Licence Committee - minutes

Centre 0094 (Barts Health Centre for Reproductive Medicine)
Renewal Licence & Investigation Report

Thursday, 6 September 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Kate Brian (Chair) Ruth Wilde Anita Bharucha	
Members of the Executive	Dee Knoyle	Committee Secretary
Legal Adviser	Ros Foster	Browne Jacobson LLP
Specialist Adviser		
Observers	Jonathan Herring (New Authority Member Induction)	

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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- Renewal Inspection Report
- Renewal Application Form
- HFEA Incident Investigation Report
- Centre's Incident Investigation Report
- Previous licensing minutes to the last licence renewal
    - 10 May 2018 - variation of premises to re-locate cryostore
    - 29 March 2017 - variation of licence to change Licence Holder
    - 19 October 2016 - interim inspection report
    - 7 August 2015 - variation of licence to change Licence Holder
    - 25 July 2014 - variation to change centre name
    - 10 July 2014 - whistleblower report
    - 10 July 2014 - renewal inspection report

1. Background

1.1. Barts Health Centre for Reproductive Medicine, centre 0094 has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services.

1.2. The current licence was varied to reflect the following changes:

- August 2015 - change of Licence Holder
- March 2017 - change of Licence Holder to Barts Health NHS Trust;
  Professor Charles Knight is the emergency contact person.
- May 2018 - change of premises to account for the addition of a new cryostore on the ground floor of the building.

Interim Inspection – July 2016

Inspection

1.3. The committee noted that following an interim inspection in July 2016 recommendations for improvement were made in relation to two major areas of non-compliance. The Person Responsible (PR) provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. The committee noted that the non-compliance relating to two unsecured cylinders in the embryology preparation room had reoccurred, but the PR has reported that new brackets have now been fitted to secure the cylinders before they are taken into the laboratory.

Monitoring

1.4. In 2017, the centre received one performance-related alert with regard to its multiple birth rate. The PR responded to the alert and the multiple birth rate is now expected to be within the acceptable range.

Renewal Inspection – May 2018

1.5. A renewal inspection was carried out on 15 and 16 May 2018 and recommendations were made in respect of a number of areas of non-compliance, including one critical area relating to access to an on-call anaesthetist and review of the sedation-analgesia procedure, to ensure that it is fit for purpose. Five major and four other areas of non-compliance were also identified.

1.6. The inspectorate has now submitted the report of the renewal inspection for consideration by the Licence Committee.

Grade A Incident – July 2018

1.7. An incorrect gas cylinder was connected to the incubator, attached as the back-up cylinder and became active on 27 July 2018 .

1.8. The Executive has now submitted the report of the incident for consideration by the Licence Committee alongside the renewal inspection report.

2. Consideration of application

Renewal Inspection

Application

2.1. The committee noted that the centre had submitted an application for the renewal of the treatment and storage licence.

2.2. The committee noted that the application contains the supporting information required by General Direction 0008 and that the appropriate fee has been paid.

Inspection Process

2.3. The committee noted that between April 2017 and March 2018 the centre provided 1118 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

2.4. The committee noted that for IVF and ICSI, HFEA-held register data for the period January 2017 to December 2017 showed the centre's success rates were in line with national averages.

2.5. The committee noted that in 2017, the centre reported 21 cycles of partner insemination with five pregnancies. This is in line with the national average.

2.6. Between January 2017 and December 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

2.7. The committee noted that the renewal inspection took place on 15 and 16 May 2018. The renewal inspection report covers the performance of the centre since the last inspection, the findings from the renewal inspection visit and communications received from the centre.

2.8. The committee noted that at the time of the renewal inspection there were a number of areas of practice that required improvement:

Critical areas of non-compliance:

- The PR should ensure that the clinical and nursing team have access to an on-call anaesthetist and that a review is performed of the sedation-analgesia procedure, to ensure that it is fit for purpose.

Major areas of non-compliance:

- The PR should ensure that the staff numbers and skills mix are appropriate to, at all times, support the licensed activity undertaken;
- The PR should ensure that the centre's premises facilitate adherence to infection control and health and safety standards;
- The PR should ensure the centre has effective risk management processes and that the premises are safe and suitable for the activities undertaken;
- The PR should ensure that effective written consent is in place for all gametes and embryos that are in storage;
- The PR should repeat the risk assessment related to the age of the incubators in the laboratory and take appropriate actions to mitigate the risks identified.

‘Other’ areas that require improvement:

- The PR should ensure that patients and donors are assessed as part of the pre-treatment pathway for risks associated with exposure to the Ebola virus;
- The PR should ensure that invoices from the HFEA are paid within the time frames stipulated by the authority;
- The PR should ensure that disclosure consent and other treatment data submissions to the HFEA register are accurate;
- The PR should ensure that a SOP for clinical emergencies is documented and that traceability audits document appropriate corrective and preventative actions.

2.9. The committee noted that since the inspection the PR has addressed three of the ‘other’ areas of non-compliance and committed to implementing all of the outstanding recommendations.

2.10. The committee noted that representatives from Barts Health NHS Trust (which is the licence holder and provides funding and premises for the centre) joined the inspection team and the PR for a meeting on the second day of the inspection to discuss areas of significant concern and that, as a result of this meeting, immediate and appropriate actions were taken.

2.11. The committee noted that the inspectorate recognises the commitment and dedication of the PR and her team to their patients and the quality of the services that they provide. The inspectorate also noted that some of the non-compliances documented in the inspection report had been identified by the PR prior to the inspection, along with solutions, and recognised that it was not in the PR’s control to implement those solutions due to financial constraints within the Trust. These non-compliances had been logged on the ‘Trust risk register’ (which the centre has input into) and, in the opinion of the inspectorate, were not addressed in a timely manner to match the risk ratings. This could have an adverse effect on treatment outcomes, patient satisfaction and ultimately on the safety of patients and staff. The inspectorate considers this is not satisfactory and the NHS Trust relationship needs to improve so as to allow identified risks to be addressed and managed appropriately.

2.12. The committee noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor and improve success rates and the quality of the service offered to patients.

Recommendation for renewal of treatment and storage Licence

2.13. The committee noted that the inspectorate recommends the renewal of the centre’s treatment and storage licence for a period of four years without additional conditions, subject to the recommendations made in the inspection report being implemented within the prescribed timescales.

