Executive Licensing Panel - minutes

Centre 0159 (Royal Surrey County Hospital)

Renewal Inspection Report

Tuesday, 12 February 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Anna Coundley Laura Riley	Director of Strategy and Corporate Affairs Policy Manager Head of Regulatory Policy
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Moya Berry Sandrine Oakes Nicola Lawrence	Senior Governance Manager Committee Officer (Induction) Inspector (Induction) Inspector (Induction)

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last three years.

1.2. The panel noted that The Royal Surrey County Hospital is located in Guildford and has held a HFEA licence since 1995. The centre holds a storage only licence and provides storage of sperm for patients who are undergoing treatment that may impair their fertility.

1.3. The panel noted that the centre stores sperm for approximately 30 gentlemen per year. In relation to activity levels this is a very small centre.

1.4. An inspection was carried out at the centre on the 12 December 2018.

1.5. The panel noted that at the time of the inspection, there was one major area of non-compliance regarding the Quality Management System (QMS). There were also four 'other' areas of non-compliance concerning adverse incidents, staffing, storage of gametes and record keeping. Since the inspection, the Person Responsible (PR) has given a commitment to fully implementing all the recommendations made in the renewal report.

1.6. The panel noted that the inspector will continue to monitor the centre's performance and the implementation of the report's recommendations within the required timescales.

1.7. The panel noted that the inspection team recommended the renewal of the centre's storage only licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

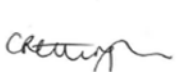
2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's storage only licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

15 February 2019

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. 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 Executive Licensing Panel (ELP) 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: 12 December 2018

Purpose of inspection: Renewal of a licence to carry out 'Storage only'

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: Andrew Leonard and Mhairi West

Date of Executive Licensing Panel: 12 February 2019

Centre name	Royal Surrey County Hospital
Centre number	0159
Licence number	L/0159/11/a
Centre address	Department of Cytopathology, Egerton Road, Guildford, Surrey, GU2 7XX, United Kingdom.
Person Responsible	Dr Behdad Shambayati
Licence Holder	Dr Stephen Whitaker
Date licence issued	01 April 2015
Licence expiry date	31 March 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Royal Surrey County Hospital is located in Guildford and has held a HFEA licence since 1995. The centre holds a storage only licence and provides storage of sperm for patients who are undergoing treatment that may impair their fertility. The centre stores sperm for approximately 30 gentlemen per year. In relation to activity levels this is a very small centre.

The centre currently has an application in progress to change the Licence Holder to Dr John De Vos. This application will be processed separately to the renewal of the centre's licence.

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 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 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 his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- 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 ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one major and four 'other' areas of non-compliance.

The PR has given a commitment to fully implementing the following recommendations:

Major area of non-compliance:

- The PR should ensure that the quality management system (QMS) is coordinated across all aspects of the centre's activities.

'Other' areas of practice that require improvement:

- The PR should ensure that incidents are appropriately investigated.
- The PR should ensure that all staff adhere to their on-going training schedules.
- The PR should ensure that the process used to monitor consent to storage expiry dates is robust and accurate.
- The PR should ensure that the process for patient identification is robust.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but does have one major area of concern.

The 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 'Storage only' licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

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 at this centre
2. The experience of patients at this centre
3. The protection of gametes at this centre
4. How this centre looks after important information

1. Protection of the patient

Witnessing and assuring patient identification

What the centre does well

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

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)
The centre does not recruit donors therefore this does not apply.

Payments for donors (Guidance note 13; General Direction 0001)
The centre does not recruit donors therefore this does not apply.

Donor assisted conception (Guidance note 20)
The centre does not provide treatment therefore this does not apply.

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 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 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 (relevant third parties) are suitable.

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

Laboratory accreditation (Guidance note 25)
The centre's laboratories which undertake the diagnosis and investigation of patients or their gametes or any material removed from them, are compliant with HFEA requirements for accreditation by UKAS, the national accreditation body for the UK, or another accreditation body recognised as 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 compliant with guidance.

