Inspection Report

Date of Inspection: 22 September 2011
Purpose of inspection: Interim inspection of a treatment and storage licence
Length of inspection: 7.5 hours
Inspectors: Chris Hall
Andrew Leonard

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 29 September 2009 and 2 December 2011.

Date of Executive Licensing Panel: 20 December 2011

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the HFEA Code of Practice (CoP), to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence interim 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 Authority's Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	Hartlepool General Hospital
Centre Number	0031
Licence Number	L0031-14-A
Centre Address	The Cameron Unit, North Tees & Hartlepool NHS Trust, University Hospital of Hartlepool, Holdsforth Road, Hartlepool, T24 9AH
Person Responsible	Dr Mohamed Hany Mostafa
Licence Holder	Dr Iona C MacLeod
Date Licence issued	1 March 2010
Licence expiry date	28 February 2014
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
Hartlepool General Hospital has been licensed since 1992. It has a good history of regulatory compliance and consequently no additional conditions on its licence.

A range of licenced treatments are offered to both NHS and privately funded patients.

The unit is self-contained and underwent substantial renovation during 2008 and the addition of new facilities.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 01/08/2010 – 31/07/2011
In Vitro fertilisation (IVF)	93
Intra cytoplasmic sperm injection (ICSI)	91
Frozen embryo transfer (FET)	16
Donor insemination (DI)	1
**Intra uterine insemination (IUI)	**105

**Data for the calendar year 2010

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	N/A
Storage of sperm	✓
Storage of embryos	✓
Research	N/A

Outcomes*

For IVF/ICSI, HFEA held register data for the period 01/08/2010 - 31/07/2011 show the centre's success rates are in line with national averages with the following exception: fresh ICSI cycles in patients aged up to 38 years which are below the national average (NB. this is discussed in more detail on page 14).

For the year 2010 the centre reported 105 cycles of partner IUI with 9 of pregnancies. This equates to an 8.5% pregnancy rate.

*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.

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to draw a conclusion on the continuation of the centre's licence.

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one critical area of non-compliance, one major area of non-compliance and eight other areas of non-compliance or poor practice.

Since the inspection visit the PR has confirmed and/or provided evidence that the following recommendations have been fully implemented:

Major areas of non-compliance:

- The PR should ensure that the pump used in oocyte recovery is validated (Standard Licence Condition (SLC) T24).

Other areas of practice that require improvement:

- The PR should arrange for the centre's "Legal Parenthood Protocol" to be revised to include the requirements that:
  - the proposed second parent is to be informed in writing if the consent to them being the legal second parent is withdrawn by the patient undergoing licensed treatment, or if another legal parenthood consent is provided by the patient (SLC T65); and
  - treatment will not to be provided when a person has withdrawn their consent to be the second parent of a child without telling the woman being treated (SLC T64).

- The PR should arrange for the "Legal Parenthood Patient Information" document to be updated to include information on withdrawal of consent (SLC T60).

- The PR should ensure there is a mechanism in place to document the competence of clinicians in witnessing procedures (SLC T12 & T15a).

- The PR should liaise with the Hospital's Finance Department to ensure any issues that prevent prompt payment are investigated and addressed (SLC T9(d)).

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

Critical areas of concern:

- **The PR should arrange for the review of all disclosure consents against the information held on the register for the period affected by the IT issue preventing independent selection of disclosure consent options on the EDI system (CoP interpretation of mandatory requirements 5F).**

Other areas of practice that require improvement:

- The PR should risk assess current out of hours cover arrangements and ensure backup and emergency clinical facilities meet the requirements of CoP Guidance Note 25.11(b).

- The PR should review “Lab protocol for import and export of gametes and embryos (LAB 37)” and “Protocol for transferring gametes into the fertility unit (LAB38)” to ensure they are compliant with all aspects of CoP Guidance Note 15: Procuring, processing and transporting gametes and embryos. Specifically to ensure they:
  - specify required information is provided when distributing material (SLC T107)
  - specify that gametes and embryos are packaged and transported in a manner that: minimises the risk of contamination; preserves the required characteristics and biological functions; prevents contamination of those responsible for packaging and transportation (SLC T105)
  - address the security of the container/ package used for transportation of gametes/embryos (SLC T108)
  - address the documenting of agreements to ensure required conditions are maintained during distribution (CoP interpretation of mandatory requirements 15C).
  - include the recall procedure and define the responsibilities and actions required when a distribution is recalled; a procedure for handling returned gametes and embryos; a procedure to investigate any recall as an adverse incident (CoP interpretation of mandatory requirements 15C).

- The PR must ensure that activities authorised by the licence and activities carried out in the course of providing treatment services that do not require a licence are audited against compliance with the approved protocols, the regulatory requirements and quality indicators at least every 2 years (SLC T36).

- The PR should ensure that EDI form data submissions are made within the periods stipulated within General Direction 0005 by 22 December 2011. Additionally appropriate arrangements for unplanned absence cover for the individual responsible for EDI submission should be made.

