# Interim Inspection Report

# Gloucester Hospital NHS Trust
# 0151

## Date of Inspection: 18th December 2008
## Date of Licence Committee: 11th February 2009

**Centre Details**

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|---|---|
| Person Responsible | Dr Alan Lees |
| Nominal Licensee | Sean Elyan |
| Centre name | Gloucestershire Hospitals NHS Trust |
| Centre number | 0151 |
| Centre address | Microbiology Department<br>Gloucestershire Royal Hospital<br>Great Western Road<br>Gloucester<br>GL1 3NN |
| Type of inspection | Interim |
| Inspector(s) | Sarah Hopper<br>Ellie Suthers |
| | |
| Fee paid | N/A |
| Licence expiry date | 31/10/2011 |
| NHS/ Private/ Both | NHS |

**Index**

**About the Inspection:**

This inspection visit was carried out on 18th December 2008 and lasted for 7 hours.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

**Brief Description of the Centre and Person Responsible**

Centre 0151 has been licensed since 1992 and offers a sperm storage service for oncology patients in the Gloucestershire, Herefordshire and Worcestershire area.

The centre is now situated within Gloucestershire Royal Hospital. Previously, the centre was located in the pathology department of Cheltenham General Hospital. The move to new premises was prompted by a Trust decision to reorganise pathology provision in Gloucestershire. The new premises licence was granted by a Licence Committee on the 25th June 2008.

The PR has been in post since 2005 and has completed the PR entry programme to the satisfaction of the Executive.

**Activities of the Centre**[1]

| | |
|---|---|
| In vitro fertilisation (IVF) | N/A |
| Intracytoplasmic sperm injection (ICSI) | N/A |
| Frozen embryo transfer (FET) | N/A |
| Intra uterine insemination (IUI) | N/A |
| Gamete intrafallopian transfer (GIFT) | N/A |
| Research | No |
| Storage gametes/embryos | Storage of sperm samples for 140 oncology patients. |

**Summary for Licence Committee**

The inspectorate noted that the PR has taken action in response to all recommendations made at the new premises inspection.

Some improvements are required in areas of organisation, premises and equipment, information and laboratory and clinical processes.

Improvements should be considered relating to the following aspects of the centre's practice:

- Third party agreements
- Complaints procedure
- Dissemination of HFEA alerts
- Validation of processes and equipment
- Traceability records
- Suitable equipment

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. 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.

- Cleaning records
- Counselling audit
- Witnessing and verification of patient identification

It is recommended that improvements are made in these areas within the prescribed timeframes.

The Executive recommends continuation of the centre's licence with no additional conditions.

**Evaluations from the inspection**

| Topic | No Improvements required | Some Improvement required | Significant Improvement required |
|---|---|---|---|
| 1. Organisation | | X | |
| 2. Quality of the service | X | | |
| 3. Premises and Equipment | | X | |
| 4. Information | | X | |
| 5. Laboratory and clinical processes | | X | |

**Breaches of the Act, Standard Licence Conditions or Code of Practice:**
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

| Breach | Action required | Time scale |
|---|---|---|
| Third party agreements have not been completed with all suppliers whose goods/services may have an impact on the quality of the gametes *(CoP A.5.1 and S.4.2.10)* | The centre should establish written agreements with all third parties for external activities which influence the quality and safety of gametes and embryos procured or processed. | To be reviewed at the next inspection |
| The centre does not have a specific complaints procedure, complaints officer or complaints log. Complaints are directed to the Trust and processed by the Trust complaints department. | It is recommended that the PR ensures that the complaints procedure is in accordance with Code of Practice Standard 9.2.2, Guidance 11.3.1, 11.3.3 and 11.3.4. | April 1st 2009. |
| A member of staff interviewed during the inspection was unaware of the HFEA Alert system. | The PR should ensure that the centre has an effective means for communicating information to staff in particular alerts issued by | With immediate effect |

