# Licence Committee - minutes

## Centre 0119 (Birmingham Women's Hospital)
## Grade A Incident Report

Thursday, 7 May 2020

Teleconference

| | | |
|---|---|---|
| Committee members | Kate Brian (Chair)<br>Anita Bharucha (Deputy Chair)<br>Gudrun Moore<br>Jonathan Herring | |
| Members of the Executive | Dee Knoyle<br>Karen Conyers (Observing) | Committee Secretary<br>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 RCA Report - Grade A Incident
- Licensing minutes up to the last licence renewal:

    - 2019-11-12 Licensing Officer Record of Consideration – Variation Licence Holder (LH)
    - 2019-10-03 Executive Licensing Panel Minutes – Variation Person Responsible (PR)
    - 2018-09-11 Executive Licensing Panel Minutes – Interim Inspection
    - 2016-09-09 Executive Licensing Panel Minutes – Renewal Inspection

## 1. Background

**1.1.** The Assisted Conception Unit at Birmingham Women's Hospital, centre 0119 has been licensed by the HFEA since 1992. The centre currently holds a treatment (including embryo testing) and storage licence and provides a full range of fertility services.

**1.2.** The centre's licence was varied in October 2019 to reflect a change of Person Responsible (PR) and in November 2019 to reflect a change of Licence Holder (LH). The current PR, Dr Jackson Kirkman-Brown is also the PR for research project R0173 at HFEA licensed Centre for Human Reproductive Science, centre 0209. An additional condition has been added to the centre's licence with regards to the recruitment of gamete and embryo donors.

### Additional condition on the licence:

**1.3.** Research project R0173 will not recruit gamete or embryo donors, from centre 0119 while Dr Jackson Kirkman-Brown holds the role of PR for treatment and storage activities at this centre.

## 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 recurring in the future.

**2.2.** The committee considered the reports and the centre's response.

**First Treatment Cycle – July 2017**

**2.3.** The committee noted that a couple attended the centre for treatment using donor sperm. Their first cycle of donor insemination (DIUI) was unsuccessful.

**Second Treatment Cycle – August 2017**

**2.4.** The couple decided to choose a different sperm donor and this was used for a further cycle of DIUI which was also unsuccessful.

**Third Treatment Cycle – October 2017**

**2.5.** The couple then opted for treatment with IVF with the same sperm donor used for their second cycle of DIUI. This cycle was again unsuccessful.

**Fourth Treatment Cycle – February 2018**

**2.6.** The couple had planned to use the same sperm donor and underwent a further cycle of IVF. However, prior to treatment, during their consent appointment, the incorrect donor identification sticker was taken from the donor folder and placed onto the patient's treatment form. This treatment cycle, using the incorrect sperm donor, resulted in a pregnancy. The patient had an early pregnancy scan and was discharged from the centre in March 2018. The couple's baby was born in November 2018.

Donor Identification

**2.7.** The donor sticker with the donor identification code differed by a single digit. The donor sticker was a single white sticker that contained the donor identification code. The donor folder contained individual sheets of stickers for each donor in sequential order. The details from the donor sticker selected were then transcribed to the laboratory sheets and this was the information that was used by the laboratory staff when removing the donor sperm from storage prior to a patients' treatment. Donor allocation was also recorded on an electronic system.

**Former PR Notified of incident – March 2018**

**2.8.** Following the patient's pregnancy scan, the patient's records were reviewed by a member of staff responsible for sperm donor allocation. It was at this point that it was noticed that the incorrect donor had been selected and had been used for the patient's treatment. This was confirmed by reviewing the electronic donor database.

**2.9.** The HFEA was advised that the former PR of the centre was immediately informed of the incident. However, the couple's baby was born in November 2018 and at this point, the couple were unaware that the incorrect donor had been used in their treatment.

**New PR Notified of Incident – October 2019**

**2.10.** The new PR appointed in October 2019 was notified of this incident by two members of staff as they were not aware of any action taken by the previous PR. The new PR immediately investigated and informed the HFEA and the Trust. The process of donor allocation was reviewed and immediate changes were put in place to make the process more robust.

**2.11.** The couple involved were contacted via telephone by the PR and then called into a meeting at the centre with the PR and the Clinical Lead of the centre and offered support and counselling.