2.14. The committee noted that the inspectorate will continue to monitor the centre’s performance and the implementation of the recommendations made in the inspection report.

2.15. The committee noted that the centre’s current licence is due to expire on 30 September 2018 and therefore the inspectorate has also recommended that the committee issues Special Directions under Section 24 (5A)(b) of the HF&E to permit the continuation of the centre’s current licensed activities when the current licence expires. This will allow time for the licence renewal process.

Grade A Incident – July 2018

Incident

2.16. The committee noted that centre staff noticed that embryos for eleven patients showed poor development, equivalent to a day behind the expected period. Some embryos were also showing signs of degeneration.

Investigation

2.17. The centre investigated the issue and found that an incorrect gas cylinder was connected to the culture incubators. Instead of pre-mixed 5% oxygen/ 6% CO2/ N2 the cylinder contained pre-mixed 9% helium in air. The helium cylinder had been delivered to the department in error. The centre does not use helium.

2.18. All eleven patients were informed and their embryo transfers cancelled. The centre allowed the embryos in culture to perish due to concerns over the effect of helium gas on the viability of the embryos and risk to the unborn child.

Findings of the centre's internal investigation:

2.19. The committee noted the findings of both the centre's and the HFEA's investigations into the incident and in particular, the fact that the Executive acknowledged the positive and proactive way the incident had been handled by the Trust. The Trust had put patients and their needs at the centre of its actions. All the patients affected by the incident had started or were about to start a complementary cycle of treatment.

2.20. The Trust had also shown a positive commitment to its staff and their wellbeing by the high level of senior management engagement and support including a debriefing meeting with the staff directly involved in the incident, a meeting involving all centre staff, the offer of counselling to all staff affected and further meeting updates.

Recommendations following Grade A Incident

2.21. The committee noted that the Executive has submitted this incident report for consideration in the interests of transparency and the opportunity to share learning with the sector. The Executive has considered whether this incident raises wider concerns about standards of quality and care in the centre and whether the centre has been non-compliant, as well as whether sanctions should be applied, in line with the HFEA Compliance and Enforcement Policy. The Executive has concluded that, in this instance, there are no such concerns.

2.22. The committee noted that the Executive has endorsed the centre's action plan as thorough and robust, identifying the root causes and opportunities available to ensure that an incident of this nature does not recur. The Executive will share a copy of the Trust's Serious Untoward Incident (SUI) report with the committee at a future meeting once this has been signed off by the Trust.

2.23. The committee noted that, in light of this incident, the Executive will issue an Alert to the sector about the safe distribution and receipt of special mixed gas cylinders.

3. Decision

3.1. The committee had regard to its decision tree, the HFEA Compliance and Enforcement Policy and HFEA Guidance on Licensing.

Administrative Requirements

Supporting Information under General Direction 0008

Application – Licence Renewal

3.2. The committee was satisfied that the application was submitted in the form required and contained all the supporting information required by General Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid.

Proposed Person responsible (PR) – Ms Bonnie Collins

3.3. The committee noted that the proposed PR, Ms Bonnie Collins is willing to assume the responsibility of the role of PR.

3.4. The committee was satisfied that the proposed PR possesses the required qualifications and experience and that the character of the proposed PR is such as is required for supervision of the licensed activities. It was further satisfied that the proposed PR will discharge her duties under section 17 of the HFE Act 1990 (as amended). The committee noted that the inspectorate was satisfied that the proposed PR had satisfactorily completed the PR entry programme. The committee agreed to the appointment of the proposed PR.

Activities

3.5. The committee was satisfied with the suitability of the activities applied for.

Premises – Barts and the London NHS Trust, 2nd Floor, Kenton and Lucas Wing, St Bartholomew's Hospital, Little Britain, London, EC1A 7BE

3.6. The committee noted that the premises were considered to be partially suitable. The committee was satisfied that the PR has committed to implementing the recommendation relating to staff facilities.

3.7. The committee noted that the centre does not use any third-party premises.

Licence

3.8. The committee had concerns about the number and seriousness of the non-compliances outlined in the renewal inspection report. The committee was particularly concerned with the critical area of non-compliance relating to access to an on-call anaesthetist and review of the sedation-analgesia procedure. The committee noted the immediate action taken by the Trust and the PR to address this critical non-compliance. The committee also expressed concern about staff numbers and skills mix to support the licensed activity undertaken and about the replacement of some of the incubators, which are seven years old and no longer serviced by the manufacturer. The committee noted that a business case for replacement of the incubators has now been approved by the Trust.

3.9. The committee considered issuing a three-year licence, rather than the usual four, due to the number and seriousness of the non-compliances. In considering the length of licence to grant, the committee had regard to the HFEA Guidance on Licensing. After careful consideration, and having noted that the major areas of non-compliance had been addressed and accountability and engagement shown by the Trust, the committee agreed to endorse the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years without additional conditions. However, the committee also agreed that a targeted inspection to follow up the implementation of the recommendations made in the inspection report should be completed within one year of the new licence coming into effect.

3.10. The committee also endorsed the inspectorate's recommendation to issue Special Directions under Section 24 (5A)(b) of the HF&E Act to permit the continuation of the centre's current licensed activities when the current licence expires on 30 September 2018, to allow time for the licence renewal process.

3.11. The committee acknowledged the commitment and dedication of the PR and her team who have taken appropriate action. The PR has committed to implementing the recommendations made in the renewal inspection report, working within the financial constraints of the Trust. The committee acknowledged that representatives from the Trust attended the renewal inspection and accepted accountability for the implementation of the recommendations. The committee requested that the Chief Executive and any other relevant representatives of the Trust be sent a copy of these minutes, which are an official record of its discussions and considerations, and urged the Trust to remain engaged and receptive to issues raised by the inspectorate.

Grade A Incident

3.12. The committee expressed sympathy for the patients involved and was satisfied that they were appropriately informed and corrective action had been taken.

3.13. The committee agreed that the centre's response to the Grade A incident was exemplary.

3.14. 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 sharing leaning 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

26 September 2018

Inspection Report

Purpose of the inspection report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee (LP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 15 and 16 May 2018

Purpose of inspection: Renewal of a licence to carry out Treatment and Storage

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Janet Kirkland (lead), Susan Jolliffe, Louise Winstone and Nicola Sugden (observing).