| | | |
|---|---|---|
| | the HFEA *(CoP S.6.2.13)* | |
| Critical laboratory processes and equipment have not yet been validated | It is recommended that the PR identifies the key processes and equipment which will need to be validated to ensure compliance with Licence Conditions 11.11 and Code of Practice Standards 7.8.3. A programme of validation should be developed: the programme should take into account the particular needs of the centre and prioritise the validation of those processes considered to be most likely to impact on the quality of the service. | Progress to be monitored at the next inspection |
| Records of the cleaning of critical pieces of equipment are not maintained. | The PR should ensure that maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment is performed regularly and recorded accordingly as per Code of Practice Standard 6.4.2. | With immediate effect |
| Staff reported that they have concerns that the dry shipper used to transport frozen samples to fertility centres is no longer fit for purpose. A request for funding has been made to one of the charities supporting the oncology department. | The PR must ensure that suitable equipment is available for the transportation of samples as required in Code of Practice Standard S.7.7.12. | On or before February 28th 2009.<br>If samples need to be transported prior to this date it is recommended the PR considers use of courier or a dry shipper belonging to another centre. |
| The counselling audit, one of the required preinspection documents, has not been submitted to the HFEA. | The counselling audit should be submitted to the HFEA as required by Licence Condition A.13.2. | April 1st 2009. |
| Traceability records for key equipment used during the processing of gametes/embryos have not been retained. The centre must ensure that logs of equipment, environmental monitoring and of products coming into contact with embryos or gametes are maintained and stored for the | Appropriate records must be maintained as per standard licence conditions A. 3.2, A.10.30 and Code of Practice Standard 7.3.1. | With immediate effect. |

| | | |
|---|---|---|
| relevant time periods, as outlined in standard licence conditions A.3.2, A.10.30 and Code of Practice Standard 7.3.1. | | |

**Non-Compliance**

| Area for improvement | Action required | Time scale |
|---|---|---|
| There is no system in place for confirming the identity of sperm providers either producing samples at the Cheltenham General Hospital site or for those delivering them to the pathology unit at Gloucester hospital. This is non compliance with Code of Practice Guidance 13.7.1, 13.7.3 and 13.8.6. | In accordance with Code of Practice Guidance 13.7.1, 13.7.3 and 13.8.6 it is recommended that the centre establishes a procedure to ensure the accurate identification of patients and their gametes and; upon sperm collection patients should be asked to actively supply the identifying information (full name and date of birth) requested by verbally stating it, rather than confirming or rejecting information read out by a member of staff; and when sperm samples are produced at home centres should ensure that protocols are in place to make sure the sperm receptacle is clearly labelled with the sperm providers full name and unique identifier, that the identity of the sperm provider is confirmed and the sperm provider confirms that the sample is his. | With immediate effect |
| The inspectorate considered that the patient information leaflet entitled “sperm storage for those undergoing radiotherapy or chemotherapy” could potentially be misleading to patients in respect of storage periods. | The PR should ensure that they provide accurate information about regulations relating to statutory storage periods for gametes (Code of Practice Guidance 5.10.1). | With immediate effect. |
| Audited patient records lacked a witness step of cross checking of identifying information provided by the sperm provider against records, laboratory data sheet and sperm receptacle or cross checking of information entered into system and allocation of barcode/RFID tag (Code of Practice Guidance 13.1.1b) and one discrepancy was noted in the witnessing records held in one patient file; the placement of gametes into the | The PR should review the witnessing procedure and ensure compliance with Code of Practice Guidance 13.1.1b. Furthermore it is recommended that the PR monitors compliance with witnessing protocols, including at the time of the centre’s quality management system audit (Code of Practice Guidance 13.3.4). | With immediate effect |

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|---|---|---|
| storage dewar had not been witnessed as per Code of Practice Guidance 13.1.1. | | |

**Recommendations**

| Area for improvement | Action required | Time scale |
|---|---|---|
| An external company is responsible for topping up the liquid nitrogen filler tanks. To fulfil this role they have access to the cryostore and staff explained that they are not always accompanied by licensed personnel. | The inspectorate recommended that the PR considers the risks, including security risks, associated with this practice and ensures compliance with Code of Practice Standard 6.3.8. | With immediate effect. |
| The PR reported that they plan to distribute patient questionnaires on a three yearly basis in the future. The inspectorate recommended that he consider how he could collate patient feedback more frequently, so that he can ensure compliance with Code of Practice Standard S.9.1.1, S.9.5.1 and S.9.5.3. | Review of collation of patient feedback to ensure that the quality management system is under continual review. | To be monitored at the next inspection. |
| One discrepancy regarding storage consent completion was noted during the audit of patient records: in one set of records it was unclear whether or not the particular patient was consenting to posthumous use of his stored sperm. If this patient subsequently died and someone wished to use his gametes, it would be difficult to do so given the lack of clarity around the consent to posthumous use (as per Code of Practice Guidance 8.1.3). | It is recommended that the MS form discrepancy noted during the records audit be resolved and that the PR reviews the procedures for taking consent from patients and for reviewing consent forms prior to treatment. | Immediate resolution of consent form error.<br><br>Consent procedure to be reviewed by April 1st 2009. |
| On rare occasions sperm samples may be produced at the oncology unit at Cheltenham General Hospital and then be delivered to the pathology department via hospital bus. The inspectorate have concerns about the safety of samples transported in this manner, the risks that they could be tampered with or delivered outside of the optimal time parameters. | It is recommended that the PR evaluates the risks involved with movement of samples between sites and ensures compliance with Code of Practice Standard 7.7.14. | With immediate effect. |