Recommendation to the Executive Licensing Panel

The inspection team considers that overall there is sufficient information available to recommend the continuation of this centre’s licence without additional conditions. In making this recommendation it is noted that the PR has responded to all recommendations made in this inspection report and further improvement is required in only a few areas of practice.

Details of Inspection findings

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood

What the centre does well.

Costed treatment plans
The centre provides fertility services to both NHS and self-funding patients. The latter are provided with a 'Private Patient Charges' list with their initial consultation appointment letter along with a patient information sheet that explains the costs and the circumstances in which full and partial refunds are made.

The 'Private Patient Charges' list is personalised at the time of the initial consultation with the main elements of the proposed treatment (including investigations and tests) being indicated along with excluded costs (e.g. drugs). The Quality Manager explained that patients are given the opportunity to discuss treatment costs at the time of the initial consultation (CoP Guidance 4.3) and are provided with the personalised copy of the 'Private Patients Charges' sheet.

There is a written standard operating procedure ("Private Patient Invoicing Protocol) for staff reference purposes describing how information regarding the cost of treatment is communicated to patients; a copy was provided.

Legal Parenthood
The senior nurse explained that patients having treatment with donor gametes or embryos created with donor gametes and their partners, who are affected by legal parenthood provisions of the Human Fertilisation and Embryology Act 2008:

- are informed about parenthood laws prior to signing consent forms via a patient information document, counselling and discussions with nursing staff (SLC T60);
- are required to complete appropriate parenthood consent forms prior to treatment with donor gametes or embryos (SLC T61).
- are not treated when a partner has withdrawn their consent to be the second parent of a child without telling the woman being treated (SLC T64).

The proposed second parent (i.e. the partner) is also informed in writing if the consent to them being the legal second parent is withdrawn by the patient undergoing licensed treatment, or if another legal parenthood consent is provided by that patient (SLC T65).

A 'Legal Parenthood Patient Information' document has been produced for patients and partners along with a 'Legal Parenthood Protocol' for staff reference (SLC T33(b)); copies

of both documents were provided on inspection.

Two sets of patient's records, where treatment with donor gametes had taken place, were reviewed, and appropriate consents to treatment and legal parenthood were found to be in place in both instances.

General
Quality indicators relevant to the provision of information have been developed. Monitoring is via an annual audit of patient questionnaire responses; a copy was provided.

What they could do better.
Although both the senior nurse and counsellor could explain in detail the procedure to follow regarding the withdrawal of consent in relation to Legal Parenthood, the procedure is not documented in the 'Legal Parenthood Protocol'. Part D of the protocol does not state that:

- the proposed second parent is to be informed in writing if the consent to them being the legal second parent is withdrawn by the patient undergoing licensed treatment, or if another legal parenthood consent is provided by the patient (SLC T65); and
- treatment will not to be provided when a person has withdrawn their consent to be the second parent of a child without telling the woman being treated (SLC T64).

The 'Legal Parenthood Patient Information' document also does not address the issue of withdrawal of consent.

Consent - particularly consent to disclosure to researchers and consent to storage

What the centre does well.

Consent to disclosure of information to researchers
The Quality Manager explained that obtaining disclosure consent is one of the consent processes undertaken by medical and nursing staff prior to treatment and/or storage (SLC T59).

Consent to disclosure is addressed within written information provided to patients and their partners, and they are given the opportunity to discuss any consent related issues with medical, nursing and counselling staff prior to treatment (SLC T58).

Consent to storage
The Principal Embryologist explained that there is written, effective consent for storage of all cryopreserved embryos in store (HF&E Act 1990 (as amended) Schedule 3, 8) and that were a gamete provider to withdraw consent, embryos would remain in storage for the "statutory cooling-off period.

Patient and/or partner consent to storage is obtained by medical and nursing staff prior to storage (SLC T57 and T59).

Withdrawal of consent is discussed with patients and their partners prior to storage and it is a matter covered in the written information provided to patients and partners, copies of which were provided to the inspection team (SLC T58(e)).

There is a protocol in place for the process to be followed when obtaining consent which is used in conjunction with a consent checklist (SLC T33(b)).

A relevant quality indicator (QI) for consents is in place and evidence of audits being undertaken was provided (SLC T35 and T36).

What they could do better.

During an audit of six sets of patient medical records, it was noted that in two instances there was a discrepancy between the information recorded on the patient/partner completed consent to disclosure form in the records and the data submitted to the HFEA by the centre for inclusion on the HFEA Register. Importantly one of the above discrepancies involved an incorrect recording on the register of the patient's consent to being contacted in relation to disclosure of identifying information to researchers (CoP, Interpretation of mandatory requirements 5F).

The Health Care Assistant responsible for EDI data input indicated that an IT issue prevented independent selection and EDI input of answers to the three questions relating to the disclosure of information to researchers (i.e. the questions could only be answered with either three yes or three no answers).

Multiple births

For the 2010/11 time period the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 14%[1].

