HFEA Licence Committee Meeting

19 September 2013

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

Minutes – Item 2

Centre 0070 (The Bridge Fertility Centre) – Grade A Incident

Members of the Committee:	Committee Secretary:
Sally Cheshire (lay) Chair Debbie Barber (professional) Andy Greenfield (professional) Gemma Hobcraft (lay)	Lauren Crawford Legal Adviser: Sarah Ellson, Field Fisher Waterhouse Observer: Sam Hartley (Head Of Governance and Licensing, HFEA)

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

The following papers were considered by the Committee:

- HFEA's root cause analysis
- Centre's final incident inspection report
- Centre's interim incident reports (1 – 7, including service report for autodialler and most current donor sperm replacement update)
- Templates of letters sent to patients
- Initial information from the MHRA (provided by the PR)
- Previous Executive Licensing Panel minutes for last 3 years:
    a) 17 December 2010 – variation of licence (change of Person Responsible)
    b) 27 June 2012 – licence renewal report
    c) 28 November 2012 – variation of licence (change of Licence Holder)
    d) 15 March 2013 – variation of licence (change of Person Responsible)
- Tabled papers: photos from Statebourne Cryogenics to accompany January 2013 report (described out at page 50 onwards).

The Committee also had before it:

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

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

Consideration

1. The Committee noted this is an incident reporting donor semen samples thawed for treatment in mid-January 2013 that appeared to have a significantly lower post thaw recovery than expected.

2. The Committee noted that the centre has identified the cause of the reported incident to be another incident which occurred over the Christmas and New Year period prior to the planned thawing of the sperm. This involved a tank containing 250 donated sperm samples for use with patients. On 2 January 2013 the local manager arrived at 9am to discover local alarms sounding in the room contain four vapour phase storage tanks containing frozen sperm samples. The nitrogen levels of the tank appeared to be lower than usual but staff observed the samples appeared to still be frozen with the temperature display showing -100 degrees Celsius.

3. The centre moved the donor sperm samples from the affected storage tank to a recently serviced and operational tank. The affected tank was reported for maintenance. The engineer who examined the affected tank explained that the malfunction of the storage tank could have led to transient increases in temperature and therefore it is not known if the temperature had increased prior to 2 January 2013. No members of staff had been present to be alerted by the local alarm and the autodial out system had no contacted the laboratory team on call. The donor semen samples thawed for treatment in mid-January 2013 with lower post thaw recovery than expected came from the affected storage tank.

4. The Committee noted that the centre has reported the incident to the Medicines & Healthcare products Regulatory Agency (MHRA), as equipment failures of this nature also fall within its remit. According to information

supplied by the PR the MHRA considered that a possible cause of the restricted flow of liquid nitrogen to the storage tanks was the positioning of the supply and pressure valves on the supply tanks. This remains the subject of an on-going investigation by the MHRA and the final report is not yet available. The Committee welcomed the updates and ongoing monitoring following the incident.

5. The Committee noted that the HFEA's report states that 'An audit of semen quality for a number of ampoules held in the tanks indicated that samples stored in the affected storage vessel appeared to be compromised. Therefore samples for 250 patients may not be of a suitable quality for use in patient treatments or alternative treatments may now be necessary, for example converting from an intrauterine insemination (IUI) to an Intracytoplasmic sperm injection (ICSI) procedure.'

Decision

6. The Committee decided to adjourn the item for receipt of further information. This information should include:
    a. The MHRA report on the equipment
    b. Further information about the number of patients affected and which treatments have been affected to update the summary as at 7 June 2013.

7. The Committee noted that the Executive is drafting a note for HFEA "Clinic Focus" reminding centre staff of the importance of maintaining critical equipment of this nature. The Committee urged the Executive, with the input of suitable experts, to provide further general guidance and advice to centres on this issue.

8. The Committee urged the centre and the Executive to provide this extra information as soon as possible given that this incident occurred in January 2013.

Signed: Date: 03/10/2013

Sally Cheshire (Chair)

The Bridge Centre (0070) incident inspection report: IN03162
(Report 1st June 2013)

Ms Janine Elson, Deputy Medical Director, HFEA Person Responsible assisted by the Quality Assurance Coordinator

Executive Summary (To 1st June 2013)

Staff at the clinic launched a *Level 2: Comprehensive* [1] root cause investigation into an apparent equipment/mechanical failure of a cryo storage device at the clinic. The incident was reported to the HFEA on 14th of January 2013.