**Changes/ improvements since last inspection**

| Recommendations | Action Taken |
|---|---|
| Lock to be fitted on the sperm processing laboratory | Seen to be in place |
| Further security (door hinge protectors) to be added to the doors of the cryostore | Door hinge protectors fitted |
| Validation and re-commissioning of key equipment to take place following move | Evidence of recomissioning of equipment provided at this inspection |
| Testing of background and working environment air in the sperm processing laboratory to take place which demonstrates that the air quality meets the requirements of Licence Condition A.10.19, Code of Practice Standard 6.3.6 (b), Standard 7.8.5 and Guidance 9.4 | Evidence that the air quality is in compliance with HFEA requirements was provided during the inspection |
| Development to take place of a protocol for response to low oxygen alarms | Response to alarms protocol in place – this includes guidance on response to low oxygen alarms |
| Placement of warning signs required outside the cryostore. | Warning signs seen to be in place |

**Additional licence conditions and actions taken by centre since last inspection**

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|---|
| N/A |

**Report of inspection findings**

### 1. Organisation

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information

| Areas of firm compliance |
| --- |
| An organisational chart is in place which defines accountability and reporting relationships. This was also seen to be supported by a document outlining the responsibilities of the key members of the team.<br><br>Risk assessments have been conducted on the laboratory procedures and records of these were seen on the electronic quality management system.<br><br>Processes are in place for the identification, recording and notification to the HFEA of all adverse incidents and near misses in accordance with Code of Practice Standard S.9.4.2. The documented protocol supporting this process was provided during the inspection and staff were able to explain the incident reporting process to the inspectorate. The incident log was also provided to the inspection team.<br><br>A contingency arrangement is in place with Bristol Centre for Reproductive Medicine, centre 0295, to ensure that the service can continue in the event of an emergency. The PR reported that the arrangement had worked effectively during their brief shutdown in June 2008 when they were moving to the new premises in Gloucester hospital.<br><br>The team involved in processing and storing the sperm samples is small and they stated that the rarely have formal meetings but information is communicated via email or verbally. All staff expressed satisfaction with the method for dissemination of information and all exhibited awareness of issues related to the service, with the exception of HFEA alerts as discussed in areas for improvement, for example the new draft HFEA consent forms and the Code of Practice, during discussions with the inspection team. |

| Areas for improvement |
| --- |
| The centre does not have a specific complaints procedure and relies on the Trust complaints department or the Patient Advice and Liaison Services **(**PALS). Information about the complaints process directs patients to the complaints manager of the Trust or PALS and not a specific individual within the licensed team. This system does not ensure that patient confidentiality is maintained as required by the HFE Act (1990). Furthermore, an accurate complaints register has not been maintained within the centre but is instead retained at Trust level. It is recommended that the PR develops a complaints procedure which is in accordance with Code of Practice Standard 9.2.2, Guidance 11.3.1, 11.3.3 and 11.3.4.<br><br>Third party agreements have not been established with all parties who supply goods or services that may impact on the quality of gametes. One third party agreement has been completed and was provided at inspection but it was noted that at least three more third party agreements are required. It is recommended that the PR reviews and identifies all suppliers whose goods/services may impact on gametes and establishes third party agreements in accordance with Licence Condition CoP A.5.1 and Code of Practice Standard 4.2.10.<br><br>A member of staff interviewed during the inspection was unaware of the HFEA alert system. The PR should ensure that the centre has an effective means for communicating information to staff in particular alerts issued by the HFEA *(CoP S.6.2.13)* |
| Areas for consideration |
| None |
| Executive recommendations for Licence Committee |
| The Licence Committee is asked to endorse the recommendations made in relation to:<br><br>➢ Third party agreements<br>➢ Complaints;<br>➢ Alert management; |
| Evaluation |
| Some improvements required. |
| Areas not covered on this inspection |
| Payment of licence/treatment fees – this was an interim inspection and this centre does not offer treatment cycles. |