The centre's multiple clinical pregnancy rate for 2010/11 represents performance likely to be better than the target and unlikely to be due to random variation for the same period.

What the centre does well.

On-going monitoring of the centre's multiple clinical pregnancy rate suggests that the centre is not likely to exceed the 2011/12 multiple birth rate target of 15% (SLC T123).

The PR has provided sufficient evidence to demonstrate compliance with HFEA General Direction 0003 in that:

- staff were able to describe their progress towards reducing their multiple pregnancy rates and subsequent multiple birth rates;
- staff at the centre have audited their strategy and protocols as part of the quality management audit programme;
- staff have maintained a log of women receiving double and triple embryo transfers who

[1] A multiple clinical pregnancy rate of 25% is calculated as likely to result in a multiple live birth rate of 20%.

meet the criteria for single embryo transfer;
- staff have maintained a log which indicates the reasons for variation from the single embryo transfer policy and outcomes which are also recorded in the patients records.

What they could do better.
The centre's eSET log is compliant with the requirements of General Direction 0003. Embryology staff may easily be able to distinguish between those transfers that are compliant and non-compliant with the centre's eSET policy, but it may not be possible for non-embryology staff to as readily discern compliance and non-compliance. Consideration could be given to increasing transparency of eSET compliance and non-compliance within the log.

Validation of critical equipment and processes

What the centre does well.
Documentary evidence was provided which indicated that all critical equipment, with one exception (see below), has been validated (SLCs T24 and T72). Validations are reviewed annually. Critical equipment is re-validated post repair and documentary evidence of revalidation is retained and provided on inspection (SLC T25).

Evidence of gametes and embryos being processed in air of suitable quality was provided (SLC T20).

Instruments and devices used for the procurement of gametes and/or embryos are of good quality, validated or specifically certified and regularly maintained (SLC T28). All procurement equipment is validated and is CE marked. Review of service data indicated that key equipment is regularly serviced.

What they could do better.
The pump used in oocyte recovery has not been validated (SLC T24).

Consideration should be given to validating other items of equipment (e.g. laboratory refrigerator, dewars, alarm system, freeze machine, centrifuge, gas cylinder change over unit, pipettes, scan machine, warming incubator and egg collection tube hot blocks) on the basis of historic data (i.e. critical parameter monitoring records, servicing history and on-going servicing arrangements) to provide evidence that equipment is performing to specification and in a manner consistent with the protection of gamete and embryo safety and quality (SLC T24).

Witnessing

What the centre does well.
The Principal Embryologist explained that the identification of samples and the patients and donors to whom they relate is witnessed by two members of staff at all critical points of all clinical and laboratory processes (SLC T71).

A standard operating procedure (SOP) for witnessing has been documented (SLC T33b) and relevant QIs for witnessing have been established (SLC T36).

The inspection team were provided with evidence of witnessing audit and with documentation indicating that appropriate changes to the witnessing SOP were made in relation to audit findings (SLC T36).

Four sets of patient records were audited at the time of inspection for records of witnessing. Each was found to record the name, status and signature of the practitioner and witness at each critical procedure; the date and time of each critical procedure was also recorded (CoP Guidance 18.7b).

What they could do better.

Assessment of clinicians' competence in witnessing has not been documented (SLC T12 and T15(a)).

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

The centre does not recruit its own donors, but does offer treatments using donor gametes supplied by another licenced centre. Donor gamete supply is governed by a third party agreement that specifies each sample must be accompanied by the documentation specified by the HFEA.

The Principal Embryologist stated that the donor samples and the suite of documents provided with them are checked on receipt.

A "Donor Insemination – Information Sheet" has been prepared and is provided to patients considering treatment with donor gametes. It is the centre's policy that all patients and their partners contemplating treatment with donated gametes, are offered counselling before the commencement of treatment.

What they could do better.

None noted at the time of inspection.

Welfare of the Child (in relation to basic partner treatment services only)
What the centre does well. The Quality Manager explained that before any patient is provided with treatment services, an assessment is undertaken of the welfare of the child that may be born as a result of treatment (including the need for supportive parenting) and of any other child who may be affected by the birth. This includes those patients receiving basic partner treatment services (SLC T56). The files of two patients who had previously undergone IUI treatment with partner sperm were reviewed to determine whether patient and partner welfare of the child assessments were undertaken. . Assessments were found to have been conducted appropriately for both the patient and partner prior to treatment in both sets of records. The inspection team reviewed the centre's protocol for welfare of the child assessment and determined that a relevant QI for welfare of the child assessment has been established, Audits of welfare of the child assessment have been conducted and appropriate remedial action was seen to have been taken to address audit findings.
What they could do better. Nothing noted at the time of inspection.

