Licence Committee - minutes

Centre 0336 (Simply Fertility)

Grade A Incident Investigation Report

Thursday, 7 March 2019

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Anita Bharucha (Deputy Chair) Ruth Wilde Jonathan Herring	
Members of the Executive	Dee Knoyle Moya Berry	Committee Secretary Committee Secretary (Observer)
Legal Adviser	Gerard Hanratty	Browne Jacobson 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:

- HFEA Incident investigation report
- Centre's Incident investigation report
- Previous licensing minutes to the last renewal:
  - 8 November 2018 – interim report
  - 19 May 2017 – interim & variation of licensed activities and change of premises report
  - 16 October 2015 – renewal report

1. Background

1.1. Simply Fertility, centre 0336 is located adjacent to Baddow Hospital in Chelmsford, Essex. The centre initially held a treatment (insemination using partner/donor sperm) and storage licence from November 2013 and subsequently became a member of The Fertility Partnership. The centre upgraded the clinical and laboratory facilities and successfully applied for a treatment and storage licence to extend its services and provide IVF in May 2017. In relation to activity levels this is a small centre.

2. Consideration of application

Grade A Incident – May 2018

First Treatment Cycle

2.1. The committee noted that a couple had their first cycle of treatment using donor sperm in 2016 at centre 0336. This treatment was unsuccessful. At this time the centre held a treatment (insemination using partner/donor sperm) and storage licence and was a satellite centre for another fully licensed centre.

Second Treatment Cycle

2.2. The couple returned to the centre for a second cycle of treatment using sperm from a different donor, with very similar characteristics to the first donor, and the outcome was successful, resulting in a live birth. By this time centre 0336 held a treatment and storage licence and was licensed to provide a full range of fertility services including IVF.

Third Treatment Cycle

2.3. In May 2018 the couple contacted centre 0336 seeking to reserve the donor sperm used in their second cycle of treatment in order to have a full genetic related sibling for their existing child. They were told that the donor sperm was available for sibling use and reassured that sperm was assigned to them. However, because stock levels were high, and it was not routine practice, the centre did not physically assign the donor to the couple.

2.4. In October 2018, prior to commencing treatment, the couple attended a meeting at the centre to provide consent to treatment and were asked to complete a paper Donor Sperm Acknowledgement Form. At the same time, a member of staff was referring to the original completed form on the computer screen, and the details of the donor characteristics and code from the screen were copied onto the paper form. The completed paper form was then scanned into the electronic system. Unknown to the couple, the Donor Sperm Acknowledgement Form which was copied from the computer screen contained the details of the first donor who had similar characteristics to the second donor.

2.5. The laboratory staff printed off the form the day before the egg collection. On the day of egg collection the couple were spoken to post egg collection and shown a Donor Form and the centre's intention to use this sperm for ICSI was explained to them. An embryo was created using the woman's eggs and the first donor's sperm. The embryo transfer took place.

2.6. The following day a staff member responsible for the sperm donor database, with in-depth knowledge of the allocated donors, identified that the incorrect donor sperm had been used. The senior management team at the centre was informed immediately, and the couple were invited to the centre where the error was explained, and an apology provided alongside the offer of further support.

2.7. The couple have since reported a positive pregnancy test result and plan to go forward with the pregnancy.

Findings of the centre's internal investigation and action taken

2.8. The process of assigning chosen donor sperm for a treatment cycle on the centre's electronic patient management system was not routine practice. The decision as to which donor sperm should be thawed was based solely on the Donor Sperm Acknowledgement Form. The process relied too much on the couple's affirmation that the sperm donor's details shown to them were those of the sperm donor they had selected. The selection process was not verified by an embryologist at the point of preparation of laboratory records.

2.9. An audit of all other cases where sibling donor sperm had been used has been carried out to identify any other discrepancies.

2.10. A review of the entire donor sperm process, from the patient selecting a donor through to laboratory staff removing the sperm from storage in preparation for treatment, and all associated documentation was completed.

2.11. Standard Operating Procedures (SOP) and associated forms have been revised and where necessary new SOPs and forms have been created to improve the sperm donor selection and acceptance process. Nursing and laboratory staff have received training on the new SOP for assigning donor sperm through the centre's electronic patient management system and regular audits of this new process will be performed every six months to assess ongoing compliance.

2.12. Key recommendations and action taken to improve processes to minimise the risk of a similar incident recurring, will be circulated to all other centres within The Fertility Partnership for shared learning. All centres will review, and where necessary, improve their practices/processes to prevent a similar occurrence.