Medicines management (Guidance Note 25)
The centre does not stock or dispense any intralipids or medicines.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
This area of practice is not relevant to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
This area of practice is not relevant to this inspection.

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

- document the justification for the storage of the patient's gametes, based on the patient's medical history and therapeutic indications;
- where sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes are compliant with HFEA requirements. This is important to ensure that all gametes 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;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes (Guidance note 15)
The centre's procedures for the receipt of gametes are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes 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 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 during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of gametes;
- to identify any person who has carried out any activity in relation to particular gametes; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is partially 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 any transport or satellite arrangements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose. All of the equipment and materials 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 clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are broadly 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, however see below. 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

Quality management system (QMS) (Guidance note 23)
The QMS for the centre ('the cryopreservation service') is embedded within the QMS for the large Cytology Department at Royal Surrey County Hospital in which the centre is located. This QMS is certified by the department's ISO15189 certification. The centre's QMS is generally well developed however the following issues were identified:

- The centre's QMS does not formally extend over the clinical aspects of the service. For example, a recent compliance audit of the centre did not review the clinical activities. Quality management of the clinical service is undertaken by the nursing staff but it was not clear to the inspection team that there is coordinated quality management across all the centre's activities. This is potentially exacerbated by management meetings between the lead staff across all the centre's activities, being held inconsistently (on average every nine months approximately), rather than six monthly, as is the specified frequency, or three monthly, which is the frequency specified as an action within the centre's recent compliance audit.
- Actions specified in the centre's management meeting minutes are not consistently undertaken within the specified timeframes. For example, a winter call out contingency plan was highlighted in April 2018 as needing to be developed, yet the minutes for the meeting in November 2018 stated that it had not been completed and a new deadline of April 2019 was assigned. The delay in this action across another winter could be considered an excessive risk.
- Biennial audits are performed of stored samples against the written log of stored samples (i.e. a physical audit) however it is not apparent that the records of storage consent are reviewed against the electronic records which are used to manage the bring forward process, to ensure their accuracy.
- SOPs generally state and provide specifications for the materials to be used, however the Cryopreservation SOP does not list the cryotubes to be used for sperm storage.

SLCs T32, T33, T36; see recommendation 1.

Adverse incidents (Guidance note 27)
The centre's incident log contained a report of a breach of storage consent for a deceased person, which also led to poor quality communication from the centre with the surviving partner. Root cause analysis (RCA) is performed of all incidents but the RCA for this incident was not well developed, despite RCA training having been provided to staff, so no effective preventative actions seem to have been implemented.

It was also noted that there were several incident reports related to typographic errors in the records and consent forms, and missing test results. Thematic review of incident reports to identify recurrent issues is carried out across the Cytology Department QMS but is not performed specifically for the licensed activity. The inspection team considers it possible that common themes related to the licensed activities, may not be apparent if all cytology incidents are considered together, and may therefore remain unaddressed. This appears to have been the case regarding the typographic errors and missing test results.

The Quality Manager advised that a new incident recording system is being implemented and further training is to be provided regarding reporting incidents and RCA.

SLC T118; see recommendation 2.

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of clinical science 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 broadly 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)
The centre has detailed on-going training programmes for staff, but very occasionally staff are not completing mandatory training items within the designated timeframes; for

example, the PR had not undertaken re-training in safeguarding within the specified timeframe.

SLC T12; see recommendation 3.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre does not provide treatment services therefore this guidance note does not apply.

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)
This area of practice is not relevant to this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors did not speak to any patients. However, the centre's most recent patient feedback received during 2018 was reviewed. 34 patients responded and all feedback was positive.

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;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

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 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 providing consent.

Gamete sharing arrangements (Guidance note 12; General Direction 0001)

The centre stores sperm only and does not offer treatment services, therefore this guidance note does not apply.