Embryo testing (if applicable)
What the centre does well. N/A
What they could do better. N/A

2. Changes / improvements since the previous inspection on 29 September 2009

Area for improvement	Action required	Action taken as evidenced during this inspection
In the course of the consent audit an anomaly was found in one set of patient records.	The PR should establish quality indicators relevant to the taking and establishment of consent and audit practice against compliance with the approved protocols, the regulatory requirements and quality indicators. (T35 and T36 8th Code of Practice). The audit should be completed by 29 December 2009. The findings and corrective actions must be documented. The HFEA should be advised when the audit is complete.	A QI relevant to consent procedures has been established (SLC T35). The QI is monitored via regular periodic audit of consents in patient records (SLC T36). The QI and consent audit documentation was reviewed on inspection. The audit found staff to be adhering to CoP requirements for consent taking (SLC T57). **No further action is required.**
Progress has been made with the validation of laboratory processes but some validations remain outstanding. Validation of air quality monitoring has not been completed. This was non-compliant with the requirements of standard licence conditions A.10.13 and A.11.11 of the Code of Practice (7th Edition). **Validation was a breach noted on the last inspection.**	In compliance with T24 and T72 of the 8th Code of Practice, the PR should ensure that procedures for air quality monitoring must be validated. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well established processing procedures. To be completed by 29 December 2009.	Air quality monitoring has now been completed In compliance with SLC T24 and T72. Evidence of compliant air quality determined by 6 monthly air quality monitoring and monthly settle plate testing was provided at inspection. **No further action is required.**
Patient information does not include information on waiting times (G.5.3.1.b) and the consequences of withdrawal of consent (G.5.2.1.d). Information for those seeking treatment with donated gametes does not include relevant information	The PR should review the patient information against the requirements of the 8TH Code of Practice. At the PR's discretion. To be monitored at next inspection.	The PR explained that there is currently no waiting list. The 'Donor Insemination' patient information document includes information on the risks of using donated sperm, donor screening and the

Area for improvement	Action required	Action taken as evidenced during this inspection
on the likelihood of inheritance of physical characteristics (G.5.4.1.b) or information on screening tests that donors undergo (BFS and BAS guidelines) (G.5.4.2).		importance of knowing about the donor and their medical history in relation to inherited characteristics and medical conditions (SLC T58). **No further action is required.**
For the year from 1 April 2009 to 27 August 2009 the centre took an average 33 days to pay invoices. This was a breach of standard licence condition A.13.3 of the Code of Practice (7th Edition). **This breach was noted on the previous inspection.**	The PR should review and consider whether there are barriers to the prompt payment of HFEA invoices. Immediately. To be monitored at next inspection.	At the time of inspection, HFEA Finance reported that the average invoice payment time was 35 days (SLC T9(d)). **Further action is required.**
At inspection several documents were found that had not been reviewed and/or updated within a 12 month period. This was a breach of S.5.2.5 of the Code of Practice (7th Edition) **This breach was noted on the last inspection.**	The PR should give consideration to the guidelines provided at 36.1 of the 8th Code of Practice that all documents should be reviewed, revised and reapproved at a frequency that ensures they remain fit for purpose. The maximum interval between reviews should be 12 months. To be completed by 29 December 2009.	The PR explained that the documents referred to are North Tees and Hartlepool NHS Foundation Trust documents and that in line with The Trust's risk management standards, such documents are subjected to a 3 yearly review. The centre reviews its own documents annually and will endeavour in future to review the content of the Trust documents on a yearly basis as well (SLC T34). **No further action is required.**

3. Areas of concern

The analysis of the centre's self-assessment questionnaire (SAQ) and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
Outcome data Pre-inspection analysis of HFEA held register data for the period 01/08/2010 - 31/07/2011 show the centre's success rates are in line with national averages except for fresh ICSI cycles in patients aged up to 38 years.	The inspectorate was able to establish pre-inspection that outstanding early outcome data could be affecting the data. The centre confirmed that due to a period of sickness absence of the Health Care Assistant responsible for data input, the submission of early outcome data had been delayed.	Further action is required.
Guidance Note 2: Staff Whether the centre is operating with a full staff complement? [see SLC T12]	The PR explained that the centre was not operating with a full staff complement but that this will be addressed in November 2011 when he and another clinician cease their antenatal clinic work in order to dedicate their time to the licensed fertility clinic. Current activity is appropriate for the reduced staffing level and the latter is actively being addressed.	No further action is required.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
Guidance Note 3: Counselling Whether the centre has assessed how far counselling procedures comply with the approved protocols, regulatory requirements and quality indictors in the last two years? [see SLC T36]	The counsellor explained that relevant QIs have been developed and audits of the counselling service have been performed. A copy of the 'Counselling Service – Survey report August 2011' was provided along with a copy of the audit report 'Audit of Practice vs Protocol for Counselling'.	No further action is required.
Whether all steps have been taken to correct counselling procedures where appropriate? [see SLC T36]	The PR explained that a new part-time counsellor had been in post since June 2011. The previous counsellor had been up to date with the development of QIs, audit and the implementation of actions to correct procedures where necessary. The new counsellor explained that corrective actions are taken in response to surveys and audits. Review of the 'Audit of Practice vs Protocol for Counselling' document provided evidence that audits result in the recommendation and implementation of corrective actions.	No further action is required.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
Guidance Note 5; Consent to treatment, storage, donation and disclosure of information Whether consent is ever obtained on the day that a procedure occurs (for example, are patients ever asked to consent to storage on the day of embryo transfer or to consent to ICSI on the day of egg collection)? [see Schedule 3, Section 3 (1)(a)].	The senior embryologist explained that all patients are consented for fertility treatment well before the actual treatment takes place, so there is no issue with IVF to ICSI switching on the day of the procedure. The only consenting on the day relates to a hospital procedural consent form and not to HFEA consents.	No further action is required.
Whether the centre ensures that in every case where embryos are being used for the purpose of training in embryo biopsy, embryo storage or other embryological techniques, both gamete providers have consented to the use of embryos, created using their gametes, for such training? [see SLC T94]	The Principal Embryologist explained that whilst training consents are obtained, the centre has not used embryos in training and that a SOP will be developed when needed.	No further action is required.
Guidance Note 6: Legal Parenthood When a nominated second parent withdraws their consent to parenthood, whether the centre ensures that the named woman is not treated until she is informed of this? [see SLC T64 (b)]	The senior nurse explained that a patient would be informed immediately by centre staff if a person has withdrawn their consent to be the second parent of a child without telling the patient (SLC T64). This process is not however documented in	Further action is required