HFEA Executive's findings and observations

2.13. The Executive concluded that there was no formal training provided for the electronic patient management system, and assumptions were made about how information about treatments and associated paperwork would be stored, assuming it would be in chronological order with the most recent first. This assumption was incorrect. The reliance on a single form was not robust enough to prevent this incident

2.14. While the couple were reviewing the Donor Sperm Acknowledgement Form, they mentioned they could not remember the donor's eye colour. This could have been taken as an opportunity to stop and further review the medical records to ensure the correct donor had been selected.

2.15. The Executive acknowledged the positive and proactive way this incident was handled by the centre. During the incident inspection the Laboratory Director clearly demonstrated that the wellbeing of this couple is paramount. The senior management team have also shown a positive commitment to their staff and their wellbeing.

2.16. The Executive is satisfied that, in terms of witnessing and traceability, the changes to practice will reduce the risk of an incident of this nature recurring.

HFEA Executive's Recommendations

2.17. The Executive noted that on occasion, an incident raises wider questions about standards of quality and care in a centre and about the centre's history of compliance and whether the application of sanctions, in line with the HFEA Compliance and Enforcement Policy, would be appropriate. In this case, the Executive do not consider that sanctions would be an appropriate response.

2.18. The Executive endorses the centre's action plan and considers that it is thorough and robust and identifies the root causes and opportunities available to ensure that an incident of this nature does not recur. As the learning has been shared across the group this will also be reviewed as part of the inspection process within the group.

2.19. The Person Responsible has committed to writing a Clinic Focus article reflecting on this incident and on the wider issue of maintaining donor anonymity whilst ensuring patients are provided with the correct donor sperm.

3. Decision

3.1. The committee deliberated on the seriousness of this Grade A incident and the impact on the couple concerned, understanding that the treatment resulted in a pregnancy and the couple are planning for the birth of this child. The committee was satisfied that support has been offered to the couple who have a good relationship with centre staff.

3.2. The committee was satisfied that the centre has managed this incident well and demonstrated that the wellbeing of this couple is paramount. The committee also acknowledged that the senior management team also showed consideration for the wellbeing of staff involved in this incident. The committee was satisfied that the centre has acted responsibly and captured the lessons learned to share across the group.

3.3. The committee accepted the Executive's recommendation not to impose any sanction on the centre as a result of this Grade A incident. However, the serious nature of this incident and the impact on the couple is of concern. Therefore, the committee expects the centre to provide clear evidence, when it applies to renew its licence, that it has learned the lessons from this incident and embedded them into its procedures. The committee is happy to consider an application to renew the licence.

3.4. 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.

4. Chair’s signature

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

Signature

Name

Kate Brian

Date

4 April 2019

Serious incident investigation report

Centre name:	Simply Fertility
Centre number:	0336
Date licence issued:	27 November 2015
Licence expiry date:	26 November 2019
Additional conditions applied to this licence:	none
Date of site visit:	20 December 2018
Inspectors:	Paula Nolan (Clinical Governance Lead), Sara Parlett (Senior Inspector)
Date of Licence Committee:	7 March 2019

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:

2.1. Simply Fertility (the clinic) is a purpose-built fertility clinic adjacent to Baddow Hospital in Chelmsford, Essex. The clinic initially commenced activity under a HFEA treatment (insemination using partner/donor sperm) and storage licence in November 2013. The clinic subsequently became a member of the Fertility Partnership, upgraded the clinical and laboratory facilities and successfully applied for a variation to its licence to a 'treatment and storage' licence in May 2017. In relation to activity levels this is a small sized centre.

3. Summary of incident

3.1. A patient had an unsuccessful treatment cycle at the clinic using donor sperm. The patient went on to have a second successful cycle using sperm from another donor. On returning for a further (third) cycle with the aim of having a genetically full sibling to the existing child, sperm from the first donor treatment cycle was used, in error.

4. Background information on incident:

4.1. The couple underwent their first cycle of treatment with donor sperm in 2016. At that time, the clinic subject of this report did not have a licence to provide IVF services. Rather it was a satellite[1] clinic for another fully licenced clinic (with a licence to provide a full suite of treatments). As such, the treatment took place at that clinic and unfortunately was not successful.

[1] Satellite IVF is where the assessment, drug therapy and monitoring take place at the secondary (satellite) centre but the egg retrieval, embryology and embryo replacement are all carried out at the licensed (primary) centre.