Date of Licence Committee: 6 September 2018

Centre name	Barts Health Centre for Reproductive Medicine
Centre number	0094
Licence number	L/0094/15/d
Centre address	Barts and the London NHS Trust, 2nd Floor, Kenton and Lucas Wing, St Bartholomew's Hospital, Little Britain, London, EC1A 7BE, United Kingdom
Person Responsible	Ms Bonnie Collins
Licence Holder	Barts Health NHS Trust
Date licence issued	1 October 2014
Licence expiry date	30 September 2018
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Barts Health Centre for Reproductive Medicine has held a Treatment and Storage licence with the HFEA since 1992 and provides a full range of fertility services.

According to HFEA data the centre provided 1118 cycles of treatment (excluding partner intrauterine insemination) between April 2017 and March 2018; in relation to activity levels this is a large centre.

Other licensed activities at the centre include the storage of gametes and embryos.

The current licence was varied on 7 August 2015 to change the Licence Holder, then on 29 March 2017 to change the Licence Holder to the Barts Health NHS Trust; Professor Charles Knight is the emergency contact person. The current licence was also varied on 10 May 2018, immediately before the inspection, to account for the addition of a new cryostore on the ground floor of the building.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period January 2017 – December 2017 show the centre's success rates are in line with national averages.

In 2017, the centre reported 21 cycles of partner insemination with 5 pregnancies. This is in line with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between January 2017 and December 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008, Standard Licence Conditions (SLCs) and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are partially suitable (see recommendation 4);
- the centre's practices are partially suitable (see recommendation 1 and 2);
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The LC is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one critical, five major and four 'other' areas of non compliance.

Since the inspection the PR has fully implemented the following recommendations:

'Other' areas that require improvement:

- The PR should ensure that patients and donors are assessed as part of the pre-treatment pathway for risks associated with exposure to Ebola virus;
- The PR should ensure that invoices from the HFEA are paid within the time frames stipulated by the authority;
- The PR should ensure that disclosure consent and other treatment data submissions to the HFEA register are accurate.

The PR has given a commitment to implement the following recommendations

Critical areas of non compliance:

- **The PR should ensure that the clinical and nursing team have access to an on-call anaesthetist and that a review is performed of the sedation-analgesia procedure, to ensure that it is fit for purpose.**

Major areas of non compliance:

- The PR should ensure that the staff numbers and skills mix are appropriate to, at all times, support the licensed activity undertaken;
- The PR should ensure that the centre's premises facilitate adherence to infection control and health and safety standards;
- The PR should ensure the centre has effective risk management processes and that the premises are safe and suitable for the activities undertaken;
- The PR should ensure that effective written consent is in place for all gametes and embryos that are in storage;
- The PR should repeat the risk assessment related to the age of the incubators in the laboratory and take appropriate actions to mitigate the risks identified.

‘Other’ areas that require improvement:

- The PR should ensure that a SOP for clinical emergencies is documented and that traceability audits document appropriate corrective and preventative actions;

Recommendation to the Licence Committee

The centre has one critical, five major and four ‘other’ areas of non compliance.

It is acknowledged that representatives from the Trust joined the inspection team and the PR for a meeting on the second day of the inspection to discuss areas of significant concern and that, as a result of this meeting, immediate and appropriate actions were taken, as detailed in the report.

The inspection team recognises the commitment and dedication of the PR and her team to their patients and the quality of the services that they provide. We also note that some of the non-compliances documented in this report had already been identified by the PR, along with solutions, but that it is not in the PR’s control to implement the solutions because of financial constraints within the Trust. Such non compliances are then logged on the ‘risk register’ and, in the opinion of the inspection team, are not addressed in a timely manner commensurate with the risk ratings. This could have an adverse effect on treatment outcomes, patient satisfaction and ultimately on the safety of patients and staff. The inspection team considers this to be a major non compliance within the centre – NHS Trust relationship, as is noted elsewhere in this report.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/ live birth rates meet the target. Some improvement is required in order for the centre to demonstrate the suitability of their practices. The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor and improve their success rates and the quality of the service offered to patients.

The lead inspector will continue to monitor the centre’s performance and the implementation of this report’s recommendations within the required timescales.

The inspection team recommends the renewal of the centre’s Treatment and Storage licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

The centre’s current licence is due to expire on 30 September 2018. If the LC approves the renewal of the centre’s licence, the LC may need to consider issuing Special Directions under Section 24 (5A) (b) of the HF&E Act 1990 (as amended) to permit the continuation of the centre’s current treatment and storage activities if a renewed licence cannot be issued in time.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests
Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
At the time of the inspection the centre team were no longer recruiting donors but had done so in the past. Their procedures were discussed and were considered to be compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre team do not currently recruit gamete donors and therefore this guidance note is not relevant to the inspection.

Donor assisted conception (Guidance note 20)
It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to

access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better
Nothing identified at this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are partially suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

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

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited

by Clinical Pathology Accreditation (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are broadly compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre has policies and procedures in place that are partially compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The single biggest risk of fertility treatment is a multiple pregnancy.
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have transport or satellite arrangements therefore this guidance note is not relevant to the inspection.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. Most of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
The inspection team notes that some non-compliances documented in this report, related to safe staffing and equipment for example, had been identified by the PR, along with solutions. It is not however in the PR's control to implement the solutions because of financial constraints. Such non compliances are logged and remain on the 'risk register'. The inspection team is concerned that such risks are being brought to the attention of Barts Health NHS Trust by the PR, but are not addressed in a timely manner commensurate with their risk rating and possible adverse effects on treatment outcomes, patient satisfaction and ultimately on the safety of patients and staff (SLCs T2 and T17).

There were two unsecured cylinders in the embryology preparation room (SLC T17; HTM 02-01 Medical Gas Systems 8.30).

Two oxygen cylinders (size J) are located in a corridor cupboard from which they supply piped oxygen. The hazard signage on the cupboard door was inaccurate because it showed CO_2 and liquid nitrogen, but not oxygen (SLC T17; HTM 02-01 Medical Gas Systems 8.2). The hazards related to oxygen are very different from those related to CO_2 and liquid nitrogen so the signage needs to be accurate.