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
	the 'Withdrawal of consent' section of the 'Legal Parenthood Protocol'.	
Should a woman being treated withdraw her consent to a nominated second parent being the legal parent, or consent to a different person being the legal parent of any child born, whether the centre have a procedure in place to ensure that the nominated second parent is informed of the change in writing?	The senior nurse explained that if a woman being treated withdrew her consent to a nominated second parent being the legal parent, or consented to a different person being the legal parent of any child born, the centre would inform the nominated second parent of the change. The mechanism for doing so is that the consultant would discuss the issue with the patient wishing to withdraw consent. The consultant would be responsible for informing the partner/nominated second parent. The 'Withdrawal of consent' section of the 'Legal Parenthood Protocol' does not however document that this process must occur (SLC T65).	Further action is required.
Guidance Note 15: Procuring, processing and transporting gametes and embryos Whether there a SOP that details the circumstances, responsibilities and	The Principal Embryologist explained that there were SOPs for receiving samples and for exporting and importing samples and provided copies of the required documentation with the samples (LABP	No further action is required

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
procedures for the release of stored material before distribution? [see SLC T33b]	37 & LABP 38).	
Whether transport conditions including temperature and time limit, are specified? [see SLC T107]	The Principal Embryologist provided evidence that a dry shipper checklist is used to ensure appropriate transport conditions are maintained. There is also a dry shipper protocol in place for staff reference.	No further action is required.
Whether all containers and packages have been validated as fit for purpose? [see SLC T108]	The Principal Embryologist provided evidence that the dry shipper has been validated [SLC T108].	No further action is required.
Whether the centre has a recall procedure that defines the responsibilities and actions required when a distribution is recalled? [CoP interpretation of mandatory requirements 15C]	The Principal Embryologist explained that the centre has not developed or documented a recall procedure or defined the responsibilities and actions required when a distribution is recalled [CoP interpretation of mandatory requirements 15C]	Further action is required.
Whether the centre has a procedure for handling returned gametes and embryos? [CoP interpretation of mandatory requirements 15C]	The Principal Embryologist explained that the centre has not yet developed or documented a procedure for handling returned gametes and embryos [CoP	Further action is required.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
	interpretation of mandatory requirements 15C]	
Whether the centre has a procedure for the investigation of any recall as an adverse incident [CoP interpretation of mandatory requirements 15C]	The Principal Embryologist explained that the centre has not yet developed or documented a procedure for investigating any recall as an adverse incident [CoP interpretation of mandatory requirements 15C]	Further action is required.
Whether when transporting gametes the centre ensures that the shipping container or a separate sheet accompanying the container includes labelling as required by SLC T107?	The centre's protocol (LABP 37) does not specify that the shipping container or a separate sheet accompanying the container should include the labelling required by SLC T107.	Further action is required.
Whether all required information is provided when distributing material? [SLC T110]	The centre's export protocol (LABP 37) does not specify that the required information is provided when distributing material [SLC T107]	Further action is required.
Whether the centre ensures that gametes and embryos are packaged and transported in a manner that minimises the risk of contamination? [SLC T105]	The centre's export protocol (LABP 37) is non-compliant with SLC T105 since it does not specify, or define conditions which ensure, that gametes and embryos are packaged and transported in a manner that:	Further action is required.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
	• minimises the risk of contamination; • preserves the required characteristics and biological functions; and • prevents contamination of those responsible for packaging and transportation.	
Whether the centre ensures that the container/ package used for transportation of gametes/ embryos is secure ? [SLC T108]	The centre's export protocol (LABP 37) did not address the security of the container/ package used for transportation of gametes/ embryos. [SLC T108].	Further action is required.
Whether there is a documented agreement in place that ensures the required conditions are maintained during distribution? [CoP interpretation mandatory requirements 15C]	The centre's export protocol (LABP 37) did not address the documenting of agreements to ensure required conditions are maintained during distribution [CoP interpretation mandatory requirements 15C]	Further action is required.
Guidance Note 23 The Quality Management System Whether the centre has training and reference manuals? [see SLC T33]	The centre holds specialist reference and equipment user manuals [SLC T33].	No further action is required.