**2. Quality of service**

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control

| Live birth rates[1] |
| --- |
| N/A – storage only centre |
| Areas of firm compliance |
| A quality manager is in post and a quality management system has been established.<br><br>The quality manual was provided during the inspection and was seen to include a description of the centre and the services it provides, an outline of the processes and the documentation required to establish the quality management system and the quality policy. The quality policy was reviewed by the inspection team and considered to be compliant with the requirements of the Code of Practice (Standard 4.2.3).<br><br>Measurable quality objectives consistent with the quality policy are in place. The list of current quality objectives was provided to the inspection team. Quality indicators for the service have also been set, these were seen to include ensuring that all samples reach the laboratory within one hour of production, ensuring that all samples are processed in the laboratory within two hours of production and maintaining satisfactory results in sperm motility and concentration quality assurance tests.<br><br>The quality management system has been subject to annual review. Minutes from the 2008 quality management review meeting were provided. The minutes show that patient feedback, audits, document control and the quality objectives were discussed. Quality issues relating to the cryopreservation service are also discussed at the monthly pathology department quality and accreditation meetings. The agenda for a recent meeting was provided to the inspection team as evidence of this.<br><br>Feedback has been obtained from patients who have used the service in the last five years. Questionnaires were sent to all 31 patients and the centre received responses from 14 patients. Evidence of feedback evaluation was seen in the annual quality management review meeting minutes. The PR was satisfied with the outcome of the questionnaire and reported that corrective action in response to one of the issues raised.<br><br>Evidence of a rolling audit programme was seen during the inspection along with the schedule of audits for the coming year. |

The centre has a document control system in place which ensures that all documents are version controlled and are subjected to an approval process prior to release to staff. This system uses a software package which was demonstrated to the inspectorate. All documents seen by the inspectorate had evidence of version control and documents which are awaiting release were seen to be marked clearly as draft documents. The quality manager explained that he ensures documents are reviewed at the appropriate intervals as the software system sends an automatic alert to the author of each document prior to review date. This system was demonstrated to the inspectorate.

| Areas for improvement |
| --- |
| None |
| **Areas for consideration** |
| The PR reported that they plan to distribute patient questionnaires on a three yearly basis in the future. The inspectorate recommended that he consider how he could collate patient feedback more frequently, so that he can ensure compliance with Code of Practice Standard S.9.1.1, S.9.5.1 and S.9.5.3. |
| **Executive recommendations for Licence Committee** |
| None |
| **Evaluation** |
| No improvements (relating to Code of Practice requirements) required. |
| **Areas not covered on this inspection** |
| Live birth rates – n/a storage only centre |

### 3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Storage of records

| Areas of firm compliance |
| --- |
| Patients are provided with information about the long term cryopreservation service within the oncology unit at Cheltenham General Hospital. Counselling is also provided on this site and consent forms are completed with the patients by members of oncology staff who are on the HFEA licence. The inspectorate visited the rooms used for provision of information and counselling and agreed that the privacy and dignity of patients has been considered and provided for.<br><br>Typically patients produce samples at home and take them to Gloucester Hospital for processing and storage. On rare occasions, when patients are unable to leave Cheltenham General Hospital due to their oncology treatment, there is an option for production of samples at the hospital. The consultant oncology nurse explained that they have four rooms which could be used for this purpose. One of the rooms was visited and considered fit for purpose.<br><br>Sperm samples are delivered to the pathology unit at Gloucester hospital either by the patients themselves or via hospital staff. Samples are then processed within a designated andrology laboratory within the pathology unit. Access to this room is restricted to licensed staff through the use of a swipe card system. This system was seen to be in operation during the inspection.<br><br>Once frozen, samples are transported to the cryostore, which is an outbuilding on the pathology department site. The door to the cryostore is secured with a key lock, the key being held by the senior biomedical scientist who was seen to store it in a secure location. Efforts have been made to enhance the security of the cryostore, particularly because it is sited in public area. Hinge protectors were seen to have been fitted to the cryostore door and kick plates to the bottom of each door.<br><br>A low oxygen monitor is in place within the cryostore and an external unit placed outside the cryostore which produces a klaxon and visible alarms. A personal low oxygen alarm has also been bought and was seen to be used when staff enter the cryostore.<br><br>Information on what to do in the event of an alarm was seen to be provided on the hazard notice fitted to the cryostore door. This included the contact number for the laboratory and |

pathology department switchboard.

Four dewars are currently in use and these were seen to be locked, two with a key lock and the other two with a combination lock. The senior biomedical scientist confirmed that he holds the keys to the dewars and licensed staff only are aware of the combination lock codes.

Wireless low nitrogen alarms were seen to be fitted to all four dewars and one holding dewar. The PR reported that these alarms and the low oxygen alarm are connected to an autodial system. The standard operating procedure for response to an autodial call out was seen and explained by staff. A system in place to check the liquid nitrogen levels in the tanks and the alarm system on a weekly basis. These checks are recorded and the log was seen during the inspection. A protocol is in place to support these checks and was provided prior to the inspection.