Surrogacy (Guidance note 14)

The centre stores sperm only and does not offer treatment services, therefore this guidance note does not apply.

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.

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 are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients 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 have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
The centre stores sperm only and does not offer treatment services, therefore this guidance note does not apply.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre provides gamete storage services only and does not ask patients to consider consent to disclosure to researchers therefore this area of practice is not relevant to this inspection.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
This is not applicable to this centre, as the centre does not create or store embryos.

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

Screening of patients and Storage of gametes

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are 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.

Storage of gametes (Guidance note 17)
The centre stores sperm only.

The storage of gametes is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing medical treatment such as chemotherapy and radiotherapy.

The centre's procedures for storing gametes are compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety.

The centre operates a bring forward system to ensure sufficient advance notice is given to patients that the end of the consented storage period is approaching. The bring forward system was reviewed on inspection and the inspection team had concerns that the system may not be sufficiently robust.

What the centre could do better

Storage of gametes (Guidance note 17)
A review of the electronic database used as the source of information for the bring forward system, which is used to monitor storage consent expiry dates, was not sufficiently robust. For example, the electronic records of stored samples do not for all samples include the storage consent expiry date and staff assume that storage consent is provided for 10 years, even though it is not in some cases. In a case of storage extension, the new expiry date had not been entered onto the database. This could lead to errors in detecting the actual date of storage expiry.

Code of Practice Guidance 17.21; see recommendation 4.

The records of storage consent have not been audited against the electronic records which are used to manage the bring forward process, to ensure the accuracy of those electronic records.

SLC T36; see recommendation 1.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre does not create or store embryos therefore this area of practice is not relevant to this inspection.

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 broadly 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 stores sperm only and does not offer treatment services, therefore this guidance note does not apply.

What the centre could do better

Record keeping and document control (Guidance note 31)
The majority of forms completed to extend storage are completed by the patient at home and submitted by post or email. If there are any doubts over the signature provided by the patient, there is no system in place to ensure the identity of the patient who has completed the form. For example, during a review of patient records, a patient had extended their storage period by completing the LGS consent form at home. The signature on the LGS form was significantly different to that on the original consent form completed ten years previously. The difference in signatures had not been acknowledged in the patient record and there was no evidence that any checks had been performed to provide confirmation that the person who had completed the LGS form was the patient.

SLC T46b; see recommendation 5.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2015, recommendations for improvement were made in relation to one major non-compliance and three 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None identified.			

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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. QMS The centre's QMS is well developed however some issues were identified, as detailed in the main body of the inspection report. SLCs T32, T33, T36.	The PR should ensure that the QMS is coordinated across all aspects of the centre's activities. The actions to achieve this should be provided to the centre's inspector by 12 March 2019. The PR should also address the other quality management concerns detailed in this report in a timely manner. The issue concerning the winter on-call contingency plan must be addressed immediately and the actions taken advised to the centre's inspector with the response to this report. Evidence of the actions taken to address the remaining	We will explore the inclusion of relevant clinical documentation relating to the service into the exsiting BSPS quality management system. Providing read only access for clinical staff to see storage facility documents. We will add an addendum to BSPS quality manual to cover the two areas of the service. We will arrange a meeting with the site manager and trust management for input how to provide contigency in adverse conditions . A clear outline of the process will be documented.	The executive acknowledges the PR's response and commitment to implementing this recommendation. A summary of changes to the QMS and confirmation that the issues identified in this report have been resolved should be provided to the centre's inspector by 12 March 2019. We acknowledge that the PR is arranging a meeting with trust management to discuss winter contingency plans. An update on progress should be provided to the centre's inspector by 14 February 2019.

	concerns should be provided to the centre's inspector by 12 March 2019.		Further action is required.