It was also a concern that staff did not appear to have a designated area to have a scheduled break from their work activities, away from their desks or work stations. This has resulted in staff eating at their desks and kettles being used within office areas. This was considered by the inspection team to be a health and safety risk and not conducive to good ways of working and staff morale (SLC T2; CoP guidance 25.18b).

See recommendation 4.

Infection control (Guidance Note 25)
From discussions with the staff and observations within the centre, the inspection team was of the opinion that space within the centre was restricted, one reason being because much space was taken up by items no longer relevant to the centre's activities and awaiting removal. This was particularly noticeable in the procedure room. This was considered by the inspection team to be a risk to both health and safety and infection control (SLC T2).

It was also noted that infection control in the procedure room was compromised because of:

- The presence of items not relevant to the activities undertaken there;
- Plug sockets were under the procedure table and were a hazard in the event of a liquid spill;
- Cupboards were cluttered with stock;
- An infection control audit from April 2018 showed theatre cabinets, surfaces and

trolleys to be dusty and a trolley in a poor state of repair (SLC T24)

See recommendation 3.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The clinical and nursing team did not have access to an on-call anaesthetist (SLCs T2 and T12). Patient feedback in 2017/2018 noted times when patients had experienced breakthrough pain during procedures. The need for on-call anaesthetist cover was identified by the PR as a preventative action but could not be implemented because of funding issues, so the 'risk' had been recorded on the risk register without any further actions being taken to mitigate the risk (SLC T2).

See recommendation 1.

A meeting was held with representatives from the Trust Senior Management Team on the second day of the inspection to discuss our concerns regarding the safety and suitability of the centre's sedation practice. Assurances were given verbally by representatives from the Trust Senior Management Team and in writing from the Managing Director of St Bartholomew's Hospital, that the clinical and nursing team had been provided with the contact details of an on call anaesthetist. The inspection team was also assured that the centre would work with the anaesthetic team to ensure that the latter were familiar with the procedure room and that the centre would urgently develop a business case to seek recurrent investment from the Trust.

Quality management system (QMS) (Guidance note 23)
The most recent traceability audit did not document corrective and preventative actions, or timelines for their implementation (SLC T36).

There was no standard operating procedure (SOP) to direct staff in the event of a clinical emergency (SLC T33b).

See recommendation 7.

Equipment and materials (Guidance note 26)
The sample pots used for the collection of sperm are not CE marked at the appropriate level (SLC T30).

Some incubators used for the culture of embryos are seven years old and, as such, are no longer serviced by the manufacturer. Centre staff and a representative from Barts Health NHS Trust informed the inspectors that this matter had been graded as a high risk on the risk register for some time, but that there were no immediate plans to replace the incubators. The inspectors were informed that the incubators are regularly maintained and checked by centre staff and there is a contingency plan in the event of incubator failure. The inspectors were concerned of the impact should the incubators fail and the lack of commitment to address the high risk associated with using incubators beyond the length of time recommended by the manufacturer (SLCs T24 and T26).

See recommendation 6.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme.

Staff (Guidance note 2)
The centre is partially compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Staff (Guidance note 2)
One nurse was designated to the post procedure recovery area regardless of workload (SLCs T2 and T12). The inspection team was concerned that staffing in the recovery area may at times be inadequate for the number of patients having procedures.

Staff competence to deliver the traceability processes has not been assessed or documented (SLC T12).

The inspection team were concerned that there is a lack of governance and leadership in the centre's procedure room because of the non compliances related to infection control observed there (SLC T12).

Further non compliance related to 'Staff' is discussed above in: 'Pre-operative assessment and the surgical pathway (guidance note 25)'.

See recommendation 2.

A meeting was held with representatives from the Trust Senior Management Team on the second day of the inspection to discuss our concerns regarding staffing in the recovery area. Assurances were given verbally by representatives from the Trust Senior Management Team and in writing from the Managing Director of St Bartholomew's Hospital, that appropriate levels of staffing would be provided for the activity undertaken in the recovery area, as a matter of urgency through use of bank nursing staff, and that the centre would urgently develop a business case to seek recurrent investment from the Trust.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better
Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not offer treatment involving embryo testing therefore this guidance note is not relevant to the inspection.

What the centre could do better
Not applicable

2. The experience of patients

Patient feedback

What the centre does well

During the inspection no patients came forward to speak to the inspector about their experiences at the centre. Seven patients provided feedback directly to the HFEA in the time since the last inspection; feedback was generally positive.

The PR also described the centre's process for obtaining patient feedback and a summary of the feedback was provided to the clinical inspector.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- generally provides patients with satisfactory facilities for their care.

What the centre could do better

A review of patient feedback received by the centre noted comments regarding distress due to breakthrough pain being experienced by some patients during clinical procedures. This matter is discussed above in: 'Pre-operative assessment and the surgical pathway (Guidance Note 25)' and in recommendation 1.

Treating patients fairly

Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non discriminatory way.

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not offer treatments involving egg and/or sperm sharing arrangements therefore this this guidance note is not relevant to the inspection.

Surrogacy (Guidance note 14)
The centre does not currently offer treatment involving surrogacy arrangements however it has done so in the past and may recommence this activity. The centre's procedures were therefore discussed and considered to be compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better
Nothing identified at this inspection.

Consent and disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the

partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in 2016, legal parenthood consenting processes were found to be robust and it was noted that the centre had responded appropriately to the cases they had identified with anomalous legal parenthood consent in their audits.

The PR confirmed on this inspection that they have had no contact from six couples who had not responded to communications from the centre about the anomalies in their consent to legal parenthood. Letters had been sent to affected couples via recorded delivery and the PR is confident that they have done all that they can to make these couples aware of the issues identified in 2014 and 2015.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of the centre's recent monthly legal parenthood consenting audits. Four sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required, were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure are broadly compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consents to disclosure, so that patient identifying information is only released to researchers with the patient's consent. Information can be used by researchers to improve knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
An audit of consent to disclosure performed by the HFEA register team on inspection noted in a sample of 17 records, nine (53%) discrepancies between completed patient/partner disclosure consents within patient files and the related consent data submitted for inclusion on the register. Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure. This failing leads to a risk that the HFEA may release patient identifying information, to researchers, without consent.