The Bridge Centre hosts a Cryobank facility that provides storage for donor sperm. At the time of the incident the donor sperm was stored in four vapour phase storage tanks and a number of smaller liquid nitrogen tanks.

Donor semen samples thawed for treatment in early January appeared to have a significantly lower post thaw recovery than expected. An audit of semen quality from a number of ampoules held in the tanks, indicates that samples stored in one vapour phase storage tank (VT3) were compromised (VT3).

Following investigation it was discovered that a drop in temperature in the vapour phase tank detrimentally affected the quality of some of the sperm stored in this tank.

The cause of the drop in storage temperature appears to be a failure in the automatic liquid nitrogen top up procedure. Unnoticed equipment damage and possibly incorrectly positioned pressure valves appear to have been contributory factors. The embryology laboratory phone did not receive a automated alarm call from the autodial alarm system so did not alert the on call embryologist to a rise in temperature in the affected storage tank.

The equipment involved includes: vapour phase storage tanks (VT3 and VT2); automatic liquid nitrogen top up system and associated equipment; alarm and alarm transmitter and mobile phone.

Reporting of the incident
A member of the laboratory staff responded to a low temperature alarm on the affected tank on the 2nd of January 2013 on arrival at the Bridge Centre. On discovery all sperm samples were immediately moved to a secondary emergency replacement tank. The incident was reported to the management team on the 15th of January 2013. The incident was immediately reported to the HFEA via the incident reporting system.
The delay in reporting between the 2nd of January and the 15th of January has been investigated and is being dealt with as part of internal JD Healthcare HR processes.

[1] National Patient Safety Agency RCA Guidelines

Terms of Reference

The Bridge Centre opened in 1983; is an HFEA licensed clinic and provides a comprehensive range of assisted reproductive treatments and services to approximately 2000 patients per year. Services include treatment with donor sperm and cryo storage of donor sperm.
A multidisciplinary team of 55 consists of scientists (embryologists and andrologists) laboratory technicians, doctors, nurses, counsellors, genetics specialists, sonographers, management and administrative support staff.

The Centre transferred ownership in December 2012 to the present owners JD Healthcare.

This investigation was commissioned by the Senior Management team and led by the HFEA Person Responsible and the Deputy Medical Director.

Investigation team:

- Dr Alan Thornhill: Scientific Director, Person Responsible until March 2013 and Quality Manager; (NB Dr Thornhill left the employ of the Bridge Centre in March 2013.
- Ms Janine Elson: Deputy Medical Director and Person Responsible from April 2013
- Senior Nurse
- Laboratory manager
- External advisor
- Embryologist
- Counsellor
- Quality Officer
- Quality Assurance Coordinator
- information officer

Reporting/Accountability

Internal

- Daily patient updates between the clinical and laboratory teams;
- Weekly investigation team meetings;
- Weekly Embryology team meetings;
- Weekly clinical meetings;
- Monthly nurse team meetings;
- Monthly management meeting;
- All investigation information/documentation and patient correspondence is stored on the centres K Drive and electronic patient database.

External: HFEA; MHRA; legal services

- Representatives of the HFEA visited the Bridge Centre on the 1st of February 2013. It was agreed that a two weekly update would be provided on progress against the action plan and in particular the number of patients who may be affected and their management.
- 2 weekly reporting to the HFEA reporting continued until the end of May 2013;
- Legal insurers informed;
- MHRA informed and external investigation commenced.
- JD Healthcare Executive Committee (21 February 2013)

Aims and Objectives:

1. Ensure the safety of all stored material at the Bridge Centre;
2. Ensure the safety and timely treatment of patients in the process of a treatment cycle;
3. Ensure continuity of treatment for patients using replacement sperm where necessary
4. Identify the root cause of the incident;
5. Instigate Corrective And Preventative Actions (CAPA);
6. Provide a formal documented report of the investigation and outcome;
7. Share learning from the investigation

Scope:
The scope of the investigation is detailed in the above aims and objectives. This report will not include and any disciplinary procedures (if required). This will be dealt with as using internal human resource, appraisal and disciplinary procedures unless individual neglect or responsibility is proven.