The gamete store is appropriate for the volume of activities conducted. The senior biomedical scientist reported that there is capacity for the next few years and the audit report from 2007 stated that there is capacity for the next 10 years.

Air quality in the area where gametes are processed is monitored on a monthly basis by the use of agar settle plates and surface swabbing. Results from the last five months were provided to the inspectorate and this evidence confirmed that both the background and working air quality is compliant with HFEA requirements.

Equipment records were observed and were detailed and well organised. These records included evidence that the key pieces of equipment has been subjected to frequent servicing and that they had been recommissioned following the move to the new centre.

Patient records are stored in two places. The original records were seen to be held securely within the andrology laboratory, access to which is restricted to licensed personnel, in a locked cabinet. Copies of these records are also held in a locked cabinet within the senior biomedical scientist's office. Patient information is also held on a database. Staff confirmed that this database is hosted on a protected server and access was seen to be controlled via a password system.

Areas for improvement

The PR reported that critical laboratory equipment have not yet been validated. It is recommended that the PR commences a programme of validation and ensures compliance with Licence Conditions 11.11, 8.11 and 10.13 and Code of Practice Standards 7.8.3, S.6.4.2 and S.6.4.2.

Records of the cleaning of critical pieces of equipment are not maintained. The PR should ensure that maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment must be performed regularly and recorded accordingly as per Code of Practice Standard 6.4.2.

Staff reported that they have concerns that the dry shipper used to transport frozen samples to fertility centres when patients require is no longer fit for purpose. A request for funding has been made to one of the charities supporting the oncology department. The PR must ensure that suitable equipment is available for the transportation of samples as required in Code of

| |
|---|
| Practice Standard S.7.7.12. |
| Areas for consideration |
| An external company is responsible for topping up the liquid nitrogen filler tanks. To fulfil this role they have access to the cryostore and staff explained that they are not always accompanied by licensed personnel. The inspectorate recommended that the PR considers the risks, including security risks, associated with this practice and ensures compliance with Code of Practice Standard S.6.3.8. It was noted that a third party agreement has not yet been established with this company but that centre staff have made efforts to complete one.<br><br>Since the last inspection a sperm production room has been built within the pathology department. This room was visited by the inspectorate and seen to include toilet and hand washing facilities. Locks and furniture are yet to be fitted but the PR anticipates that the room will be fit for use by February 2009. |
| Executive recommendations for Licence Committee |
| The Licence Committee is asked to endorse the recommendations made in relation to:<br><br>➢ Validation of critical equipment<br>➢ Cleaning records<br>➢ Use of suitable equipment |
| Evaluation |
| Some improvements required |
| Areas not covered on this inspection |
| Staff facilities |

**4. Information**

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Access to health records

| Outcome of audit of patient records |
| --- |
| The inspectorate reviewed six sets of patient records. HFEA consent forms were found to be present in all of the records reviewed. However, the following discrepancies were noted:<br><br>- In one patient record the posthumous use section on the MS consent form had been completed inconsistently and it was not clear whether the patient had consented to continued storage of his samples or that the samples should perish. If this patient subsequently died and someone wished to use his gametes, it would be difficult to do so given the lack of clarity around the consent to posthumous use (as per Code of Practice Guidance 8.1.3).<br><br>- In one patients record evidence that the process of placing samples in storage had been witnessed was not present (section 5). |
| Areas of firm compliance |
| Patient information is provided by the consultant nurse and a checklist used to confirm that all relevant information has been provided. A copy of this checklist was provided to the inspection team and was seen to include information about the availability of counselling and the complaints process. This checklist and the written patient information provided evidence that, in accordance with Code of Practice Guidance 5.10.1, patients are informed about the possible deterioration or loss of viability of as a consequence of storage and the potential risk of cross contamination between samples and screening tests to be carried out, the reason for these tests and the implications of the tests for the gamete providers. The written patient information also includes information about parenthood and the registration of any child resulting from posthumous use of his sperm samples (Code of Practice Guidance 5.10.3). |
| Areas for improvement |
| One discrepancy with consent completion records was noted during the audit of patient records. It is recommended that the MS form discrepancy noted during the records audit be resolved and that the PR reviews the procedures for taking consent from patients and for reviewing consent forms prior to treatment.)<br><br>The patient information leaflet entitled “sperm storage for those undergoing radiotherapy or chemotherapy” outlines the conditions of storage and states that storage to the age of 55 years is normally allowed. However, the leaflet also states that at the end of the storage period the patients will be contacted to organise “alternative storage arrangements”. The inspectorate had concerns that this statement could potentially be misleading for patients as it suggests that storage beyond the maximum period permitted by the HFE (Statutory Storage Period) Regulations 1991 may be possible. This issue was discussed with staff who agreed to review and revise the leaflet. The PR should ensure that they provide relevant information |

about: regulations relating to statutory storage periods for gametes and embryos, and regulations relating to extension of storage periods including, in the case of embryos, the requirement for the consent of both gamete providers to any extension of storage (Code of Practice Guidance 5.10.1).

