity to identify the error of Fragmin not being prescribed for this patient.

2.22. Staff involved are clearly distressed by this incident and the impact that this has had on the patient and her family. Staff affected are being supported and the PR has demonstrated a positive commitment to staff and their wellbeing.

2.23. The PR has engaged with the HFEA in a proactive way, providing regular updates to the Clinical Governance team.

2.24. The PR has fulfilled his duty of candour, maintained close contact with the patient and her family and maintained a positive relationship with the couple. The couple were offered psychological support.

2.25. The Executive is satisfied that the new processes in place are sufficient.

Centre's Action Plan

2.26. The centre has completed a root cause analysis investigation and developed a plan to Introduce a new process for identifying and managing complex patients.

Patients' care plan

- There will be a clear inclusive care plan in place, shared with staff involved in the patient's care and the patient, so that they are proactively involved in their own care.

Medical Review – complex patients

- Complex patients are to have a medical review following each treatment cycle.

IDEAS Alert System

- Guidance for staff has been developed to reduce the number of non-essential alerts on IDEAS and to ensure that the alert function is correctly and consistently used by all staff.
- A new positive test result 'progress note' on IDEAS that confirms the reading of and acting on alerts.

2.27. The committee noted that the centre is part of The Fertility Partnership, a group of fertility centres, and therefore this guidance is to be adopted across the whole group.

HFEA Executive's Recommendations

2.28. The committee noted that on occasion, an incident raises wider questions about standards of quality and care in a centre. As the licensing body, the HFEA considers whether a centre has been non-compliant and whether sanctions, in line with the HFEA Compliance and Enforcement Policy, should be recommended. In this instance the Executive do not consider this would be an appropriate response.

2.29. The committee noted that, as part of the centre's renewal inspection, the Executive will follow up corrective actions to ensure they have been implemented.

3. Decision

3.1. The committee deliberated on the details of the incident and action taken by the centre.

3.2. The committee was deeply concerned about the serious nature of this incident, considering the impact on the couple with much empathy. The committee noted that the couple were offered further meetings and psychological support.

3.3. The committee noted that staff involved are clearly distressed by this incident and the impact that this has had on the patient and her family.

3.4. The committee agreed that such important alerts should always be clearly visible and staff should have the relevant training and guidance available on how to access the information.

3.5. The committee also agreed that medical review is of the utmost importance to identify any pre-existing conditions and help to prevent complications during treatment.

3.6. The committee is satisfied that the centre has managed this incident well and demonstrated that the wellbeing of the couple concerned is paramount.

3.7. The committee accepted the Executive's recommendation not to impose any sanction on the centre as a result of this grade A incident, acknowledging the positive and proactive way this incident has been handled.

3.8. The committee endorsed the Executive's recommendation to follow up corrective actions at the licence renewal inspection to ensure they have been implemented and are effective.

3.9. The committee noted that the HFEA Incident Investigation Report will be published alongside the minutes of this meeting on the HFEA website in the interests of transparency and shared learning with the sector.

3.10. The committee was keen for the learning from this incident to be shared with all licensed centres and requested that the Executive consider how this could be disseminated. In particular, the need for a medical review after each treatment cycle in complex cases and the need for centres to audit their own Alert systems to ensure they are fit for purpose.

4. Chair's signature

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

Signature

Name

Kate Brian

Date

1 June 2020

Serious incident investigation report

Centre name:	Oxford Fertility
Centre number:	0035
Date licence issued:	1 October 2017
Licence expiry date:	30 September 2021
Additional conditions applied to this licence:	None
Date of site visit:	31 January 2020
Inspectors:	Louise Winstone (clinical governance deputy) Sharon Fensome-Rimmer (chief inspector)
Date of Licence Committee:	7 May 2020

1. Purpose of the report

1.1. The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses clinics providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

1.2. Licensed clinics usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a clinic's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

1.3. When a licensed clinic reports a 'grade A' incident (a serious adverse reaction or event) to the HFEA, we immediately contact the clinic to obtain further information and agree what further action needs to be taken. We will also carry out an incident inspection visit to find out why the incident occurred, and the action needed to minimise the risk of a similar incident reoccurring in the future.

1.4. The report together with the clinic's response is presented to the HFEA's Licence Committee for its consideration and to determine if any regulatory action should be taken. The report and the minutes of the Committee decision are published on the HFEA website on the relevant clinic's page in the Choose a Fertility Clinic section. The exception to this practice is where the information may identify a patient.