The incident was referred to the MHRA on the 28th March 2013. They are conducting an external investigation. At the time of this report the results of the investigation has not been completed.

Equipment involved.

Statebourne cryogenics Bio system 10 (Vapour phase storage tanks)

The Bridge Centre operates a system where two Biosystem 10 tanks (VT3 and VT2) are automatically filled (on demand from the Biosystem tanks) from a single liquid nitrogen tank Cryostor 180.

November 2012 (pre incident service)
The affected tank, VT3 vapour phase tank is 9 years old and has a full service record. It was last serviced on the 15th of November 2012. The service report showed that the *Biosystem Cryogenically OK and functioning normally.* The service report also states that all alarms were tested as fully functional. The next service was schedule by the engineer for Nov 2013.

The service report also made the recommendation that as two tanks VT3 and VT2 were connected to one automatic liquid nitrogen filler tank that future action should be the manual checks of the liquid nitrogen levels should be checked by dipstick. These were carried out and no concerns about the level of liquid nitrogen were raised. The temperature of the tank was manually monitored with no drop in temperature observed.

January 29th 2013 (post incident service)
On testing the service engineer reported that

- both Biosystems (VT3 and VT2) were working normally with normal fill patterns;
- both Biosystems have good insulation systems with fills every 40-48 hours;
- previous to Christmas of 2012 both Biosystems had been in a “non fill” alarms states due to the lack of liquid nitrogen but this was not a regular occurrence and was correct before any damage to the stored material could occur;
- the Biosystem VT3 had damage done to both the fill line and the external supply pipe. While this would not have stopped the flow of liquid nitrogen it would have restricted the flow of liquid nitrogen (this damage had been done since the last service visit on 15/11/2012)
- the supply tank Cryostor did not have the pressure raising vale open;
- all temperatures on temperature print out are of the warmest temperatures (top of racks)
- VT2 (the second tank) did have slight temperature increases but not outside the working temperature range

Recommendations
All the recommendations including connecting each tank to a single supply source; positioning of pressure and supply valves; review and replacement of alarm systems; weekly testing of alarms; training of staff in liquid nitrogen use and management; check of supply tanks have been addressed.

MHRA investigation
A possible cause of the restricted flow of liquid nitrogen to the storage tanks was the positioning of the supply and pressure valves on the Cryostor180 supply tank. This is the subject of an on going investigation by the MHRA. A report has not yet been made available.

Auto dialler call out:

The auto dialler was routinely tested as part of the servicing contract. The last service was on the 20 March 2012 and showed that one of the telephone numbers entered was incorrect. At the time of the service the correct number was entered and the system passed after retesting. The auto dialler was fully operational.

The report of a service visit on the 29th of January 2013 indicated that:

- the receiver was checked for all the correct alarm functions after setting of the alarm from the transmitter unit.
- all functions were checked and worked including the auto dialler phoning the mobile phone;
- the customer (The Bridge Centre) reported that not all alarms were being phoned out. I would suggest the phone lines are checked, the SD1+ is an exceptionally reliable product and faults reported which involve the SD1+ usually result in intermittent telephone line faults. (Asper Systems Ltd January 2013)

At the time of the incident 4 telephone numbers were connected to the auto dial out system. 3 were not owned or part of the Bridge Centre circuit. The 4th is the embryology laboratory dedicated mobile phone. The 3 unknown telephone numbers were from people who had previously worked for the Cryobank but had left.

During the time period 24/12/2012 – 02/02/2013 the embryology laboratory telephone attached to the auto dialler was not contacted. There is no record on the internal phone log of an incoming call.

The auto dialler system in place at that time was an older model and does not contain a log of call outs. The laboratory contact telephone does not contain a record of being called over this period. The phone company does not maintain a log of incoming calls to the laboratory contact telephone.

CAPA

I. A new auto dialler and alarm system has been purchased and fitted and is tested weekly; This dials out to the existing laboratory telephone number which is checked daily.
II. The call out phone is check and tested weekly and a record made;
III. Checks include a review and reporting of any equipment damage seen;
IV. Staff have been reminded of their responsibility to ensure equipment is checked at every use and any damage immediatly reported.