| Areas for consideration |
| --- |
| None |

| Executive recommendations for Licence Committee |
| --- |
| The Licence Committee is asked to endorse the recommendations made in relation to:<br><br>➢ Consents<br>➢ Information provision |

| Evaluation |
| --- |
| Some improvement required. |

| Areas not covered on this inspection |
| --- |
| Welfare of the child<br>Provision of information to the HFEA register<br><br>*Both not applicable as this is a storage only centre |

## 5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

**Full time equivalent staff[2]**

| | |
|---|---|
| GMC registered doctors | 5 |
| NMC registered nurses | 2 |
| Non NMC registered clinical staff | |
| HPC registered scientists | 4 |
| Scientists working towards registration | |
| Support staff (receptionists, record managers, quality and risk managers etc) | 1 |
| Counsellors | 1 |

| Summary of laboratory audit |
|---|
| The centre conducts a rolling audit of their stored material. An audit report detailing the monthly findings was submitted to the Executive. This stated that by June 2008 two of the four tanks had been audited and 25 discrepancies noted. The discrepancies related to the absence of supporting statements from medical practitioners which are required for extension of gamete storage beyond 10 years. This issue was discussed with centre staff who confirmed that these instances referred to samples that had not yet been stored beyond 10 years and that this information is now being collated. A new form to be completed by medical practitioners has been generated and was seen to be used for more recent patients. |
| Summary of spot check of stored material |
| N/A – interim inspection |
| Summary of counselling audit |
| A counselling audit was not submitted to the HFEA prior to the inspection. On inspection the PR stated that the counselling service has not been audited. Staff stated their perception is that the take-up of counselling is low, possibly because the issues associated with storage of sperm samples are not a priority for patients who are dealing with a cancer diagnosis and |

[2] These members of staff also have other duties within the oncology unit or pathology department, these figures are therefore not true full time equivalent numbers. The PR reports that there are sufficient resources available for licensable activity which was confirmed by the inspectorate at the time of inspection.

upcoming treatment. As a response to the low take-up rate, the PR stated that the information sent to patients yearly about their stored samples is to be reviewed to include a reminder that counselling is available at any time, including after their oncology treatment.

Areas of firm compliance

The centre participates in inter-laboratory comparisons using the UK NEQAS system. Results from their participation in 2007 and 2008 were provided and this evidence also included documentation of corrective actions which were to be taken in response to the results outside of the acceptable range.

Staff interviewed expressed their satisfaction with the support they have received for continual professional development (CPD). The senior biomedical scientist explained that he is enrolled on the Association of Biomedical Andrologists (ABA) continuing professional development scheme. The inspectorate reviewed his ABA log book which contained evidence of his CPD. The senior biomedical scientist stated that in the next year other members of the team will be asked to complete relevant modules within the ABA scheme. The quality manager has completed a diploma in quality management and evidence of this was provided to the inspection team.

The inspectorate were informed that the consultant nurse, who acts as information provider to those considering placing samples in storage, and the counsellor have undergone counselling training in Warwick. According to the PR the counsellor is BICA accredited, evidence of this was not available during the inspection and has been requested by the inspectorate.

A training program has been developed for staff involved in the processing and cryopreservation of sperm samples. This programme was provided during the inspection and was seen to include an evaluation of all the key competencies required for the role.

Areas for improvement

The critical laboratory processes have not yet been validated. It is recommended that the PR identifies the key processes which will need to be validated to ensure compliance with Licence Conditions 11.11 and Code of Practice Standards 7.8.3. A programme of validation should be developed: the programme should take into account the particular needs of the centre and prioritise the validation of those processes considered to be most likely to impact on the quality of the service.

The inspectorate's audit of patient records indicated that traceability information, other than for media batch numbers, has not been recorded. Staff acknowledged that this information has not been kept to date but assured the inspectorate that it will be in the future. A standard operating procedure has been documented to support the future practice of maintaining traceability records. The PR must ensure that procedures are in place to ensure that data relating to anything contacting the gametes is held, as outlined in standard licence conditions A.3.2 and A.10.30.