## Action Plan

**2.12.** The committee noted that the PR has carried out a review of the entire donor sperm process and a new SOP 'matching donors to recipients' has been developed and put into practice. Nursing and laboratory staff have received training on the new process and regular audits of this SOP will be performed to assess ongoing compliance.

**2.13.** The key change is that the couple both sign the donor information description form to confirm that the correct donor has been chosen.

**2.14.** Checks have been introduced to confirm the donor identity match between the donor profile and the donor allocation profile sheet. The donor allocation is also checked and confirmed on the electronic allocation record.

**2.15.** Forms must also be checked against the donor record and recipient treatment sheets at the time any treatment occurs. If a patient swaps their donor choice, the previous forms are stamped with 'superseded'.

**2.16.** The committee noted that the PR aims to instigate a culture change within the centre to empower staff to speak more freely to ensure that an incident of this nature does not reoccur.

### HFEA Executive's findings and observations

**2.17.** The committee noted that there was no detailed process in place for donor allocation and no second person checks. The system relied upon a single white sticker which was not robust enough to prevent an incident.

**2.18.** It is not clear why this incident was not reported to the HFEA or why no action was taken at the time. This is subject to a separate investigation by the Trust and is outside of the remit of this report.

**2.19.** The centre's investigation report was received in excess of five months after the notification of the incident. The HFEA's Chief Inspector met with the Chief Medical Officer of the Birmingham Women's and Children's NHS Foundation Trust on 13 March 2020 to discuss the outstanding incident investigation report and when it was likely to be provided to the Executive. Further communication with the PR was also required before the report was submitted. However, it is acknowledged that the investigation was conducted by the Trust Clinical Governance team and therefore the centre was not in control of the time frame.

**2.20.** The committee noted that an audit of current patients using donor sperm has been carried out to ensure that the correct donor has been allocated, there were no other discrepancies found.

Witnessing and Traceability

**2.21.** The Executive has reflected 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 there are now check points in place during a patient's treatment cycle to ensure that the correct donor sperm has been assigned. The committee noted that the Executive is satisfied that these checks in place are sufficient.

### HFEA Executive's Recommendations

**2.22.** 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 applied. In this instance the Executive do not consider this would be an appropriate response.

**2.23.** The Executive endorses the centre'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 reoccur.

**2.24.** The Executive will follow up as part of the centre's renewal inspection to ensure all corrective action has been implemented.

## 3. Decision

**3.1.** The committee had regard to the HFEA Compliance and Enforcement Policy.

**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 counselling and the opportunity for further meetings and discussions.

**3.3.** The committee also noted that staff involved were clearly distressed by this incident and the lack of immediate duty of candour to this couple. The committee acknowledged that the new PR has demonstrated a positive commitment to staff and their wellbeing and was reassured to hear that the PR aims to instigate a culture change within the centre to empower staff to speak more freely to ensure that an incident of this nature does not reoccur.

**3.4.** The committee deliberated on the root cause analysis and action taken by the centre. The committee is satisfied that the centre has managed this incident well and demonstrated that the wellbeing of the couple concerned is paramount.

**3.5.** 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 since the new PR was made aware of it. The committee noted that corrective action will be followed up as part of the centre's licence renewal inspection to ensure that more robust systems have been implemented and are effective.

**3.6.** The committee hopes that the Trust has acted upon the lessons learned from this incident and good governance is in place to avoid such an incident reoccurring.

**3.7.** 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

1 June 2020

# Serious incident investigation report

| | |
|---|---|
| **Centre name:** | Birmingham Women's Hospital |
| **Centre number:** | 0119 |
| **Date licence issued:** | 1 December 2016 |
| **Licence expiry date:** | 30 November 2020 |
| **Additional conditions applied to this licence:** | a) Research project R0173 will not recruit gamete or embryo donors, from centre 0119, whilst Dr Jackson Kirkman-Brown holds the role of PR for treatment and storage activities at this centre. |
| **Date of site visit:** | 26 November 2019 |
| **Inspectors:** | Louise Winstone (clinical governance deputy)<br>Paula Nolan (clinical governance lead) |
| **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

**2.1.** The Assisted Conception Unit at Birmingham Women's Hospital 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 November 2019 to reflect a change of Licence Holder and in October 2019 to reflect a change of Person Responsible (PR) and the addition of an additional condition on the licence.