Instruction manual for liquid nitrogen supply tank

A review of the supplied manual found no specific instructions as to how to supply two storage vessels from the same supply tank (and thus nothing to say what position the pressure valve should be in for this eventuality). While the supply of two dewars from one supply tank may not be common practice, the fact that there are two ports for supply hoses and the lack of either verbal or documented concern during servicing and frequent refilling visits suggests that this practice was not, in itself, hazardous or prohibited. This has been reported to the MHRA **on 28th March 2013.** The MHRA has instigated an incident investigation, however has yet to report its findings.

Equipment conclusions:

- The automatic liquid nitrogen filler system had been damaged by the user (s), this had not been noted or repaired;

- Supply and pressure gauges may have been incorrectly positioned and we await the outcome of the MHRA investigation

- Spills from liquid nitrogen had caused damage to some of the alarm transmitters; this has not been noted or repaired.

Objective 1: Ensure the continued safety of all stored material at the Bridge Centre;

CAPA

I. Manual/visual inspection of the vapour phase tanks continues to be checked daily for temperature and liquid nitrogen levels with recorded temperature, dipstick level, filling vessel pressure checks, general preventative maintenance and routine observations;

II. All vapour phase tanks and related liquid nitrogen equipment and paraphernalia has been fully serviced by qualified engineers and where necessary fully replaced;

III. The internal/local alarms on all the vapour phase tanks have been services and are fully functional

IV. New external alarms have been fitted to the tanks with a new outgoing auto dialler (12 February 2013) – the cycle of nitrogen filling and use for vapour phase tanks is being monitored using dedicated software and reviewed weekly;

V. The alarm testing procedure has been reviewed and updated. All alarms are tested (and documented) weekly by the laboratory staff;

VI. Staff received on site training in the use of liquid nitrogen and equipment management on the 12th of February. All staff will repeat their online liquid nitrogen training/update over 2013;

VII. All donor semen samples are split between two storage dewars;

VIII. All donor semen samples are being moved from the vapour phase storage tanks to new liquid nitrogen tanks;

IX. All donor sperm samples are being moved to the specialist cry store The London Sperm Bank

Objective 2: Ensure the safety and timely treatment of patients in the process of a treatment cycle; and

Objective 3: Ensure continuity of treatment for patients using replacement sperm where necessary

All the sperm stored in the vapour phase tank in question is donor sperm stored between 2002 and 2012. There are a number of sources of the sperm including sperm from Bridge donors and overseas donor banks.

There is evidence that some of the sperm has been affected by the variation in storage temperature. The investigation report from the vapour phase tank manufacture states that sperm may be affected differently depending on its location in the storage tank. This sperm will only be considered for treatment following fully informed consent from patients.

Sperm thaw audit:
Viable and motile sperm were observed in 39 out of the 40 ampoules; however, the post thaw quality in all samples was lower than expected. The clinics accepted motility range in donor samples is 30% or greater, with at 15% or greater cells showing forward progressive motility. The quality of motion was poor in the thawed samples and the percentage of sperm showing rapid progression was not at the level expected for donor samples.

The samples would be suitable for use in ICSI treatment.

The embryo development results obtained after performing ICSI with donor samples that were stored in the affected storage tank, has been promising.
In the two cases, a total of 26 eggs were inseminated with 21 showing normal signs of fertilisation. All of the resulting embryos cleaved, as expected, and were of a suitable quality on the third day of culture to attempt to generate blastocysts. Thirteen blastocysts were formed, of which eight were of 'top' quality.

Reimbursement/Compensation for patients
A schedule of reimbursement/compensation has been agreed and is being offered as appropriate.

Treatment summary:
Four patients were treated with the affected sperm before the incident was recognised and reported. All these patients were offered free further treatment. One patient chose to use replacement donor sperm and is pregnant, one patient chose to use the affected sperm and using ICSI is now pregnant and has a number of good quality embryos in storage. Two patients have replacement sperm and a treatment plan is in place.

Supporting and communication with patients
An emergency mobile telephone line was immediately set up and the number offered in the initial letter to each patient. This was used quite successfully and most patients made contact.
All patients have been informed of the incident, all patient have been offered individual consultation with the Deputy Medical Director and other relevant professionals. Where required alternative treatment plans have been offered at the discretion of the patients. All patient have been offered reimbursement for the cost of the damaged sperm, storage fees over a two year period and where relevant for further additional treatment costs.