The PR reported that the majority of patients produce samples and deliver them to the pathology department. Although a home procurement form is in place which outlines the date and time of procurement there is no process in place for the active verification of patients. The lack of active identification of patients was evident in the audit of patient records. In accordance with Code of Practice Guidance 13.7.1, 13.7.3 and 13.8.6 it is recommended that:

- The centre establishes a procedure to ensure the accurate identification of patients and their gametes and;
- Upon sperm collection patients should be asked to actively supply the identifying information (full name and date of birth) requested by verbally stating it, rather than confirming or rejecting information read out by a member of staff.
- When sperm samples are produced at home centres should ensure that protocols are in place to make sure the sperm receptacle is clearly labelled with the sperm providers full name and unique identifier, that the identity of the sperm provider is confirmed and the sperm provider confirms that the sample is his.

Audited patient records lacked a witness step of cross checking of identifying information provided by the sperm provider against records, laboratory data sheet and sperm receptacle or cross checking of information entered into system and allocation of barcode/RFID tag (Code of Practice Guidance 13.1.1b). Although the record of sperm production form includes a section for this witness step, the PR acknowledged that this section is not always completed by a member of staff who has received the sample from the patient.

One sets of patient record had a witnessing discrepancy; the placement of gametes into the storage dewar had not been witnessed as per Code of Practice Guidance 13.1.1. This was discussed with the PR and the inspectorate observed that the most recent copy of the witnessing sheet is designed so that the witnessing is comprehensive and in compliance with the requirements of the Code of Practice. It is recommended that the PR monitors compliance with witnessing protocols, including at the time of the centre's quality management system audit (Code of Practice Guidance 13.3.4).

On rare occasions sperm samples may be produced at the oncology unit at Cheltenham General Hospital and then be delivered to the pathology department via hospital bus. The inspectorate have concerns about the safety of samples transported in this manner, the risks that they could be tampered with or delivered outside of the optimal time parameters. The PR stated that the new sperm production room at the pathology department is due for completion in the new year and that the majority of patient will produce on site. However, he stated that it will still be possible that some patients may be too ill to travel to Gloucester and that for these events he is considering the use of an urgent courier rather than the hospital bus. It is recommended that the PR evaluates the risks involved with movement of samples between sites and ensures compliance with Code of Practice Standard 7.7.14.

The counselling audit requested in the pre inspection questionnaire has not been submitted to the HFEA. The audit should be submitted to the HFEA as required by Licence Condition A.13.2.

Areas for consideration

The inspectorate recommended that the competency record documentation be updated so that each individual element of the competency framework is signed off individually. This would provide clarity for the PR as to when each individual competency was last assessed and when the repeat assessment will be required as specified in the quality management system

The counsellor was not available for interview at this inspection due to illness. It is recommended that the counsellor is interviewed by an external counsellor advisor at the time

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| of the next inspection to clarify the relationship between info provision and counselling both in terms of oncology and infertility care. |
| Executive recommendations for Licence Committee |
| The Licence Committee is asked to endorse the recommendations made in relation to:<br><br>➢ Validation of processes<br>➢ Traceability<br>➢ Witnessing<br>➢ Counselling audit |
| Evaluation |
| Some improvements required. |
| Areas not covered on this inspection |
| Three embryo transfer<br>Screening of donors<br>* both not applicable as this is a storage only centre |

**Report compiled by:**

Name…Sarah Hopper…….

Designation…Inspector…….

Date…19th December 2008……

**Appendix A: Centre staff interviewed**

PR and three other members of licensed staff

**Appendix B: Licence history for previous 3 years**

**Licensing History**
**Centre:** Gloucestershire Hospitals NHS Trust
**Number:** 0151

**2008**

*Licence Committee 25 June 2008*
On the basis of the information reported to them by Dr Bloor, the Committee agreed to vary the centre's licence to reflect the new address.

**2007**

*Licence Committee 14 May 2007*
The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

**2006**
**Inspection 25th May 2006**

*Licence Committee 27 July 2006*
The Committee noted the centre's low risk status and agreed to renew the centre's licence for a period of 5 years, with no conditions.

**2005**
**Inspection 19th July 2005**

*Licence Committee 28 April 2005*
The licence committee agreed to recognise Dr Alan Lees as the person responsible

*Licence Committee 5th September 2005*
The Committee noted the progress being made by the centre to address the issues raised in the inspection report. However, the Committee agreed that the centre should be strongly advised to ensure that the splitting of its oncology samples is completed by the end of December 2005 at the latest.