2. Brief description of the centre and its licensing history

Oxford Fertility has been licensed by the HFEA since 1992. The centre provides a full range of fertility services including embryo testing. The centre's licence was varied in July 2019 to reflect a change of Licence Holder.

3. Summary of incident

3.1. A patient attended Oxford Fertility for her second cycle of frozen embryo transfer. This cycle was successful, and the patient had a positive pregnancy result. The patient sadly suffered a cerebral infarction in early pregnancy, and she was admitted to the neurological intensive care unit at the John Radcliffe Hospital, Oxford. The patient had a previous history of OHSS, deep vein thrombosis (DVT) and necrotising fasciitis[1] following her fresh egg collection cycle in 2018 (HFEA incident number IN06026). In view of her previous history and prior to commencing her frozen embryo transfer cycles, advice was received from an obstetric physician. The advice stated that the patient was to start Fragmin[2] at the time of a positive pregnancy test. An alert was placed on IDEAS[3] but this was not acted upon by clinic staff during her treatment cycles or when the patient had her positive pregnancy test.

[1]Necrotising fasciitis is a bacterial infection that affects the soft tissue and fascia (a sheet or band of fibrous connective tissue separating or binding together muscles and organs). It can occur following a cut or some other opportunity for the bacteria to enter the body, such as surgery.
[2]Fragmin is an anticoagulant that helps prevent the formation of blood clots.
[3]IDEAS is a medical database management software that is used by fertility clinics to store patient records and treatment information.

4. Background information on incident

4.1 The patient had her first fresh IVF treatment cycle in June 2018. Following this cycle, the patient was admitted to hospital with severe OHSS. The patient did not have an embryo transfer and the embryos created from this cycle were frozen.

4.2 Following this hospital admission, the patient developed further medical complications of pelvic sepsis, pneumonia, DVT and necrotising fasciitis.

4.3 This was reported as an incident to the HFEA on 7 June 2018 (incident number IN06026). The HFEA were kept updated by the PR of the centre.

4.4 Following intensive medical and surgical interventions, the patient made a full recovery.

4.5 On 10 September 2018, the patient attended a consultation at Oxford Fertility with a view to undergo treatment using her frozen embryos.

4.6 Due to the patient's previous medical history, the consultant arranged for the patient to see an external obstetric physician for a medical opinion on her suitability to commence treatment.

4.7 The obstetric physician wrote back with the following '….the Royal College of Obstetrician and Gynaecologists would recommend antenatal prophylaxis from positive pregnancy test and this would be in the order of 7500 units of Fragmin daily throughout pregnancy and for six weeks postnatal.'

4.8 On 4 December 2018, the consultant documented this recommendation on the patient's electronic patient record (IDEAS), as a medical 'progress note' and created a high priority 'alert' visible to all clinic staff, which stated: 'Fragmin from positive test (prev DVT)'.

4.9 The patient attended Oxford Fertility for her first frozen embryo transfer cycle in January 2019. This cycle resulted in a biochemical miscarriage at 5 weeks. Fragmin was not commenced during this cycle and she did not have a medical review before commencing her second cycle of frozen embryo transfer[1].

4.10 The patient had her second frozen embryo transfer cycle in December 2019. She had a positive pregnancy test on 27 December 2019.

4.11 On 17 January 2020, the clinic was informed by The John Radcliffe Hospital, Oxford, that the patient had been admitted to the neurological intensive care unit with a severe cerebral infarction[2].

4.12 The clinic reported this as an incident to the HFEA on the same day.

4.13 The clinic immediately began an investigation and it was discovered that Fragmin had not been prescribed to the patient and there was no documentation of any discussion with the patient regarding the requirement for her to be given this drug with a positive pregnancy test in either of her frozen embryo transfer cycles.

4.14 The patient had to be fully ventilated and the hormone replacement therapy supporting her pregnancy had to be removed. On 20 January 2020, the patient sadly miscarried her pregnancy.

[1]At this time, a medical review was not mandatory at the clinic until a patient had undergone three failed cycles, however a consultation was strongly advised.
[2]A cerebral infarction is a blood vessel blockage in the brain affecting the supply of blood and oxygen. It is commonly referred to as a stroke.

4.15 The patient has now been discharged from hospital. She is making a surprise recovery and can now walk and hold conversations. As of 20 March 2020, the patient let the clinic know that she is doing well, driving and going back to work. The PR is keeping in regular contact with the family.

5. Summary findings of the clinic's internal investigation

5.1 The clinic's alert function on the IDEAS system was over-used. Other non-critical information in relation to a patient's treatment cycle was also added as an alert, for example, general billing and storage billing information. This non-critical information which could also be classed as 'high priority' could have masked the importance of the Fragmin alert. At the time of the patient's positive pregnancy result, there were seven high priority alerts on the patient's record.