Counselling has been offered for all patients and their partners as required.

Reimbursement/Compensation for patients
A schedule of reimbursement/compensation has been agreed and is being offered as appropriate.

Summary of complaints received to date
Feedback and complaints from patients is being coordinated within the management of the incident. At the time of the last report 7 patients had complained via the complaints system; 4 have now been resolved by providing an alternate supply of donor sperm, offering alternate form of treatment or discussion and explanation of the incident.
The remaining complaint is being managed via the Bridge Centre complaints process.

Incident Investigation Report – IN03162

Since October 2009 the HFEA has published A grade incident reports and the associated Licence Committee minutes on our website.

Background of the centre and the licensing history

The Bridge Centre (0070) is a privately run unit offering a wide range of assisted reproduction treatments, including pre-implantation genetic diagnosis (PGD) and pre-implantation genetic screening (PGS). The centre carries out approximately 1600 cycles of licensed treatment a year. The centre has been licensed by the HFEA since 1992, and an inspection following an application to renew the licence took place on 17 and 18 April 2012. At the time of inspection one critical non-compliance, ten major non-compliances and six 'other' non-compliances were noted. The Executive Licencing Panel (ELP) granted the centre a four year licence with no additional conditions.

In January 2012, JD Healthcare Ltd entered into a management agreement to evaluate and restructure the organisation and management of the centre. The centre continues to operate as a separate company. JD Healthcare also owns The London Women's Clinic (LWC) centres (HFEA licensed centres 0059, 0075, 0105 and 0301) and the London Sperm Bank (HFEA licensed centre 0011).

A change of Person Responsible (PR) from Dr Alan Thornhill to Ms Janine Elson was approved by the ELP, with Ms Elson taking up post from 26 March 2013.

Summary Incident Description & Consequences

The centre was closed on 1 January 2013 for the Bank Holiday (no staff were working that day). On 2 January 2013 the laboratory manager arrived at 9am and the local alarms were sounding in the room containing four storage tanks (vapour phase storage tanks containing frozen sperm samples). The laboratory manager and a second member of staff immediately investigated the cause of the alarm, which appeared to be an alarm originating from one of the four storage tanks (storage tank VT3) containing 250 donated sperm samples for the use of patients .

On inspection it was noted that the liquid nitrogen in the tank appeared low and the temperature display showed -100 degrees Celsius. The interior of the unit was examined: lower levels of liquid nitrogen than usual was observed and additional liquid nitrogen was immediately added to the affected tank. The laboratory staff observed that the sperm samples appeared to be frozen.

The laboratory manager then confirmed the recently serviced (November 2012) neighbouring tank was operational and the temperature was correct and, along with a second embryologist, systematically moved the donor sperm samples from the affected storage tank to it. The affected storage tank (VT3) was then turned off, removed from service and allowed to dry out. Following these actions the engineer was then called out.

Subsequently, donor semen samples thawed for treatment in mid-January 2013 appeared to

have a significantly lower post thaw recovery than expected. Donor sperm from the affected tank thawed previously for use in treatment met its expected post thaw quality. An audit of semen quality for a number of ampoules held in the tanks indicated that samples stored in the affected storage vessel appeared to be compromised. Therefore samples for 250 patients may not be of a suitable quality for use in patient treatments or alternative treatments may now be necessary, for example converting from an intrauterine insemination (IUI) to an Intracytoplasmic sperm injection (ICSI) procedure.

This is the first time an incident of this nature has been reported by this centre.

The engineer who examined the affected tank explained that the malfunction of the storage tank could have led to transient increases in temperature and therefore it is not known if the temperature had increased prior to 2 January 2013, but that no members of staff had been present to be alerted by the local alarm.

The PR explained that he can only narrow down a period of time that the equipment malfunction may have occurred to between 24 December 2012 and 2 January 2013. Further it is clear he was unable to interrogate temperature data to determine the exact time point(s) when the temperature increased, as these data are not kept. As regards this particular model of storage tank only when the temperature has increased in the tank is the alarm triggered. The PR explained that the centre is exploring replacing the monitoring system with one that will record the data points measured.

It is also unclear why the 'autodial out' system had not telephoned the number held by the member of the laboratory team on-call. As with the tank alarms, the dial out system is an older model and does not have the facility to log when it is triggered making it difficult to explore this aspect of the incident in any further detail.