(NB. The Centre's designated HFEA Form Returnee has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected).

CH(10)05 and General Direction 0005.

See recommendation 10.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

The centre's procedures for screening patients are broadly compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety and only in accordance with the gamete providers' consent. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Screening of patients (Guidance note 15)

The centre does not have procedures in place to consider the risks of Ebola virus exposure during patient and donor assessment (SLC T50d). See recommendation 8.

Storage of gametes and embryos (Guidance note 17)

On the day of inspection, centre staff informed the inspection team that they did not have

written effective consent for the storage of cryopreserved eggs for one patient and cryopreserved embryos for 13 patients.

HF&E Act 1990 (as amended), Schedule 3, 8(1).

One patient had extended storage past the statutory storage period of 10 years but did not have a Medical Practitioners Statement (MPS) in place. Two other patients had signed to extend storage past the statutory storage period but the MPS had been signed one and three years later.

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 Paragraph 4.

See recommendation 5.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

What the centre could do better
Nothing identified at this inspection.

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

All 124 IVF and 20 DI treatments reviewed at inspection had been reported to the HFEA (General Direction 0005).

Licensed treatment reporting by the centre is timely (97% of IVF and 95% of DI treatments reviewed at inspection had been reported to the HFEA in the period required by General Direction 0005.

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
A significant number of historic donor-related register data inaccuracies were identified at inspection. At the time of completing the report a small number remain to be addressed. A small number of other minor data quality issues were also identified (General Direction 0005; SLC T41).

See recommendation 10.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016 recommendations for improvement were made in relation to two areas of major non compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. However, the following non-compliance has since recurred:

There were two unsecured cylinders in the embryology preparation room.

On-going monitoring of centre success rates

In 2017, the centre received one performance related alert with regards to their multiple birth rate. The PR responded to the alert and the multiple birth rate is now expected to be within the acceptable range.

Areas of practice requiring action

This section sets out matters which the inspection team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, General Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

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

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Pre-operative assessment and the surgical pathway. The clinicians and nurse sedationists did not, at the time of the inspection, have access to an on call anaesthetist to provide support in the event of a difficult clinical case. A review of patient feedback received in 2017/2018, noted that some patients were experiencing breakthrough	The PR should ensure that the clinical and nursing team have access to an on-call anaesthetist and that a review is performed of sedation-analgesia to ensure that it is fit for purpose. The Trust took immediate action on the day of the inspection and provided written assurance to the HFEA that the centre team would have immediate access to an on call	The centre has access to an on-call anaesthetist team at all times. The contact details are now displayed on noticeboards in key areas such as; the egg collection theatre and adjacent recovery area. The centre's egg collection standard operating procedure will be reviewed against the new Trust policy for 'Non-anaesthetist administered sedation to adult patients' by	The executive acknowledges the action the Trust and the PR took on the day of the inspection to address this critical non compliance. The inspector notes that the formal review of the centre's egg collection procedure has not yet been completed and has discussed the time frames with the PR.

pain during clinical procedures, which may have benefited from the presence of an on call anaesthetist. The need for on-call anaesthetist cover was identified by the PR as a preventative action but could not be implemented, so the 'risk' had been recorded on the centre's risk register. SLC T2 and SLC T12.	anaesthetist. The PR should ensure that the regime for peri-operative sedation is reviewed to ensure that it is fit for purpose. The PR should provide a summary of actions taken to address this non-compliance when responding to the report, along with the review of the regime for peri-operative sedation.	30 September 2018.	The PR to inform the centre's inspector when the review has been completed by 30 September 2018.

Major area of non compliance

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

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

A major area of non compliance is identified in the report by a statement that an area of practice is partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Staff Only one nurse was assigned to the post procedure recovery area regardless of workload (SLC T12). The inspection team were concerned that there appeared to be a lack of governance and leadership in the theatre because of the infection control hazard identified there (SLC T12): Staff competence to deliver the traceability processes is not assessed or documented (SLC T15a).	The PR should ensure that the staff numbers and skills mix are appropriate to support the licensed activity undertaken at all times. For example, the PR should ensure that the post-operative recovery area always has sufficient suitably qualified staff to safely care for patients and their partners following a clinical procedure. The Trust took immediate action on the day of the inspection and provided written assurance to the HFEA that a recovery nurse would be provided on days when the	Two trained recovery nurses are now based in the post-procedure recovery area each day. A new storage space has been identified to allow for non-essential items to be removed from the procedure room. The premises have been reviewed by members of the Fertility Senior Management Team and action taken accordingly. The cleaning rota will also be reviewed by 30 September 2018.	The inspection team acknowledge the action the Trust and the PR took on the day of the inspection. The PR has informed the centre's inspector that they have received positive feedback from patients regarding the additional recovery nurse in the postoperative area. The PR should inform the centre's inspector when the cleaning rota has been reviewed by 30 September 2018.

	centre requested one due to higher levels of activity. The PR should nominate an appropriately skilled person to lead on governance in the procedure room. Together with a lead theatre nurse and an anaesthetist from Barts hospital theatre team, the nominated procedure room lead should review the environment, de-clutter and assess cleaning rota adequacy. Competence to deliver the traceability processes should be assessed and documented for all relevant staff. The PR should provide the centre's inspector with a summary of the actions taken to comply with this recommendation when responding to the inspection report.	A peer review of the Theatre, Recovery and storage areas has been undertaken. Following on from this visit, a detailed action plan is being written, with implementation of the plan being managed through the monthly meeting with the St Barts Cancer Centre Senior Management team, where support will be given for delivery by 31 October 2018. Through this business case funding will be sought to establish the additional recovery nurse, anaesthetic support above the on-call team, and anaesthetic kit for the treatre area. Traceability competency is a key part of the assessment of new staff (SF 164) and is regularly assessed (SF 63).	The PR should inform the centre's inspector when actions have been completed following the peer review of the theatre, recovery and storage area by 31 October 2018. The PR to provide the centre's inspector of assurance that the establishment of the additional nurse and anaesthetic support will be maintained by 31 October 2018.
3. Infection control and health and safety The inspection team considered that space within the centre was restricted, one	The PR should ensure that the centre is free from unnecessary clutter and risks, to facilitate the adherence to infection control and health and safety standards.	A new purpose built storage area has been identified to allow for non-essential items to be removed from the procedure room.	The actions taken to comply with this recommendation are acknowledged. The PR to inform the centre's

