Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
24 July 2015

Minutes – item no. 3

Centre 0151 (Gloucestershire Hospitals NHS Trust) – Renewal Inspection Report

Members of the Panel:	Paula Robinson Head of Business Planning (Chair) Nick Jones Director of Compliance & Information David Moysen Head of IT
Members of the Executive in attendance:	Dee Knoyle Committee Secretary

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:

- HFEA protocol for the conduct of meetings of the Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA Direction 0008 (where relevant) and any other relevant directions issued by the Authority
- guide to Licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers

Consideration of application

1. The panel considered the papers, which included an application form, inspection report and licensing minutes for the past three years.

2. The panel noted that this is a storage only centre. The centre offers a sperm storage service for the preservation of fertility to oncology patients in the Gloucestershire, Herefordshire and Worcestershire area.

3. The panel noted that the centre has been licensed by the HFEA since 1995.

4. The panel noted that at the time of the inspection on 12 May 2015, the inspectorate identified three major and three other areas of non-compliance. The panel noted that since the inspection the Person Responsible (PR) has addressed five of the recommendations and has committed to fully implementing the one outstanding recommendation.

5. Subsequent to the inspection, there was a further review of the centre's counselling service by an HFEA external adviser and as a result one critical area of non-compliance was identified. The panel noted that the PR has taken immediate action and committed to fully implementing the recommendation to address this critical area of concern, ensuring that patients are able to access a suitably qualified counsellor prior to giving consent.

6. The panel noted that some improvement is required in order for the centre to demonstrate suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

7. The panel noted that the inspectorate recommends the renewal of the centre's storage only licence for a period of four years without additional conditions.

Decision

8. 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.

9. 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 has discharged their duty under section 17 of the HFE Act 1990 (as amended).

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

11. The panel endorsed the inspectorate's recommendation to continue to monitor the centre's performance and agreed that failure to complete implementation of the recommendation relating to the critical area of non-compliance within the prescribed timescale may result in the submission of a further report to the ELP, with a recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy. However the panel was pleased to note the swift initial action already taken by the PR to ensure that cancer patients using the centre's services would have improved opportunities for counselling in the future.

12. The panel endorsed the Inspectorate's recommendation to renew the centre's storage only licence for a period of four years without additional conditions.

Signed: Date: 4 August 2015
Paula Robinson (Chair)

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 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 May 2015

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: Karen Conyers (lead), Lesley Brown

Date of Executive Licensing Panel: 24 July 2015

Centre name	Gloucestershire Hospitals NHS Trust
Centre number	0151
Licence number	L/0151/11/a
Centre address	Microbiology Department, Gloucestershire Royal Hospital, Great Western Road, Gloucester, GL1 3NN,
Person Responsible	Dr Alan Lees
Licence Holder	Dr Sean Elyan
Date licence issued	01 November 2011
Licence expiry date	31 October 2015
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The centre is part of Gloucestershire Hospitals NHS Foundation Trust, located in Gloucester, and has held a storage only licence since 1995. The centre offers a sperm storage service for the preservation of fertility to oncology patients in the Gloucestershire, Herefordshire and Worcestershire area.

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 Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- there was some concern that the PR had not fully discharged his duties under Section 17 of the HF&E Act 1990 (as amended) having failed to ensure that 'proper' counselling is offered to patients. Actions taken since the inspection indicate that the PR is now fully discharging his duties;
- 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 their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note at the time of the inspection there were six areas of practice that required improvement, three major and three 'other' areas of non compliance.

Subsequent to the inspection, there was a further review of the centre's counselling service by an HFEA counselling external adviser and as a result of this one further recommendation with respect to a critical non-compliance was identified as follows. In response to this critical non compliance the PR has taken immediate actions and has given a commitment to fully implementing the recommendation.

Critical area of non-compliance:

- **The PR should ensure provision of a 'proper' counselling service.**

Since the inspection visit, the following recommendations have been fully implemented:

Major areas of non compliance:

- The PR should ensure that the conditions of transport relevant to the quality and safety of gametes during transport to the centre from third party premises are specified.
- The PR should ensure that only CE marked medical devices are used wherever possible.