The executive advised that the PR report the incident to the Medicines & Healthcare products Regulatory Agency (MHRA), as equipment failures of this nature also falls within its remit. According to information supplied by the PR the MHRA considered that a possible cause of the restricted flow of liquid nitrogen to the storage tanks was the positioning of the supply and pressure valves on the supply tanks. This remains the subject of an on-going investigation by the MHRA and the final report is not yet available. The PR will provide a copy of the report to the Executive when it is available[1].

Incident type:	Equipment malfunction
Specialty:	Cryostorage facility
Effect on patient/donor:	Psychological distress Patients may have to cancel and re-schedule treatment cycles while replacement samples are sourced. Stock may no longer be available for patients to have genetically related siblings. Donors may be asked to provide further samples at a time they may not be convenient for them.
Severity level:	A grade incident

[1] If the MHRA findings are dramatically different to those above a copy of the report will be provided to the Licence Committee.

Terms of Reference

- To identify the root causes and key learning from this incident and use the information to significantly reduce the likelihood of future harm to material stored in similar vessels
- To provide a means of sharing learning from the incident sector wide

Scope and Level of Investigation

Site visit took place on 1 February 2013. Present from the HFEA: Paula Nolan (Clinical Governance Lead/Inspector), Sara Parlett (Scientific Inspector). Present from the centre: Person Responsible and the Quality Assurance Coordinator.
Interview with senior staff
Document and Standard Operating Procedures review
Root Cause Analysis

The executive has taken longer than usual to put this report before the Licence Committee. This is partly due to unexpected peaks in incident management workload and new licence committee schedules.

Involvement and support of Patient and Relatives

The HFEA has received several telephone queries from patients enquiring if the centre has reported this as an incident and how to make a complaint. The HFEA has written to the centre on behalf of one couple asking for further clarification in relation to a complaint response. See below for support the centre has offered to patients potentially affected by this incident.

Chronology of events - See table overleaf

Notable Practice

Senior staff at the centre triaged the different categories of patients potentially affected by the incident as a matter of priority. Patients who were to attend the centre for treatment that month were contacted by telephone and the situation explained to them (with the offer of counselling and a meeting with the PR). Following this a number of bespoke letters (depending on the impact on the patient) were sent out. Patients were offered a meeting with the PR and sessions with the counsellor if required. The letters included a dedicated "support line" available 24 hours a day, as well as the contact telephone number for the centre's counsellor.

The previous and current PR initiated a global search to match and/or replace the donor sperm samples no longer suitable for patients' treatment.

The PR was required to provide an update every two weeks regarding the number of patients potentially affected/no longer affected by this incident. The PR was diligent in providing this information.

Care and Service Delivery Problems (Themed and prioritised)

The liquid nitrogen supply tank did not have the pressure valve open therefore was not on the optimum setting for supplying liquid nitrogen to two storage vessels.

The storage tank had damage to both the fill line and the external supply pipe (however this damage would not be visible to centre staff unless they physically checked the back of the equipment). While this would not have stopped the flow of liquid nitrogen it would have restricted it.

The storage tank alarm system did not dial out to alert centre staff.

Contributory Factors

The manufacturer's user manual does not mention valve positioning if running two storage vessels from one liquid nitrogen supply tank.

Centre staff were not aware that the affected tank had suffered damage to both the fill line and the external supply pipe.

Inadequate SOP in relation to routine alarm testing: an external company performed annual alarm checks however the SOP stated regular checks need to be performed without giving the frequency.

Routine assessment and maintenance of tanks suboptimal.

Older types of equipment (both storage tanks and alarm systems) do not have the facility to continuously record and store data making it difficult to ascertain the exact time of the equipment malfunction (and if the temperature fluctuated once or on several occasions).

Root Cause

Critical equipment (both tank and alarm system) was not maintained correctly.

Lessons Learned

- Critical equipment must be maintained to suit their intended purpose. Frequency of maintenance needs to be carefully assessed by the centre and reflected in its SOPs.
- The scope of maintenance also needs to be carefully assessed and the following should be considered:
    - 360^{o} visual inspection of critical equipment
    - Thorough interrogation of the alarm system to include confirmation that the auto-dial facility works and will contact the correct telephone numbers of staff outside normal working hours.
    - If possible use alarm systems where call out information can be logged or recorded.
- Staff should be fully trained in the operation of the specific make/model of all critical equipment. Refresher training should be provided as applicable in relation to staff changes.