Whether relevant SOPs detail the	The Quality Manager stated that, where	No further action is required.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
specifications for any critical materials and reagents used in the procedures? [see SLC T31]	appropriate, protocols detail the specifications for any critical materials and reagents used in the procedure [SLC T31]	
Whether the centre has established quality indicators for all licensed activities and for other activities carried out in the course of providing treatment services that do not require a licence? [see SLC T35]	The Quality Manager stated that quality indicators have been established for all licensed activities. For the areas under review documented examples were provided.	No further action is required.
Whether in the last two years, the centre has audited how far all licensed activities, or activities carried out in the course of providing treatment services that do not require a licence, comply with the approved protocols, the regulatory requirements and quality indicators? [see SLC T36]	The Quality Manager stated that a programme of audits has been constructed to assess how far all licensed activities, or activities carried out in the course of providing treatment services that do not require a licence, comply with the approved protocols, the regulatory requirements and quality indicators. A copy of the current years audit timetable was provided [SLC T36].	No further action is required.
Whether the centre has established written agreements with third parties who provide goods or services that influence the quality and safety of gametes and	The Principal Embryologist explained that agreements with third parties who provide goods or services that influence the quality and safety of gametes and	No further action is required.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
embryos? [SLC T99]	embryos have been established. A list of thord party agreements was provided on inspection [SLC T99]	
Whether the centre has evaluated the ability of all third parties to meet the required standards? [SLC T100]	The Principal Embryologist provided evidence of the assessment of third parties based on a 1 to 4 scoring system across several areas of service. Additionally, evidence of finding a supplier unsuitable and taking appropriate action was provided [SLC T100]	No further action is required.
Whether it is a condition of all agreements that the third party will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice? [SLC T104]	The Principal Embryologist explained that it is a condition of all agreements that the third party will meet the requirements of the relevant licence conditions and the guidance set out in the HFEA Code of Practice. The inspection team confirmed this by reviewing a randomly selected third party agreement [SLC T104]	No further action is required.
Guidance Note 25: premises and Facilities Whether the centre is equipped with backup and emergency clinical facilities that: (i) are equivalent to those provided as	North Tees and Hartlepool NHS Foundation Trust out of hours cover for the centre's patients is provided by an on-call gynaecology consultant based at the University Hospital in Cleveland. The PR considers this to be inadequate and so	Further action is required.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
standard practice in other medical facilities; (ii) are appropriate to the degree of risk involved in any planned procedure; and (iii) can cope with emergencies known to occur in this clinical field	centre staff provide around the clock out of hours specialist fertility cover on a voluntary basis. The PR is liaising with the Trust in an attempt to get this officially recognised by the Trust. [Guidance Note 25.11(b)]	
Guidance Note 26: Equipment and Materials Whether equipment with a critical measuring function is calibrated against a traceable standard if available (e.g. CO_2 monitoring devices, particle counting devices, thermometers)? [SLC T24]	The Principal Embryologist stated that equipment with a critical measuring function is calibrated against a traceable standard, e.g. the particle counters used for air quality monitoring purposes are calibrated against a traceable standard described in the air quality report.	No further action is required.
Whether, where possible, medical devices used in the centre are CE marked? [SLC T30]	With the exception of two dishes, all items used are CE marked. The Principal Embryologist explained that CE marked dishes have been sourced and will be used in future.	No further action is required.
Guidance Note 30: Confidentiality and privacy Whether in the last two years, the centre has audited how far procedures to ensure that all information is kept confidential	The centre has not audited within the last 2 years its procedures for maintaining the confidentiality of information to ensure they comply with the approved protocols, regulatory requirements and quality	Further action is required.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
comply with the approved protocols, regulatory requirements and quality indicators? [SLC T36]	indicators.	
Guidance Note 31: Record keeping and document control Whether relevant staff can provide documented evidence of having received training in submitting data to the HFEA? [SLC T15a]	The Quality Manager explained that both she and one of the Health Care Assistants have received training in submitting data to the HFEA. The Quality Manager provided a copy of her training record to confirm this.	No further action is required.