- The PR should ensure that all critical equipment is validated and subject to ongoing monitoring.

‘Other’ areas that requires improvement:

- The PR should ensure that containers and packages used to transport gametes are labelled in compliance with requirements.
- The PR should ensure that all information is kept confidential and only disclosed in circumstances permitted by law.

The PR has given a commitment to fully implementing the following recommendation.

‘Other’ areas that requires improvement:

- The PR should ensure that the written patient information is accurate.

Recommendation to the Executive Licensing Panel

The centre has one critical area of concern and three major areas of concern. Immediate actions to address the critical area of concern were taken ensuring that patients are able to access a suitably qualified counsellor prior to giving consent.

Some improvement is required in order for the centre to demonstrate suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

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.

The inspector will continue to monitor the centre's performance. Failure to implement the outstanding recommendations relating to the critical area of non compliance within the prescribed timescale may result in the submission of a further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

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) 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 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 area of practice is not relevant to this inspection.

Payments for donors (Guidance note 13; General Direction 0001)
The centre does not recruit donors therefore this area of practice is not relevant to this inspection.

Donor assisted conception (Guidance note 20)
The centre does not treat patients with donated gametes or embryos therefore this area of practice is not relevant to this inspection.

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
Transport and distribution of gametes
Receipt of gametes
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 a third party agreement with the oncology centre on the Cheltenham hospital site from which patients are referred to the cryopreservation service. Key clinical staff from the centre are based there and licensed activities conducted on that site are covered by a third party agreement.

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

The centre does not have any satellite or transport facilities.

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 and/or third party 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 CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
This area of practice is not relevant to this inspection.

Pre-operative assessment and the surgical pathway
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;
- 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 does not store embryos. The centre's procedures for the transport, distribution and recall of gametes are broadly 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;
- 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 the gametes are appropriately labelled and has enough information to permit the gametes be stored in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
This area of practice is not relevant to this inspection.

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 gamete provider,
- 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 in place 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 partially compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
This area of practice is not relevant to this inspection.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements.

The centre is partially 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 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

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
When distributing gametes the shipping container, or a separate sheet accompanying it, does not include all the required information (see recommendation 5, SLC T107b and c).

Quality management system (QMS) (Guidance note 23)
The centre does not have a standard operation procedure (SOP) for the provision of counselling. The inspection team did not consider that the quality indicator (QI) and related audit of provision of counselling met regulatory requirements (see 'Counselling'

section below).

Third party agreements (Guidance note 24)
The centre's third party agreement with the oncology centre in Cheltenham does not document the third party's responsibilities in relation to ensuring that the conditions relevant to the quality and safety of gametes during transfer are maintained. The inspection team does acknowledge however, that most samples are produced by the patients on site and that production of samples in Cheltenham and their subsequent distribution to the centre is a rare occurrence (see recommendation 2, SLC T113).

Equipment and materials (Guidance note 26)
The following medical device used by the centre is not CE marked: serological pipettes used to measure sperm samples (see recommendation 3, SLC T30).

The cold room used for the storage of the gamete cryopreservation media has not been validated (see recommendation 4, SLC T24). The inspection team noted that the cold room is subject to temperature monitoring although this is not monitored out of working hours and there are no processes in place to note out of range values or initiate action if the temperature is out of range (see recommendation 4, SLC T24).

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 medicine 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 (T/1073/7).

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)
The counsellor could not provide evidence of the assessment of her competence to provide infertility counselling and it was also noted that the counsellor is not accredited by the British Infertility Counselling Association (BICA) and does not have equivalent accreditation (see 'Counselling' section below).

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre provides gamete storage services only therefore this area of practice is not relevant to this inspection.

Safeguarding
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

The inspection team did not have an opportunity to speak with any patients. The inspection team were advised that centre staff regularly seek feedback from patients about their experiences of the service via patient questionnaires.

On the basis of this feedback 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 partially compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients providing relevant consent.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)
This area of practice is not relevant to this inspection.

Surrogacy (Guidance note 14)
This area of practice is not relevant to this inspection.