## 3. Summary of incident

**3.1.** A couple attended the clinic for treatment using donor sperm. Their first cycle of donor insemination (DIUI) was unsuccessful. The couple decided to choose a different donor and this was used for a further cycle of DIUI which was also unsuccessful. The couple then opted for treatment with IVF with the same donor used for their second cycle of DIUI. This cycle was again unsuccessful, and the couple undertook a further cycle of IVF using the same donor. However, during the couples' consent appointment for this final cycle, the incorrect donor sperm was allocated. The couple's treatment using this incorrect donor achieved a live birth.

## 4. Background information on incident

**4.1.** The couple underwent their first cycle of DIUI treatment with donor sperm in July 2017. This cycle was unsuccessful. See appendix A for a detailed timeline.

**4.2.** The couple selected a different donor and returned for a further DIUI cycle in August 2017. This treatment was again unsuccessful.

**4.3.** In October 2017, the couple decided to embark on a further round of treatment this time with IVF and donor sperm. They decided to use the same donor that had been used during their second DIUI cycle. This cycle of treatment was unsuccessful.

**4.4.** In February 2018, the couple had a further cycle of IVF choosing to use the same donor. During their consent appointment prior to treatment, the wrong donor identification sticker was taken from the donor folder and placed onto the patient's treatment form.

**4.5.** This cycle resulted in a pregnancy. The patient had an early pregnancy scan and was discharged from the clinic in March 2018.

**4.6.** Following the patient's pregnancy scan, the patient's records were reviewed by the member of staff who is responsible for sperm donor allocation. It was at this point that it was noticed that the incorrect donor had been selected and had been used for the patient's treatment. This was confirmed by reviewing the electronic donor database.

**4.7.** The incorrect donor identification sticker had been taken from the donor folder and placed on the patient's treatment form. The donor sticker with the donor identification code differed by a single digit.

**4.8.** When the incident occurred, the system used by the centre to allocate donor sperm relied on the member of staff selecting the correct donor identification sticker from the donor folder and placing this sticker onto the patient's treatment form. The donor sticker was a single white sticker that contained the donor identification code. The donor folder contained individual sheets of stickers for each donor in sequential order. The details from the donor sticker selected was then transcribed to the laboratory sheets and this was the information that was used by the laboratory staff when removing the donor sperm from storage prior to a patients' treatment. Donor allocation was also recorded on an electronic system.

**4.9.** The HFEA was advised that the PR of the clinic was immediately informed of the incident.

**4.10.** The couple's baby was born in November 2018. At this point, they were unaware that the incorrect donor had been used in their treatment.

**4.11.** In October 2019, the clinic had a change of PR. The new PR was notified of this incident by two members of the clinic staff as they were not aware of any action taken by the previous PR. The new PR immediately investigated and informed the HFEA and the Trust. The process of donor allocation was reviewed and immediate changes were put in place to make the process more robust.

**4.12.** The couple involved were contacted via telephone by the PR and then called into a meeting at the clinic with the PR and the clinical lead of the clinic. They were offered support and counselling.

**4.13.** It is not clear why this incident was not reported to the HFEA at the time and no action was taken. This is subject to a separate investigation by the Trust and is outside of the remit of this report.

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

**5.1.** The decision on the donor sperm to be thawed and used in treatment was based solely on the donor identification sticker that had been placed on the patient's treatment form at the start of the patient's treatment cycle. The process relied on the correct donor identification sticker being chosen from the donor folder by one person. There were no other checks during treatment to

confirm that the correct donor had been allocated and there was no standard operating procedure (SOP) directing staff for the selection of sperm donors.

## 6. The clinic's action plan

**6.1.** The PR 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:

- a new SOP 'matching donors to recipients' has been developed and put into practice. The key change is that the recipient and partner both sign the donor information description form to confirm that the correct donor has been chosen. Two staff members then confirm the donor identity match between the donor profile and the donor allocation profile sheet (DAPA; see Appendix B). The donor allocation is also checked and confirmed on the electronic allocation record. The DAPA form must also be checked against the donor record and recipient treatment sheets at the time any treatment occurs. If a patient swops their donor choice, the previous forms are stamped with 'superseded'.
- nursing and laboratory staff have received training on the new process. Regular audits of this SOP will be performed to assess ongoing compliance.
- an audit of current patients using donor sperm has been carried out to ensure that the correct donor has been allocated, there are no other discrepancies**.**

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

**7.1.** There was no detailed process in place for donor allocation and no second person checks. Reliance on a single white sticker was not robust enough to prevent this incident.