Areas of practice that require the attention of the Person Responsible

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, Directions or the Code of Practice, and the recommended improvement actions require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. 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
Guidance Note 5; Consent to treatment, storage, donation and disclosure of information Discrepancies were noted between information recorded on the patient/partner consent to disclosure form in the medical records and the data submitted by the centre to the HFEA for inclusion on the	A member of staff stated that they were unable to independently select yes and no for the three Registry data related questions on the consent form. The three questions could only all be answered as yes or no. The inspector has asked for the HFEA's EDI Support team to liaise with the centre to	After discussion with IT department, they are trying to resolve this issue. Following this we will undertake audit of disclosure forms to identify any discrepancies.	The inspectorate is aware that the centre staff and the HFEA's IT team are still investigating this issue. Due to the fact that a significant number of disclosure consents are potentially involved, a 6 month time timeframe to review consents has been allowed (i.e. 31 May 2012). Progress in resolving the IT issue and checking the

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
HFEA Register. Importantly one of the above discrepancies involved an incorrect recording on the Register of the patient's consent to being contacted regarding the disclosure of identifying information to researchers (COP interpretation of mandatory requirements 5F).	investigate and resolve this matter. The PR should ensure this matter is followed up by centre staff as soon as possible. Once this matter is resolved, the PR should review all disclosure consents in patient records against the information held on the HFEA Register for the period affected by this IT issue. Corrections should be made to update the Register as appropriate. This should be completed by 22 December 2011.		affected disclosure consents against the Register data submitted will be monitored by the inspectorate.

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
Guidance Note 26: Equipment and Materials The pump used in oocyte recovery has not been validated (SLC T24).	The PR should ensure that the pump used in oocyte recovery is validated by 22 December 2011. Consideration should also be given to validating other items of equipment (e.g. laboratory refrigerator, dewars, alarm system, freeze machine, centrifuge, gas cylinder change over unit, pipettes, scan machine, warming incubator and egg collection tube hot blocks), on the basis of historic data (i.e. critical parameter monitoring records,	Pump validated Oct. 2011 validation certificate attached. Principle embryologist to complete lab equipment validation by Feb 2012 Scan machine validation and service reports were provided at the time of inspection.	The progress of laboratory equipment validation will be monitored via the inspectorate's on-going monitoring process.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	servicing history and on-going servicing arrangements) to provide evidence that these items of equipment are performing to specification and in a manner consistent with protection of gamete and embryo safety and quality.		

Other areas of practice that require improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Guidance Note 6: Legal parenthood The documented legal parenthood procedures do not record the centre's processes for: • advising the second parent in writing if the patient withdraws their consent to them being the second parent; and • ensuring treatment is not provided when a person has withdrawn their consent to being the second parent of a child without first telling the woman being treated of the withdrawal of consent. (SLC T64 & T65)	The PR should arrange for the centre's 'Legal Parenthood Protocol' to be revised by 22 December 2001, to include the processes that ensure: • the second parent is advised in writing if the patient withdraws their consent to them being the second parent; and • treatment is not provided when a person has withdrawn their consent to being the second parent of a child without first telling the woman being treated of the withdrawal of consent.	Protocol revised and attached. (ref. CP30 v.2 nov 2011)	No further action is required.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The 'Legal Parenthood Patient Information' document also does not address the issue of withdrawal of consent (SLC T60).	The PR should arrange for the 'Legal Parenthood Patient Information' document to be updated to include information on withdrawal of consent by 22 December 2011.	Information revised and attached (ref. CPI 32 v.2 nov 2011)	No further action is required.
Guidance Note 2: Staff Assessments of clinicians' competence in witnessing have not been documented (SLC T12 & T15(a)).	The PR should ensure that by 22 December 2011 there is a mechanism in place to document the competency of clinicians in witnessing procedures.	Competency assessments undertaken, evidence attached.	No further action is required.
Guidance Note 1: Person Responsible At the time of inspection the average invoice payment period for the previous 12 months was 35 days (SLC T9(d)).	The PR should speak to the Hospital's Finance Department to ensure any issues preventing prompt payment are investigated and addressed by 22 December 2011 (SLC T9(d)). At the PR's request the inspectorate has asked the HFEA Finance Department to address invoices to the PR and LH.	Discussed by PR with finance dept.	To be monitored via the inspectorate's on-going monitoring process.
Guidance Note 25.11 (b): North Tees and Hartlepool	The PR should risk assess current out of hours cover	At the present time there is a 24/7 on call bleep carried by	To be monitored via the inspectorate's on-going