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 broadly 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

Counselling (Guidance note 3)
The centre's counsellor is a clinical psychologist based at the oncology centre but is not accredited by BICA or able to demonstrate equivalent accreditation. She attended a BICA foundation workshop in 2012 but could not demonstrate any further infertility counselling specific training. The counsellor was not available on the day of the inspection but agreed to participate in a review of the counselling service following the inspection. In view of the training and suitability of the counsellor's expertise in infertility counselling provision, the inspection team were concerned that the counselling service was not considered fit for purpose or 'proper', potentially undermining the effectiveness of consents provided by patients (HF&E Act 1990 (as amended) Schedule 3, 3.1) (see recommendation 1, SLCT12).

The PR could not provide documented evidence of the assessment of the counsellor's competence. The centre does not have a SOP for the provision of counselling, and this activity is not integrated into the centre's QMS as the QI and audit did not meet the standard required (see recommendation 1, SLCT12, SLCT33b, SLCT35 and SLCT36).

Confidentiality and privacy (Guidance note 30)
It was noted during the inspection that when results of screening tests and semen analyses are recorded on the hospital's pathology database the annotations clearly identified that the tests were done prior to cryopreservation of gametes. This means that there is a risk of inadvertent disclosure of identifying information to non licensed individuals, although it is noted that there has not been any instances of such disclosures reported to or by the centre (see recommendation 6, SLCT43).

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients are broadly 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

Information (Guidance note 4; CH(11)02)
The centre's patient information leaflet was considered confusing in relation to the ability of the man to register as the father of the child if his sample was used posthumously. The inspection team were assured that the patients are provided with accurate information verbally (see recommendation 7, SLCT58).

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

What the centre does well

Consent (Guidance note 5 and 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.

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

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.

Screening of patients
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'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. Furthermore, the centre only stores gametes in accordance with the consent of the gamete provider. The storage of gametes 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.

What the centre could do better

Nothing identified at this inspection.

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
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 does not undertake patient treatments therefore this area of practice is not relevant to this inspection.

What the centre could do better

Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2013 no recommendations for improvement were made and there were no outstanding recommendations from the renewal inspection in 2011.

On-going monitoring of centre success rates

The monitoring of success rates is not applicable to this inspection because the centre does not provide treatment services.

Areas of practice requiring action

The 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
1. The centre's counsellor is not accredited by BICA or able to demonstrate equivalent accreditation. In view of this, the counselling service was not considered fit for purpose or 'proper', potentially undermining the effectiveness of consents provided by patients (HF&E Act 1990 (as amended) Schedule 3, 3.1). The PR could not provide documented evidence of	The PR should ensure the provision of a proper counselling service. The PR should take immediate actions to ensure that the centre can access a suitably qualified counsellor to provide patients with an opportunity to receive proper counselling and confirm to the centre's inspector that this action has been implemented. It is also recommended that	Agreed An interim arrangement with a BICA accredited counsellor is being made pending provision of a definitive counselling service. Action plan to be developed	The Executive acknowledges the PR's response and confirmation that an interim arrangement has been put in place to ensure that patients are able to access a suitably qualified counsellor with immediate effect. The PR has provided assurance that he will keep the Executive updated on progress and actions being taken to secure the services of a suitably qualified counsellor on

the assessment of the counsellor's competence, the centre does not have a SOP for the provision of counselling and the QIs and audit did not meet the standard required. SLCT12, SLCT33b, SLCT35 and SLCT36.	the PR contacts patients who have stored gametes in the time since the current counsellor has been in post to offer them an opportunity to review their consent at which time they could be provided with an option to have counselling with a more suitably qualified person. It is suggested that patients who opted to have counselling are contacted as a priority. The HFEA should be provided with updates on the implementation of this recommendation and it is expected that all patients will be contacted by 12 May 2016.	and agreed with HFEA prior to implementation. Time frame for completion noted and interim updates on implementation will be provided.	a permanent basis. Once this has been established the PR should ensure that the counselling service is fully integrated into the QMS system such as with a SOP, QIs and audits in place. Further action is required.