4.2. In 2016, the couple underwent a further treatment cycle at the clinic as it then held a full licence. The couple selected a second donor (with very similar characteristics to the original donor). The treatment was successful, resulting in a live birth.

4.3. The couple contacted the clinic in May 2018, to embark on a further round of IVF to achieve a sibling pregnancy. To do so they sought to reserve the donor sperm used in their second cycle. The clinic confirmed the sperm was available.

4.4. In October 2018 the couple attended a meeting for them to provide consent to treatment (this took place some days prior to commencing treatment) and were asked to complete the Donor Sperm Acknowledgement Form[2].

4.5. When the incident occurred the Donor Sperm Acknowledgement Form was a paper form and was completed by the couple. The member of staff had the original Donor Sperm Acknowledgement Form on the computer screen, so they could check the donor characteristics and the code.

4.6. The form was then scanned into the electronic system and printed off by the laboratory staff the day before the egg collection. The laboratory staff then removed the selected donor sperm from storage and prepared it for treatment.

4.7. On the day of treatment when the woman's eggs were to be collected, the couple were informed by staff that the sperm identified by details on the form was to be used in their treatment. An embryo was created using the woman's eggs and the donor sperm. The embryo transfer took place.

4.8. The following day a member of staff, updating the couple's records on the electronic database, identified the incorrect donor sperm had been used. This member of staff is responsible for the sperm donor database and with their in-depth knowledge of the allocated donors identified that the incorrect donor had been selected.

4.9. The senior management team in the clinic was informed immediately, and the couple were invited to the clinic where the error was explained, and an apology provided alongside the offer of further support.

4.10. The patient has since reported a positive pregnancy test result and plans to go forward with the pregnancy[3].

5. Summary findings of the clinic's internal investigation:

5.1. The process of assigning chosen donor sperm for a treatment cycle on the clinic's electronic patient management system was not routine practice. The decision on what donor sperm to be thawed was based solely on the Donor Sperm Acknowledgement Form. The process relied too much on the patients' affirmation that the sperm donor's details shown to them was the sperm donor they had selected. The selection process was not verified by an embryologist at the point of preparation of laboratory records.

6. The clinic's action plan:

[2] Blank version of the Donor Sperm Acknowledgement Form in use at the time is at appendix B.

[3] See Appendix A for the chronology of events.

6.1. The Person Responsible has carried out a review of the entire donor sperm process (from the patient selecting a donor through to laboratory staff removing the sperm from storage in preparation for treatment) including all associated documentation.

6.2. Based on this review several actions have been carried out:

- the standard operating procedure (SOP) for the sperm donor selection process and the sperm donor acceptance form have been revised;
- a new SOP has been created: "assigning donor sperm through the clinic's electronic patient management system". Nursing and laboratory staff have received training on the new process[4]. Regular audits of this SOP will be performed every six months to assess ongoing compliance;
- embryologists will review and pre-authorise use of all donor sperm;
- sperm donor selection training has been conducted for all relevant staff;
- ensuring sufficient laboratory administration time allocated for all IVF cases. This has been reviewed and accounted for in the 2019/2020 budget for two days per week;
- an audit of all other cases where sibling donor sperm has been used has been carried out to identify any other discrepancies[5];
- an incident "learning log" summarising the incident, key recommendations and actions taken to improve clinic processes to minimise the risk of a similar incident recurring, will be circulated to all other TFP[6] clinics for group-wide learning. All clinics will review, and where identified, improve their practices/processes to prevent a similar occurrence in another clinic.

7. Findings and observations of the HFEA's investigation:

7.1. Although all staff at the clinic had a working knowledge of the electronic patient management system, no formal training had been provided. It was assumed the treatments and associated paperwork would be stored in chronological order (most recent first). Unfortunately, this assumption was not correct. Reliance on a single form was not robust enough to prevent this incident.

7.2. Whist the couple were reviewing the Donor Sperm Acknowledgement Form, the couple mentioned they could not remember the donor's eye colour. This could have been taken as an opportunity to stop and further review the medical records to ensure the correct donor had been selected.

7.3. The positive and proactive way this incident was handled by the senior management team at the clinic should be acknowledged. The couple and their wellbeing are paramount and clearly demonstrated by the Laboratory Director at our incident inspection site visit. The senior management team have also shown a positive commitment to their staff and their wellbeing by the high level of senior management engagement.

7.4. This incident has caused the inspection team to reflect further on good practice in donor sperm identification and allocation. In terms of witnessing and traceability the changes to practice will reduce the risk of the incorrect sperm donor being used because donor sperm is now assigned to a

[4] Training carried out on 3 December 2018.