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
NHS Foundation Trust out of hours cover for the centre's patients is provided by an on-call gynaecology consultant based at the University Hospital in Cleveland. The PR considers this to be inadequate and so centre staff provide around the clock out of hours specialist fertility cover on a voluntary basis. The PR is liaising with the Trust in an attempt to get this officially recognised by the Trust. [Guidance Note 25.11(b)] .	arrangements and where appropriate take action to ensure backup and emergency clinical facilities: (i) are equivalent to those provided as standard practice in other medical facilities; (ii) are appropriate to the degree of risk involved in any planned procedure; and (iii) can cope with emergencies known to occur in this clinical field.	medical team on voluntary basis. The on-call fertility consultant will manage and closely liaise with the on call gynaecologist regarding the management of any fertility treatment emergency. The PR will negotiate with the CD to identify that level of cover in the job plans of the different consultants working in the unit. A full risk assessment of the medical cover for the unit will be carried out by the PR and the QM and the result will be discussed with the CD and the women's health manager. That will be concluded by the end of January 2012.	monitoring process.
Guidance Note 15: Procuring, processing and transporting gametes and embryos The 'Lab protocol for Import and export of gametes and	The PR should arrange for the review of the 'Lab protocol for Import and export of gametes and embryos' (LAB 37) and 'Protocol for transferring gametes into the fertility unit' (LAB38) to ensure compliance with all aspects of	Principle embryologist will review protocols and amend by feb 2012	Progress to be reviewed via the inspectorate's on-going monitoring process.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
embryos' (LAB 37) and 'Protocol for transferring gametes into the fertility unit' (LAB38) do not fully reflect the requirements contained within Code of Practice, Guidance Note 15: Procuring, processing and transporting gametes and embryos.	Guidance Note 15: Procuring, processing and transporting gametes and embryos. Specifically the PR should ensure the SOPs: - specify the required information to be transferred with distributed material (SLC T107) - specify that gametes and embryos are packaged and transported in a manner that: minimises the risk of contamination; preserves the required characteristics and biological functions; prevents contamination of those responsible for packaging and transportation [SLC T105]; - address the security of the container/package used for transportation of gametes/embryos [SLC		

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
	T108]; - address the documenting of agreements with couriers to ensure required conditions are maintained during distribution (CoP interpretation mandatory requirements 15C). - include procedures for: recall which define the responsibilities and actions required when a distribution is recalled; handling returned gametes and embryos; investigation of any recall as an adverse incident (CoP interpretation of mandatory requirements 15C). The review should be undertaken by 22 December 2011.		
Guidance Note 30:	The PR must ensure that	Audit to be completed by	Progress to be reviewed via

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
Confidentiality and privacy Procedures to ensure that all information is kept confidential have not been audited in the last 2 years to ensure they comply with the approved protocols, regulatory requirements and quality indicators (SLC T36).	activities authorised by the licence and activities carried out in the course of providing treatment services that do not require a licence are audited at least every 2 years against compliance with the approved protocols, the regulatory requirements and quality indicators.	22.12.2011 by Quality Manager.	the inspectorate's on-going monitoring process.
Guidance Note 31: Record keeping and document control Some early outcome forms have not been submitted within the deadlines specified in General Direction 0005.	The PR should ensure that EDI form data submissions are made within the periods stipulated within General Direction 0005 by 22 December 2011. Appropriate arrangements for unplanned absence cover of the individual responsible for EDI submission should be put in place.	Training arranged for 19.12.11 for all staff, to be followed by competency assessment. Quality manager to cover holidays/absence until all staff competent in all aspects of data submission.	Progress to be reviewed via the inspectorate's on-going monitoring process.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

20 December 2011

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

Minutes – Item 2

Centre 0031 – (Hartlepool General Hospital) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Nick Jones, Director of Compliance	Joanne McAlpine

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of 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 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 Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has been licensed since 1992 and offers a range of licensed treatments to NHS and privately funded patients.

2. The Panel noted that the centre underwent substantial renovation during 2008 and the addition of new facilities.

3. The Panel noted that during the period of 1 August 2010 – 31 July 2011 the centre conducted 93 IVF (In Vitro fertilisation) treatment cycles, 91 ICSI (Intra cytoplasmic sperm injection), 16 FET (frozen embryo transfers), 1 Donor insemination (DI) and 105 Intra uterine insemination (IUI) treatment cycles.

4. The Panel noted that for IVF/ICSI, the HFEA held register data for the above period show that the centre's success rates are in line with the national averages, with the exception of fresh ICSI cycles in patients aged up to 38 years which are below the national average. The Panel also noted the centre's multiple pregnancy rate for 2010-11 for all age groups is 14%.

5. The Panel noted that at the time of the inspection there were a number of areas of practice that required improvement: one critical area of non-compliance, one major and eight other areas of non -compliance.

6. The Panel noted that since the inspection the Person Responsible (PR) has confirmed and/or provided evidence that one major and eight other areas of non-compliance have now been implemented.

7. The Panel noted the one critical area of concern relating to the review of all disclosure consents against information held on the HFEA register. The PR has given a commitment to implement this area as soon as an IT issue with the EDI system is resolved. The Panel noted the extended timeframe to complete this review and urged the HFEA's IT team and the centre to resolve any IT problems quickly so that the review could begin.

8. The Panel noted the very detailed SAQ and the comprehensive detail that the PR has provided.

9. The Panel noted the Inspectorate's recommendation for the continuation of the centre's licence with no additional conditions, and the recommendations in respect of non-compliances made in the report.

Decision

10. The Panel urged the PR to work with the Inspectorate to resolve the critical area of non-compliance as fast as practicable.

11. The Panel endorsed the Inspectorate's recommendation to continue the centre's licence, with no additional conditions.

Signed: Peter Thompson Date: 9/1/12.
Peter Thompson (Chair)