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
2. The centre's third party agreement with the oncology centre in Cheltenham does not document the third party's responsibilities in relation to ensuring that the conditions relevant to the quality and safety of gametes during transfer are maintained. SLC T113.	The PR should ensure that the conditions of transport relevant to the quality and safety of gametes during transport to the centre from third party premises are specified. The PR should review the centre's third party agreement with Cheltenham to ensure that the responsibilities of the third party, agreed procedures and any specific criteria that the service provided by the third party must meet (for example the conditions of transfer) are specified. The PR should provide a copy of the revised	Agreed	The Executive acknowledges the PR's response. An updated third party agreement has been provided which specifies the conditions of transfer of the samples. No further action is required.

	third party agreement to the centre's inspector by 12 August 2015.		
3. The following medical device used by the centre is not CE marked: serological pipettes used to measure sperm samples. SLC T30.	The PR should conduct a review of all medical devices currently in use to identify where products are not CE marked and take action to source alternatives. The PR should provide the centre's inspector with a list of all medical devices including disposable plastic ware, equipment, and culture medium indicating the CE mark status of these products. Where devices are not CE marked then the PR should indicate the proposed timescale for sourcing alternatives by 12 August 2015. We do not recommend the implementation of precipitous changes that might impact on the quality of service that is provided to patients. In consideration of this it is expected that all medical	Agreed	The Executive acknowledges the PR's response. The requested list and confirmation of the implementation of all CE marked devices where available has been provided. No further action is required.

	devices should be CE marked by 12 November 2015.		
4. The cold room used for the storage of the gamete cryopreservation media has not been validated. The inspection team noted that the cold room is subject to temperature monitoring although this is not monitored out of working hours and there are no processes in place to note out of range values or initiate action if the temperature is out of range SLCT24.	The PR should ensure that all critical equipment is validated and subject to ongoing monitoring. The centre's inspector should be advised of any immediate actions taken to mitigate the risks of failing to monitor critical equipment at all times by the time this report is considered by a licensing committee. The PR should ensure that validation of critical equipment is completed by 12 August 2015. On completion the validation the centre's inspector will ask for a copy of the validation document to be submitted for review.	Agreed	The Executive acknowledges the PR's response. Documents confirming validation of the cold room and implementation of ongoing monitoring have been provided. No further action is required.

Other areas of practice that requires improvement

Areas of practice that requires 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
5. When distributing gametes the shipping container, or a separate sheet accompanying it, does not include all the required information. SLC T107b and c.	The PR should ensure that containers and packages used to transport gametes are labelled in compliance with the requirements. The PR should provide the centre's inspector with copies of updated versions of the relevant SOPs and/or sheets accompanying the shipping container by 12 August 2015.	Agreed	The Executive acknowledges the PR's response. A copy of the updated sheet has been provided. No further action is required.
6. It was noted during the inspection that when results of screening tests and semen analyses are recorded on the hospital's pathology database the annotations clearly identified that the tests were done prior to cryopreservation of gametes. This means that there is a risk of inadvertent	The PR should ensure that all information is kept confidential and only disclosed in circumstances permitted by law. The PR should review the centre's processes for mitigating the risk of inadvertent disclosure of information to unauthorised individuals. The PR should	Agreed	The Executive acknowledges the PR's response. Actions taken in response to the centre's review of processes have been provided. No further action is required.

disclosure of identifying information to non- licensed individuals, although it is noted that there has not been any instances of such disclosures reported to or by the centre. SLCT43.	provide a copy of the review including any corrective actions identified and timescales for implementation to the centre's inspector by 12 August 2015.		
7. The centre's patient information leaflet was considered confusing in relation to the ability of the man to register as the father of the child if his sample was used posthumously. The inspection team are assured that the patients are provided accurate information verbally. This puts the centre at risk of failing to provide proper information to patients giving consent, as required by the HF&E Act 1990 (as amended), Schedule 3 (1) (b). SLC T58.	The PR should ensure that the written patient information is accurate. The PR should review written information provided to patients against regulatory requirements. A copy of the revised patient information (indicating what has been changed) should be submitted to the centre's inspector by 12 August 2015.	Agreed	The Executive acknowledges the PR's response. A copy of the revised patient information leaflet has been provided and is pending publication. Further action is required.

Reponses from the Person Responsible to this inspection report
We agree with the findings of the inspection report and are working to clear these areas of non-compliance within the required timescale.