**Appendix C: Response of Person Responsible to the inspection report**

Centre Number 0151

Name of PR Dr Alan Lees

Date of Inspection 18/12/2008

Date of Response 28/1/2009

I have read the inspection report and agree to meet the requirements of the report.

Signed 

Name Alan Lees

Date 28/1/09

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

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| Page 11, paragraph re contingency arrangement. This arrangement is currently informal, any paperwork you saw at the inspection must have related to the temporary cover Bristol agreed to provide around the time of our site move in 2008. I will contact Bristol to formalise a contingency arrangement. **report revised accordingly* |

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

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3. Please state any actions you have taken or are planning to take following the inspection with time scales

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| We agree with the actions and timescales outlined in the draft report and will work towards implementing these. |

We welcome comments about the inspection on the inspection feedback form, a copy of which should have been provided at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

# HFEA Licence Committee Meeting
## 11 February 2009

21 Bloomsbury Street London WC1B 3HF

### Minutes – item 3

**Interim Inspection, Gloucester Hospital NHS Trust (0151)**

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| Members of the Committee: | |
| Anna Carragher, Lay Member (Chair) | Committee Secretary: |
| Emily Jackson, Lay Member | Claudia Lally |
| Richard Harries, Lay Member | |
| William Ledger, Professor of Obstetrics and Gynaecology at the University of Sheffield | Legal Adviser: Stephen Hocking, Beachcroft LLP |
| | Observers: |
| Attending via video conference link: | Mair Crouch |
| Rebekah Dundas, Lay Member | Gemma Hobcraft |

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

The following papers were considered by the Committee:

- papers for Licence Committee (31 pages)
- one tabled paper: email from Dr Lees (2 pages).

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and

- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

1. Gloucestershire Hospital NHS Trust is a storage only centre, offering sperm storage for oncology patients in the Gloucestershire, Herefordshire and Worcestershire area. The Committee considered the report of the interim inspection visit to the centre, which took place on 18 December 2008, along with the tabled update from the Person Responsible.

2. The Committee noted the areas for improvement identified in the report. The key areas for improvement were summarised at pages five and six. These were:

- third party agreements
- the complaints procedure
- dissemination of HFEA alerts
- validation of processes and equipment
- traceability records
- suitable equipment
- cleaning records
- counselling audit; and
- witnessing and verification of patient identification.

3. The Committee noted that the Person Responsible states in his response to the report that he will work towards addressing the areas for improvement identified in the report in accordance with the timelines set out. The Committee further noted the update from the Person Responsible in the tabled email to Ms Hopper, dated 10 February 2009. This email reports made so far by the Person Responsible. In relation to the key areas for improvement listed above the Committee noted that:

- a system has been put in place to pass on HFEA Alerts and other communications to staff using email.
- traceability record logs have been put in place for equipment and produces in contact with gametes
- cleaning records are being introduced imminently; and
- additional checks on the identify of the sperm providers are being introduced imminently.

4. The Committee noted that there are a number of areas for improvement which the Person Responsible does not refer to in his update, in particular the

requirements to complete third party agreements and to implement a complaints procedure. The Committee noted that the time scale suggested in the report for addressing the latter point was 1 April 2009.

5. The Committee noted that the requirement to validate processes and equipment is also outstanding and that progress in this area will be monitored at the next inspection.

6. The Committee noted that the dry shipper used to transport frozen samples to fertility centres was identified at the inspection as being no longer fit for purpose. The Committee noted that a deadline of 28 February 2009 was given in the report for the replacement of this shipper. The Committee asked the Executive to check that the shipper is replaced by this date.

7. The Committee further noted that the Person Responsible did not mention whether he would be submitting the required counselling audit by 1 April 2009. The Committee asked that this be followed up.

8. The Committee noted that the inspection identified the patient information leaflet entitled “sperm storage for those undergoing radiotherapy or chemotherapy” as being potentially misleading in respect of storage periods. The Committee noted that this should be addressed with immediate effect. The Committee also agreed that the centre should consider whether it would be appropriate to contact previous patients to ensure that they have an accurate understanding of the statutory storage periods.

8. The Committee asked that all the actions completed in response to the inspection report be reviewed at the next inspection of the centre.

9. The Committee noted that this inspection report identified that the centre has now addressed all the recommendations made at the previous inspection.

10. On the basis of the inspection report and the response by the Person Responsible, the Committee decided that the centre’s licence should continue with no additional conditions.

Signed…… … Date……..
Anna Carragher (Chair)