Action Plan (from the centre's report and already implemented)

Immediate action following incident:

- Ensure the three remaining tanks are operational.
- Decant samples from the affected tank and tank taken out of use.
- Daily manual assessment of the integrity of the tanks, daily temperature logging, daily visual assessment of external displays, daily visual confirmation of liquid nitrogen levels (including checking at weekends).

- Alarms tested on all storage tanks not involved in the incident.
- Servicing and evaluation of the vapour phase tanks involved, the liquid nitrogen "feeder" cylinders and associated equipment, analysis of electronic print outs of temperature and automatic liquid nitrogen "top ups". Following initial inspection, servicing and repair by the engineer of the liquid nitrogen tank, the electronic top up system and equipment for the three tanks in service (VT1, VT2, VT4).
- Service and evaluation of the external "call out" autodial alarm system.

Triage & escalation re patient contact:

- Determine the number of patients who may have their treatment cycles affected
- Triage the categories of patients that may be potentially affected giving priority to patients planning treatment for sibling use, patients in a treatment cycle and patients about to begin treatment[2].
- All patients contacted to receive an individualised letter from the Deputy Medical Director explaining the situation, offering support and providing the contact details of a dedicated "support line", an offer of a consultation with a doctor (the Deputy Medical Director or alternative on the choice of the patient), an offer of a counselling session with the counsellor if required.
- To source replacement sperm.

On-going remedial actions (all completed):

- The internal/local alarms on all the vapour phase tanks are functional and new external alarms have been fitted to the tanks with new outgoing autodialler.
- The cycle of nitrogen filling and use for vapour phase tanks is being monitored using dedicated software and reviewed weekly.
- The new alarm replacement programme continues for the (unaffected) liquid nitrogen dewars.
- Further replacement work is on-going including new level gauges for existing filling vessels.
- The alarm testing procedure has been reviewed and updated. All alarms will be tested weekly.
- Staff have received on-site training in the use of liquid nitrogen and equipment management. The training will be repeated/updated for all staff later on in the year
- All donors semen samples have been split between two storage dewars, the samples have been moved from the vapour phase tanks to the new liquid nitrogen tanks and will be moved to the specialist cryostorage facility at The London Sperm Bank.

HFEA actions

- Draft article for "Clinic Focus" reminding centre staff of the importance of the maintaining critical equipment of this nature.

Authors	Paula Nolan (Clinical Governance Lead/Inspector) Sara Parlett (Scientific Inspector)	**Date**	1 July 2013

[2] In the first instance these patients will have been contacted by telephone and then followed up with a letter.

Chronology of events	
Date & Time	**Event**
31/12/2012	Normal working day at the centre: no internal audible alarms were heard from the four vapour phase tanks (VT1, VT2, VT3 and VT4).
01/01/2013	Centre closed for the Bank Holiday.
02/01/2013	Normal working day at the centre. The Laboratory Manager arrived at 9am to hear the local alarms sounding in the room containing the 4 vapour phase tanks. On hearing the alarm the Laboratory Manager and another embryologist immediately investigated. Only the alarm on vapour phase tank 3 was sounding. On visual inspection it was noted that the liquid nitrogen in the tank appeared low and the external temperature display showed -100^{o}C. The interior of the unit was examined: approximately 5cm of liquid nitrogen observed and on visual inspection the sperm samples appeared to be frozen. Additional liquid nitrogen was immediately added to the affected tank. The Laboratory Manager then ensured the operational status and correct temperature of the recently serviced neighbouring tank (VT1) and, along with a second embryologist, systematically moved the donor sperm samples from the affected tank (VT3) to VT1. VT3 was then turned off, put out of service and allowed to “dry out” before the engineer was called out.
14/01/2013	During the course of providing treatments it was noted that sperm samples from three separate donors were of an unexpected low quality post thaw. This was reported as an internal non-conformity and following further assessment and investigation an adverse incident was raised. The HFEA informed via the incident reporting system.
01/02/2013	HFEA Site visit.

28/03/2013	Incident reported to the MHRA (Medicines and Healthcare Regulatory Agency).