‘Other’ areas of practice that requires 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.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Adverse incidents The centre’s incident log contained an incident which had not been subjected to effective RCA, and several incidents with common themes had not been considered together and investigated effectively. SLC T118.	The PR should ensure that incidents are appropriately investigated for their root causes and for common themes, so that effective corrective and preventative actions can be implemented. The actions taken to implement this recommendation should be advised to the centre’s inspector by 12 March 2019. After the further RCA training is provided to the team, the incident involving a breach of storage consent and poor-quality communication by the centre to the surviving partner, should be reconsidered by the team to determine the root causes so that effective corrective actions can be implemented. A report of this review including the actions taken, should be provided to	We will form a Root Cause Analysis Group which will hold meeting to investigate incidents. We will write a policy highlighting triggers which should be reported to HFEA as incidents. The team will undertake Root Cause Analysis training, provided by the BSPS quality manager. This will include PR, 4 technical staff and lead nurse for clinical activites. We will provide an amended RCA of the incident which involved communication by the centre with the surviving partner.	The executive acknowledges the PR’s response and commitment to implementing this recommendation. The outcome of the review and amended RCA is due by 12 March 2019. Further action is required.

	the centre's inspector by 12 March 2019.		
3. Staffing The centre has detailed on-going training programmes for staff but staff are very occasionally not completing mandatory training items within the designated timeframes; e.g. the PR had not undertaken re-training in safeguarding within the specified timeframe. SLC T12.	The PR should ensure that all staff adhere to their on-going training schedules. The PR should audit the training of all staff to determine where training needs to be provided to bring staff up to date and should take actions to ensure that the training is undertaken by 12 March 2019. The audit should also include actions to address the reasons why some training is behind schedule and to better monitor training provision. A copy of the audit should be provided to the centre's inspector by 12 March 2019.	We will provide a Mandatory training matrix with up to date compliance for all of the team. We will complete an audit of mandatory training and provide reasons for gaps.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The audit is due by 12 March 2019. Further action is required.
4. Storage of gametes A review of the electronic database used as the source of information for the bring forward system monitoring storage consent expiry dates was not sufficiently robust as detailed in the main body of the inspection report.	The PR should ensure that the process used to monitor consent to storage expiry dates is robust and accurate. The PR should review the electronic storage database for completeness, including the presence of an expiry date for all stored samples, and the process for ensuring the	We are currently updating the database retrospectively with expiry dates for completeness. We will update the department SOP to clearly state that any changes made to the database are double checked and documented on the patient communication form with two signatures.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The audit is due by 12 March 2019. Further action is required.

Code of Practice Guidance 17.21. The records of storage consent have not been reviewed against the electronic records which are used to manage the bring forward process, to ensure their accuracy. SLC T36.	accuracy of the database when there is a change in the status of the patient, their partner, or their consented storage period. The PR should audit the electronic storage database for accuracy against the storage consents in place and provide the results of this audit, including any corrective actions to the centre's inspector by 12 March 2019. Three months after any changes have been implemented, the database should be audited for effectiveness. A summary of this audit should be provided to the centre's inspector by 12 June 2019.	An audit of 100 cases (25%) will be carried out to check for accuracy between the consent forms and the electronic database. An further audit of 100 cases will be completed three months after we have made changes and documentation provided.	
5. Record keeping The majority of forms completed to extend storage are completed by the patient at home and submitted by post or email. If there are any doubts over the signature	The PR should ensure that the process for patient identification is robust. The PR should review the process followed when changes are made to	We will update our SOP to state that signatures are checked and documented if there is a discrepancy. We will provide a policy for contacting patients to make	The executive acknowledges the PR's response and commitment to implementing this recommendation. A copy of the policy for contacting patients and audit

provided by the patient, there is no system in place to ensure the identity of the patient who has completed the consent forms. SLC T46b.	consented storage periods without the physical presence of the patient and provide a copy of the review to the centre's inspector by 12 March 2019.	enquiries if signatures do not match. We will provide an audit to show that signatures have checked alongside previous consent forms and any corrective actions put in place.	should be provided to the centre's inspector by 12 March 2019. Further action is required.

Responses from the Person Responsible to this inspection report