**7.2.** Staff involved are clearly distressed by this incident and the lack of immediate duty of candour to this couple.

**7.3.** The positive and proactive way this incident has been handled since the new PR was made aware should be acknowledged. The couple and their wellbeing are paramount and clearly demonstrated by the PR and clinical lead at our incident inspection site visit. The couple have been offered counselling and the opportunity for further meetings and discussions. The staff affected are being supported and the PR has demonstrated a positive commitment to the staff and their wellbeing. Moving forwards, the PR aims to instigate a culture change within the clinic to empower the staff to speak more freely so that an incident of this nature will not reoccur.

**7.4.** The centre's investigation report was received in excess of five months following the notification of the incident. The Chief Inspector of the HFEA met with the Chief Medical Officer of the Birmingham Women's and Children's NHS Foundation Trust on 13 March 2020 to discuss the outstanding incident investigation report and when it was likely to be provided to the executive. Further communication was also required with the PR before the report was submitted. However, it is acknowledged that the investigation was conducted by the Trust clinical governance team and therefore the clinic were not in control of the time frame.

This incident has again 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 there are now check points in place during a patient's treatment cycle to ensure that the correct donor sperm has been assigned. We are satisfied that these checks 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 to ensure all follow-up corrective actions have been implemented.

## Appendix A Chronology of events

| Date and time | Event |
|---|---|
| July 2017 | First attendance.<br>Couple select donor sperm (A) for DIUI. Treatment is not successful. |
| August 2017 | Second attendance.<br>Couple select a different donor (B) for DIUI. Treatment is not successful. |
| October 2017 | Third attendance.<br>Couple switch to IVF treatment using donor B. Treatment is not successful. |
| February 2018 | Fourth attendance.<br>Couple have a further cycle of IVF using donor B (donor C used in error). Treatment is successful. |
| March 2018 | Couple attend the clinic for their first pregnancy scan. The scan shows a single intrauterine pregnancy, couple are discharged from the clinic. |
| March 2018 | The patient's records are handed to the member of staff responsible for donor allocation. It is noticed that the wrong donor sperm had been used for treatment.<br>The staff member notifies the PR of the incident. |
| November 2018 | The couple's child is born. They are unaware that the wrong donor was used for treatment. |
| 3 October 2019 | Committee minutes are released for a change of PR at the clinic. |
| 21 October 2019 | The new PR is made aware of the incident. He contacts the clinic's inspector by telephone to notify her of the incident. The clinic's inspector notifies the clinical governance deputy. |
| 22 October 2019 | The PR discusses the incident via telephone with the clinical governance deputy and submits an incident report form.<br>The couple are informed of the incident by the PR via telephone and are invited into the clinic for a meeting. They are offered counselling and are given a Trust telephone number to contact the PR any day or time until 9pm. |

## Appendix B donor allocation forms

**Donor Phenotype**

| | | | |
|---|---|---|---|
| Ethnic background | | Build | |
| Religion | | Height | |
| Skin Colour | | Weight | |
| Hair Colour | | Blood Group | |
| Eye Colour | | CMV status | |

| |
|---|
| Donor Stipulations / Conditions: |
| Donor Details |

| | |
|---|---|
| Recipient | Partner (if couple) |

| Signature | Signature |
|---|---|
| DATE | DATE |

**Donor Allocation Phenotype Sheet** **DONOR ID: ……**

| Ethnic background | | Build | |
|---|---|---|---|
| Religion | | Height | |
| Skin Colour | | Weight | |
| Hair Colour | | Blood Group | |
| Eye Colour | | CMV status | |

| Donor Stipulations / Conditions: | |
|---|---|
| Donor Details | |
| Recipient | Partner (if couple) |

CONFIRMATION

| Staff Member | Witness |
| --- | --- |
| DATE | DATE |
| Other Notes:<br><br>TREATMENT TYPE: SIBLING: Y / N | |

## Appendix C Clinic's root cause analysis investigation report

See document included in paper set.