reason being because space was taken up by items no longer relevant to the centre's activities and awaiting removal, noticeably in the procedure room. This was considered by the inspection team to be a risk to both health and safety and infection control (SLC T2). It was also noted that infection control in the procedure room was compromised because of: • The presence of items not relevant to the activities undertaken there; • Plug sockets were under the procedure table and were a hazard in the event of a liquid spill; • Cupboards were cluttered with stock; • An infection control audit from April 2018 showed theatre cabinets, surfaces and trolleys to be dusty and a trolley in a poor state of repair (SLC T24)	The PR should, with discussion with the Trust, review the suitability of the premises to ensure that they adhere to health and safety regulations. The review should include the provision of support to remove decommissioned equipment and unwanted items. The PR should provide the centre's inspector with a summary of the actions taken to comply with this recommendation when responding to the inspection report.	A peer review of the theatre space and storage area has identified key actions required. Planned changes to the premises will be completed by 31 October 2018.	inspector when the planned changes have been implemented by 31 October 2018.
4. Premises and facilities. Non-compliances identified by	The PR should ensure that risks on the risk register are addressed	All risks are reviewed on a regular basis by both the	The actions taken to comply with this recommendation are

the PR are logged in the 'risk register' without corrective actions being taken to resolve them. The inspection team is concerned that such risks are not addressed in a timely manner commensurate with their risk rating and possible adverse effects on treatment outcomes, patient satisfaction and ultimately on the safety of patients and staff (SLCs T2 and T17). There were two unsecured cylinders in the embryology preparation room (SLC T17; HTM 02-01 Medical Gas Systems 8.30). This was noted at the time of the last inspection in 2016. Two oxygen cylinders (size J) are located in a corridor cupboard but the hazard signage on the cupboard door was inaccurate because it showed CO_2 and liquid nitrogen, but not oxygen (SLC T17; HTM 02-01 Medical Gas Systems 8.2). Staff do not appear to have a	with appropriate risk mitigating actions in a timeframe commensurate with the risk rating. The PR should ensure the correct signage is used for medical gas storage, and that cylinders are secured to prevent them falling over. The PR should review the facilities available for staff and put in place plans to achieve compliance with CoP guidance 25.18b by 16 November 2018. The PR should provide detailed plans of the actions to be taken to implement this recommendation, when responding to the inspection report.	service and Barts Cancer Centre Management team as per Trust requirements. Mitigating actions are logged for each risk within the Trust Datix system. New safety signs are now in place. New brackets have been fitted to secure the newly delivered mixed gas cylinders before they are taken into the laboratory. An application has been made for additional space, that will include a designated area for scheduled breaks, away from desks and workstations.	acknowledged. The PR to keep the centres; inspector informed regarding the application for additional space for staff facilities.

designated area to have a scheduled break from their work activities, away from their desks or work stations. This was considered by the inspection team to be a health and safety risk and not conducive to good ways of working and staff morale (SLC T2; CoP guidance 25.18b).			
5. Storage of gametes and embryos. The centre does not have written effective consent for the storage of cryopreserved eggs for one patient and cryopreserved embryos for 13 patients. Schedule 3, 8(1) HF&E Act 1990 (as amended). One patient had extended storage past the statutory storage period of 10 years but did not have a Medical Practitioners Statement (MPS) in place. Two other patients had signed to extend storage past the statutory storage period but the MPS	The PR should ensure that there is effective written consent in place for all gametes and embryos that are in storage. The PR should establish an action plan for resolving the cases where eggs and embryos are in store beyond the consented storage period. A copy of the plan should be provided to the HFEA when responding to this report. The PR should provide monthly updates to the HFEA on progress in implementing the proposed actions. The PR is reminded of guidance issued by the HFEA in CH (03)03 in relation to the timely disposal of	Of the fourteen patients without effective written consent for the storage of cryopreserved eggs and embryos at the time of the inspection, all have now been resolved. i. four have extended their consent to store ii. ten have now been discarded, as planned, in the next monthly storage disposal session. This will now be monitored on the Fertility Dashboard. MPS forms are now in place. Going forward at the point of one year and one month,	The actions taken to comply with this recommendation are acknowledged. The inspector awaits the summary of any legal advice obtained regarding the two cases identified where patients had signed to extend storage past the statutory storage period but the MPS had been signed at a later date. The PR to provide a summary of the review of all long term stored samples to ensure that all appropriate consents and written medical opinions are in place by 16 August 2018.

had been signed one and three years later. The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 Paragraph 4.	cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material. With regards to the absent MPS and delays in the signing of the MPS form, the PR should provide the centre's inspector with a summary of any legal advice obtained regarding the two cases identified, as well as with the centre's intended actions and anticipated timescales for their implementation, when responding to this report. The PR should also review all long term stored samples to ensure that all appropriate consents and written medical opinions are in place. A summary of the findings of the review, including any corrective actions with timescales for implementation, should be provided to the centre's inspector by 16 August 2018.	prior to the expiry. The case will be reviewed by the Lead Clinician and Laboratory Manager to ensure that, where appropriate, the MPS will be in place. SOP 79 and the storage review form have been updated to reflect this.	
6. Equipment The sample pots used for the collection of sperm are not CE	The PR should repeat the risk assessment related to the age of the incubators. This assessment	Sample pots that are CE marked at an appropriate level are now is use.	The actions taken to comply with this recommendation are acknowledged.

marked at the appropriate level (SLC T30). Some incubators are seven years old and are no longer serviced by the manufacturer. This matter has been graded as a high risk but there are no immediate plans to replace the incubators, though they are regularly maintained and checked by centre staff and there is a contingency plan should they fail. The inspectors were concerned about the impact should the incubators fail and about the lack of commitment to address this high risk (SLCs T24 and T26).	should include the impact that incubator failure could have on patient treatment. Whilst the HFEA acknowledge the issues with funding within the Trust the centre must have equipment that is fit for purpose and failure to do so may result in regulatory action. The PR should provide the centre's inspector with a summary of the actions taken to comply with this recommendation when responding to the inspection report.	The business case for the replacement of incubators has now been approved for capital investment, by the Trust. The risk has been updated to reflect this progress. The risk assessment will be reviewed as advised by 31 August 2018.	The executive also acknowledges and welcomes the Trust approval of the business case for replacement of the incubators. The centre's inspector looks forward to receiving an update from the PR when the current incubators have been replaced. Risk assessment to be received by 31 August 2018.