5.2 A medical review is not mandatory at the clinic until a patient has had three failed cycles, however a consultation is always strongly advised. However, the lack of medical review following the patients first frozen embryo cycle was a missed opportunity to identify the error of Fragmin not being prescribed for this patient.

6. The clinic's action plan

6.1. The clinic has carried a root cause analysis investigation (see appendix 2). Based on this investigation, the clinic plans to:

- Introduce a new process for identifying and managing complex patients so there is a clear care plan in place, and this is shared with staff involved in the patient's care and the patient so that they are proactively involved in their own care.
- Complex patients are to have a medical review following each treatment cycle.
- Guidance for staff has been developed to reduce the number of non-essential alerts on IDEAS and to ensure that the alert function is correctly and consistently used by all staff.
- On IDEAS, there is a new positive test result 'progress note' that confirms the reading of and acting on alerts.
- The clinic are part of The Fertility Partnership therefore this guidance is to be adopted across the whole group.

7. Findings and observations of the HFEA's investigation

7.1. The alert function on IDEAS was over-used for non-critical information. This meant that the alert to prescribe Fragmin for this patient was over looked at various points of the patient's treatment cycle. The errors that occurred during the patients first frozen embryo transfer cycle were not picked up as the patient did not have a medical review before commencing her second cycle.

7.2. Staff involved are clearly distressed by this incident and the impact that this has had on the patient and her family.

7.3. The PR has engaged with the HFEA in a proactive way providing regular updates to the clinical governance team. He has fulfilled his duty of candour responsibilities, has maintained close contact with the patient and her family and has maintained a positive relationship with the couple. The couple have been offered further meetings when they are ready and support, particularly

psychological, if required. The staff affected are being supported and the PR has demonstrated a positive commitment to the staff and their wellbeing.

7.4 We are satisfied that the new processes in place are sufficient.

8. Recommendation to the Licence Committee

8.1 The HFEA, in line with other healthcare regulatory bodies, promotes an open reporting culture – where healthcare professionals are more likely to learn from incidents when they feel safe and secure reporting them – internally and on to the appropriate regulatory bodies.

8.2 On occasion, an incident raises wider questions about standards of quality and care in a clinic. It is right, as the licensing body, that we consider whether a clinic has been non-compliant and whether sanctions, in line with the HFEA Compliance and Enforcement Policy, should be applied.

8.3 In this instance we do not consider this would be an appropriate response. The executive wishes to place this report before the Licence Committee in the interests of transparency and in providing an opportunity for the sharing of learning with the sector.

8.4 The executive endorses the clinic's action plan as thorough and robust and which identifies the root causes and opportunities available to ensure that an incident of this nature does not recur.

8.5 This will be followed up as part of the clinic's renewal inspection in February 2021.

Appendix A Chronology of events

Date and time	Event
June 2018	Patient has fresh IVF treatment cycle. Following this cycle, the patient is admitted to hospital with severe OHSS. Patient then develops further complications of pelvic sepsis, pneumonia, DVT and necrotising fasciitis. All embryos created from this cycle are frozen.
10 September 2018	Patient attends a consultation at Oxford Fertility with a view to undergo treatment using her frozen embryos. Consultant arranges for the patient to see an external obstetric physician for a medical opinion on her suitability for treatment.
4 December 2018	The Obstetric physician writes back with the following '….the Royal College of Obstetrician and Gynaecologists would recommend antenatal prophylaxis from positive pregnancy test and this would be in the order of 7500 units of Fragmin daily throughout pregnancy and for six weeks postnatal.'
4 December 2018	Consultant documents this recommendation on the patient's electronic patient record (IDEAS), as a medical 'Progress note' and creates a high priority 'Alert' visible to all clinic staff, which states: 'Fragmin from positive test (prev DVT)'.
30 January 2019	Patient undergoes her first frozen embryo transfer cycle.
11 February 2019	Patient has a positive pregnancy result, Fragmin is not prescribed.
21 February 2019	Biochemical miscarriage confirmed.
15 December 2019	Patient has her second frozen embryo transfer cycle.
27 December 2019	Patient has a positive pregnancy test.
16 January 2020	The patient is admitted to the neurological intensive care unit at the John Radcliffe Hospital with a severe cerebral infarction. The clinic are informed the following day.

Appendix B Clinic's root cause analysis investigation report

See document included in paper set.