[5] An audit of 49 records was completed on 18 December 2018. All paperwork correct, and no discrepancies identified. This will feed into the audit cycle and be undertaken every 6 months

[6] The Fertility Partnership.

patient using the electronic patient management system. We are satisfied that a double check by laboratory staff that this assignment is accurate takes place.

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. As the learning has been shared across the group this will also be reviewed as part of the inspection process within the group.

8.5. The Person Responsible has committed to writing a Clinic Focus article reflecting on this incident and on the wider issue of maintaining donor anonymity whilst ensuring patients are provided with the correct donor sperm.

Appendix A

Chronology of events

Date and time	Event
End of 2015	First attendance – couple select donor sperm (**SD A**[7]). IVF treatment not successful. At this time the clinic was a satellite for a centre with a full treatment and storage licence.
July 2016	Second attendance – couple select a different donor (***SD B***[8]). IVF treatment is successful (live birth reported in spring 2017). At this time the clinic was a satellite for a centre with a full treatment and storage licence.
May 2018	Couple contact the clinic explaining they would like to undergo a further cycle of treatment using ***SD B*** (for a full genetic sibling) clinic staff confirmed ***SD B*** sperm was available.
October 2018	Third attendance. Clinic now holds a full treatment and storage licence, so all aspects of treatment carried out on site.
10 October 2018	Couple attended the clinic for the consent meeting. The couple were asked to complete the donor sperm acknowledgement form. This was completed by copying from the screen the details of the donor characteristics from the original donor (**SD A**) sperm acknowledgement form, as directed by the member of staff.
19 November 2018	Prior to the egg collection procedure, it was confirmed with the couple this was the donor sperm to be used in their treatment. The donor sperm acknowledgement form[9] is the only source of reference used to confirm the correct donor sperm has been selected. The donor sperm was removed from storage and used in the couple's treatment.
22 November 2018	Embryo transfer carried out.
23 November 2018	A laboratory technician was collating the couple's records (post treatment) and noticed the original donor sperm (**SD A**) was used in this treatment cycle rather than ***SD B***.

[7] Sperm Donor A
[8] Sperm Donor B
[9] At the time of the incident.

	The laboratory technician immediately escalated this information to the Person Responsible, General Manager and the couple's Consultant. Following this discussion, it was decided to contact the couple and invite them to the clinic to inform them of the error. The options given: Remove luteal support, therefore inducing a bleed and preventing a pregnancy. To carry on with the cycle and await outcome. Counselling was offered. The couple decided to go away and consider the options and were informed senior clinic staff available at all times on the emergency number. Incident reported to the HFEA.
24 – 25 November 2018	Senior clinic staff maintain telephone contact/support with the couple. Couple have been informed senior staff are available at all times. Serious incident investigation process explained to couple. Senior staff expressed a sincere desire to be open and transparent with the couple regarding the incident and what measures have been put in place to minimise the risk of recurrence.
early January 2019	Couple booked in for routine early pregnancy scan. At the appointment the offer of support and counselling was reiterated.

Appendix B

Sperm Donor Acceptance Form

Patient's ~~F~~full Nname:	DOB:
Partner's ~~F~~full Name:	DOB:
Clinic ~~N~~umber:	

Treatment Cycle	Month	Year	
Donor Code:		Centre Number:	

Chosen Donor Characteristics						
Skin:	□ Light/fair	□ Medium	□ Dark	□ Freckles	□ Olive	
Natural Hair Colour:	□ Black	□ Brown	□ Blonde	□ Strawberry Blonde		
Eye Colour:	□ Blue	□ Brown	□ Green	□ Grey	□ Hazel	□ Other
Height:		Comments:				
Weight:						
CMV Status:						

	Please initial to acknowledge
I / We accept that these are the characteristics and Donor code for the donor that is to be used for my / our treatment.	
I / We confirm that we have attended Counselling	
I / We are fully aware of legal parenthood implications and have signed a WP/PP form where applicable.	
Delete the following if not appropriate:	

I am using a CMV +ve donor when my own status is CMV –ve	
I am fully aware of the implications of using a CMV +ve donor in these circumstances.	

Patient's Name:		**Date of Birth:**	**/ /**
Signature:		**Date:**	**/ /**

Partner's Name:		**Date of Birth:**	**/ /**
Signature:		**Date:**	**/ /**

Staff Witness:		**Status:**	
Signature:		**Date:**	**/ /**