Other areas of practice that require improvement

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

An 'other' area of non compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
7. QMS The centre does not have a SOP to direct staff in the event of a clinical emergency (SLC T33b). The most recent traceability audit did not document corrective and preventative actions or the timeframe for their implementation (SLC T36). All other audits reviewed were all compliant in this regard.	The PR should ensure that there is a clinical emergency SOP and that all staff are suitably trained and informed as to the actions to take in a clinical emergency. The PR should, in responding to this report, provide the centre's inspector with the clinical emergency SOP and evidence of relevant staff training. The PR should also ensure that the traceability audit has documented corrective actions including deadlines for implementation. The revised audit should be provided with the response to this report.	SOP to direct staff in the event of a clinical emergency is in the process of being written. The Trust Corporate Induction and Fertility Local Induction are completed by all staff. In addition to this, role specific compentency assessments are completed by clinical staff. These include; assessments of the understanding, and actions required to, address any adverse consequences or clinical emergencies. The audit template for traceability has now been updated with a section to confirm how many lot numbers were updated once all consumables had been	The actions taken to comply with this recommendation are acknowledged. The centre's inspector notes that the clinical emergency SOP has not been provided in the response to the inspection report and is in the process of being written. The inspector has sought assurances from the PR of the staff ability to respond to a clinical emergency until such times as the SOP is in place and is satisfied with the PR's response. The PR to inform the centres inspector when the clinical emergency SOP has been

		checked.	completed and implemented. The revised traceability audit has not been received and should be submitted by 30 September 2018.
8. Screening The centre does not have procedures in place to identify when additional screening for Ebola may be required (SLC T50d).	The PR should, with immediate effect, ensure that prospective patients and donors are assessed for risks associated with prior exposure to Ebola virus. The PR should assess with expert advice if there has been any risk to patients, gametes or embryos from the centre's failure to consider this risk. The PR should provide the centre's inspector with a summary of the actions taken to comply with this recommendation when responding to the inspection report.	The current version of the travel questionnaire has been reviewed and updated. These forms are completed by the patient at least every six months and provide the clinical team with the destination details of their most recent and planned travel arrangements. This gives the team the opportunity to inform them of any potential risks prior to starting their treatment.	The actions taken to comply with this recommendation are acknowledged. No further action.
9. Finance The centre is at times late in paying HFEA invoices, averaging 42 days against our 28-day stipulation.	The PR should ensure that treatment fees are paid within the time frames stipulated by the Authority.	An annual puchase order number is now in place so that going forward, invoices will be matched more quickly and any issues observed during the	The actions taken to comply with this recommendation are acknowledged.

	The PR should provide the centre's inspector with a summary of the actions taken to comply with this recommendation when responding to the inspection report.	weekly audit will be escalated.	No further action.
10. Data submission to the HFEA An audit of consent to disclosure noted in a sample of 17 records, nine (53%) discrepancies between completed patient/partner disclosure consents within patient files and the related consent data submitted for inclusion on the register. Therefore, the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure (CH(10)05 and General Direction 0005). A significant number of historic donor-related register data inaccuracies were identified at inspection. At the time of completing the report a small number remain to be corrected. A small number of	The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms. The PR should correct the disclosure consent submissions that have been identified as being incorrect. The PR should also ensure that the general data quality issues identified, including within donor treatment data, are corrected. These recommendations should be implemented by the time the PR responds to this inspection report and the PR should provide the centre's inspector with a summary of	All discrepancies of consent to disclosure between the patient records and data submitted to the register have been corrected. HFEA CD permissions reported at the point of registering the patient and partner, where applicable, will be checked at ITT submission. This will capture errors in original reporting and cases where the forms have been completed again. All historic errors for donor-related register issues for cycles undertaken between 1994 and 2005 have been corrected. Weekly EDI data submission audits will continue as they highlight any more recent	The actions taken to comply with this recommendation are acknowledged. No further action.

other minor data quality issues were also identified (General Direction 0005; SLC T41).	the actions taken, with their response. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the corrective actions have been effective. A summary of the audit should be provided to the centre's inspector by 16 November 2018.	errors due to data entry errors.	

Reponses from the Person Responsible to this inspection report

Incident Investigation Report

Centre name: Barts Health Centre for Reproductive Medicine
Centre number: 0094
Date licence issued: 1 October 2014
Licence expiry date: 30 September 2018
Additional conditions applied to this licence: none
Date of site visit: 10 August 2018
Inspectors: Paula Nolan (Clinical Governance Lead), Sara Parlett (Senior Inspector)
Date of Licence Committee: 6 September 2018

Purpose of the report

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

Licensed centres 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 centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

When a licensed clinic reports a 'grade A' incident (a serious adverse reaction or event) to the HFEA, we immediately contact the centre 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.

The report together with the centre's response is presented to the HFEA's Licence Committee which decides if any further regulatory action needs to be taken. The report and the minutes of the Committee decision are published on this 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.

Section 1

Brief description of the centre and its licensing history:

Barts Health Centre for Reproductive Medicine has held a Treatment and Storage licence with the HFEA since 1992 and provides a full range of fertility services.

According to HFEA data the centre provided 1118 cycles of treatment (excluding partner intrauterine insemination) between April 2017 and March 2018; in relation to activity levels this is a large centre. Other licensed activities at the centre include the storage of gametes and embryos.

Background information on incident:

The embryos for eleven patients showed poor development, equivalent to a day behind that expected. Some embryos were also showing signs of degeneration.

The centre's investigation found that an incorrect gas cylinder was connected to the culture incubators. Instead of pre-mixed 5% oxygen/ 6% CO_2/ N_2 the cylinder contained pre-mixed 9% helium[1] in air. The helium cylinder had been delivered to the department in error. The centre does not use helium.

All eleven patients were informed, and their embryo transfers cancelled. The centre allowed the embryos in culture to perish due to concerns over the effect of helium gas on the viability of the embryos and risk to the unborn child.

Findings of the centre's internal investigation:

- The storage of all special mixed gases were in the same compartment in the hospital's central gas store.
- The cylinders were not tracked out per cylinder from the central gas store. The incorrect cylinder was delivered to the embryology laboratory.
- The cylinders were not tracked into the centre and signed in and out by porters and/or the centre staff.
- The embryologist who attached the cylinder did not check it was the correct gas.
- Daily laboratory checks of the active cylinders failed to identify the incorrect gas cylinder was connected.
- The two cylinders are the same shape, size and colour and are only distinguishable by the label attached to the collar of the tank and on the side of the cylinder (see images in centre's investigation report).

[1] Helium in the hospital setting is used in the lung function unit as well as a component of a balloon pump (an invasive medical procedure to help the pumping action of the heart using a tube with a balloon at the end).

Findings and observations of the HFEA's investigation:

At the time of the incident the centre had the appropriate amount of staff on duty. The unit was not usually busy. Staff have completed the Trust's Medical Gas Safety training and had followed the SOPs in place at the time (re changing and connecting gas cylinders and daily laboratory checks). It should therefore be considered that a degree of automaticity[2] contributed to the events leading up to the incident.

When completing a task often performed it can become so familiar that it may be performed with little conscious effort. In this case it could be considered the staff involved in the incident expected the gas cylinder to contain pre-mixed 5% oxygen/ 6% CO_2 / N_2, as this is the only special mix gas used in the centre for the incubators.

The fact the two different cylinders are the same (in terms of size, shape, colour and connections), could have led to a degree of automaticity entering the checking process, leading to this incident. The only, yet significant, difference being the labelling on the shoulder of the cylinder.

The positive and proactive way this incident was handled by the Trust should also be acknowledged. The patients and their needs were at the centre of the Trust's actions. All the patients[3] affected by this incident have started or are about to start a complementary cycle of treatment.

The Trust have also shown a positive commitment to their staff and their wellbeing by the high level of senior management engagement and support including a debriefing meeting with the staff directly involved in the incident, a meeting involving all centre staff, offer of counselling to all staff affected and further meeting updates.

[2] The ability to do things without occupying the mind with the low level details required.
[3] All patients are booked for a further treatment cycle. The majority in August and one couple booked for September and one for October.

Recommendation to the Licence Committee

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.

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 lie with the HFEA Compliance and Enforcement Policy should be applied.

In this instance there are no such concerns. The Executive wishes to place this report before the Licence Committee in the interests of transparency and the opportunity for the sharing of learning with the sector.

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 recur.

We will share a copy of the Trust's Serious Untoward Incident (SUI) report with Licence Committee at a future meeting once this has been signed off by the Trust. In light of this incident, the Executive will be issuing an Alert to the sector about the safe distribution and receipt of special mixed gas cylinders.

Additional information from the Person Responsible

Appendix A

Chronology of events

Date and time	Event
Not known	Incorrect gas cylinder delivered to the fertility centre.
23 July 2018	Incorrect gas cylinder transferred to the embryology laboratory.
27 July 2018	Incorrect gas cylinder connected to the incubator (it had been attached as the back-up cylinder, but only became active 27/08/18).
28 July 2018	Embryos noticed to be growing slowly. Several cases seemed to show development that was a day behind schedule and some degeneration was seen. After investigation it was found that the wrong gas cylinder was connected to the culture incubators. It was helium instead of pre-mixed 5% Oxygen / 6% CO_2 / N_2. **Immediate action taken:** • Incorrect gas disconnected, correct gas attached, and all incubators purged. • PR informed, followed by Lead Clinician, then hospital management. • New culture dishes were made with pre-gassed media that had been cultured overnight in one of the large incubators. These are served by a separate gas source and therefore unaffected. • All embryos moved into the new fresh dishes. • All patients informed, and embryo transfers cancelled. • Plan for embryos to be cultured with a view to freezing any blastocysts, whilst impact of incorrect gas is assessed. **All patients were advised:** • There had been an issue with the culture environment of the laboratory that was affecting embryo development. • Some were advised of the full nature of the incident - an incorrect gas used. Not all patients asked for details. • Embryo transfers were cancelled.

	• Embryos were to be cultured to day 5 to assess for development to the blastocyst stage. • If blastocyst development was seen, the embryos would be frozen. • Lead Clinician informed and would be reviewing each file. • Follow up appointments with the Lead Clinician arranged ASAP. • Counselling made available to all affected patients.
29 July 2018	The decision was made to allow the embryos in culture to perish due to concerns over the effect of helium gas on the viability of the embryos and risk to the unborn child. All patients contacted via telephone by the Lead Clinician and informed of the decision to allow the embryos to perish. Patients reassured appointments were being set up to discuss the incident and their future treatment plans.
30 July 2018	All staff involved offered additional support, such as counselling.
02 August 2018	Wider team meeting held to inform all staff of the incident, the impact on the patient and the need to prioritise their care. As well as offering support from both counselling team and senior management for any member of staff affected by the incident.
30 July 2018	Serious incident review meeting held.
30 – 31 July 2018	All patients seen face to face. Plans made to continue with treatment (complementary cycle) at the patients' convenience and support offered by the clinical team. Counselling appointments given to all patients.
2 August 2018	Individual letters sent to each couple, highlighting the know details of the incident, the outcome of the face to face consultation with the senior consultant, the clinical management plan and fast access phone numbers and e-mail addresses.
6 August 2018	All patients contacted to provide on-going support and to answer any queries.

09 August 2018	Letter sent to affected patients from the Managing Director, offering apologies on behalf of the Trust and reiterating the offer of on-going support and commitment to ensuring treatment continues without delay.
9 August 2018	Further team meeting held to update staff on the investigation and actions taken. The Site Executive attended to offer senior support to all the staff.
10 August 2018	Site visit from HFEA: incident and the follow up actions discussed, staff welfare and support discussed. The Lead Clinician confirmed all patients were booked for a further treatment cycle the majority in August and one couple booked for September and one for October).