HFEA Executive Licensing Panel Meeting

29 November 2013

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

Minutes – Item 1

Centre 0031 – (Assisted Reproduction Unit – ARU, University Hospital of Hartlepool) – Renewal Treatment & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Dee Knoyle
Rachel Hopkins – Head of Human Resources	**Observing:**
Paula Robinson – Head of Business Planning	Sam Hartley – Head of Governance and Licensing

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 considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a treatment and storage centre which provides a full range of licensed treatments. The Panel noted that in relation to activity levels this is a small centre.

3. The Panel noted that the centre has been licensed by the HFEA since 1992. The Panel noted that the centre is on a four-year licence due to expire on 28 February 2014.

4. The Panel noted that the centre provided 199 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2013.

5. The Panel noted that for IVF and ICSI, HFEA-held register data for the period 1 April 2012 to 31 March 2013 show the centre's success rates are in line with national averages.

6. The Panel noted that in 2012, the centre reported 107 cycles of partner insemination with four pregnancies. This equates to a 4% clinical pregnancy rate which is consistent with the national average.

7. Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rates for all IVF, ICSI and FET cycles for all age groups was 27%. This represented performance that was not statistically different from the 20% maximum multiple live birth rate target for this period.

8. Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 24%. This represented performance that was not likely to be statistically different from the 15% maximum multiple live birth rate target for this period.

9. The Panel noted the Inspectorate's recommendation that the PR should ensure that the quality management system is used to best effect to monitor and reduce their multiple pregnancy rates in line with the current target, and in doing so improve the quality of the service offered to patients.

10. The Panel noted that at the time of the inspection on 4 and 5 September 2013, the Inspectorate identified three major and five other areas of non-compliance. The Panel noted that, since the inspection, the centre has provided evidence that some of the recommendations for improvements have been fully implemented, and some recommendations require further monitoring. The Panel, in particular, noted the non-compliance relating to the reporting of DI treatments although it was satisfied that this has been addressed and all future licensed treatment activities will be reported to the Authority within the timeframe required by General Directions 0005. The Panel noted the PR's commitment to implement the outstanding recommendations within the set timescales.

11. The Panel noted the Inspectorate's recommendation that some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides.

12. The Panel noted that the Inspectorate recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions.

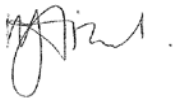
Decision

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

14. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and that he has discharged his duty under section 17 of the HF&E Act 1990 (as amended).

15. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

16. The Panel endorsed the Inspectorate's recommendation to renew the centre's Treatment and Storage licence for four years, without additional conditions, subject to compliance with the recommendations made in this renewal inspection report being implemented within the prescribed timescales.



Signed: Date: 13 December 2013

Juliet Tizzard (Chair)

Inspection Report

Purpose of the Inspection Report

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

Date of inspection: 4 & 5 September 2013
Purpose of inspection: Renewal of a licence to carry out 'Treatment and Storage'

Inspection details:

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

Date of Executive Licensing Panel: 29 November 2013

Centre name	Assisted Reproduction Unit (ARU), University Hospital of Hartlepool
Centre number	0031
Licence number	L/0031/14/c
Centre address	North Tees & Hartlepool NHS Trust, University Hospital of Hartlepool, Holdforth Road, Hartlepool, Cleveland, TS24 9AH
Person Responsible	Dr Mohamed Hany Mostafa
Licence Holder	Dr Iona C MacLeod
Date licence issued	01 March 2010
Licence expiry date	28 February 2014
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

The Assisted Reproduction Unit (ARU), University Hospital of Hartlepool has held a licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 199 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2013. In relation to activity levels this is a small centre.

The centre's current licence was last renewed in March 2010 for a period of four years without additional licence conditions. The centre's last inspection was an announced interim inspection in September 2011.

An application to vary the centre's licence to reflect a change of name from 'The Cameron Unit, Hartlepool General Hospital' to 'Assisted Reproduction Unit (ARU), University Hospital of Hartlepool' was granted by the ELP on 16 August 2013.

Activities of the centre:

Type of treatment	Number of treatment cycles for the period 01 Jul 2012 - 30 Jun 2013
In Vitro Fertilisation (IVF)	108
Intracytoplasmic sperm injection (ICSI)	65
Frozen embryo transfer (FET)	19
Donor insemination (DI)	7
Partner insemination (IUI) (Jan to Dec 2012)	107

Other licensable activities	
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research (if applicable)	N/A

Outcomes*

For IVF and ICSI, HFEA held register data for the period 1 April 2012 to 31 March 2013 show the centre's success rates are in line with national averages.

In 2012, the centre reported 107 cycles of partner insemination with four pregnancies. This equates to a 4% clinical pregnancy rate which is consistent with the national average.

Multiple births[2]

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

Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 27%. This represented performance that was not statistically different from the 20% multiple live birth rate target for this period.

Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy** rate for all IVF, ICSI and FET cycles for all age groups was 24%. This represented performance that was not likely to be statistically different from the 15% multiple live birth rate target for this period.

*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. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

**[2]The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

Summary for licensing decision

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

- the PR is suitable and has discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The ELP is asked to note that at the time of the inspection there were recommendations for improvement in relation to three major and five 'other' areas of non-compliance.
Since the inspection visit, the centre has provided evidence that the following recommendations have been fully implemented:

Major areas of non compliance:

- the PR should ensure that gametes and embryos are stored in accordance with the gamete provider's consent.

'Other' areas of poor practice that require improvement:

- the PR should ensure that there is a mechanism in place to identify when additional screening tests are required;
- the PR should ensure all tubes used to collect follicular fluid during egg collection are labelled with the patients / donor's full name and a further unique identifier.
- the PR should ensure that the temperature and time limits for use of shipping containers are specified within the relevant standard operating procedures (SOPs).

The centre has provided evidence that the following recommendations have been implemented but further monitoring is required:

Major areas of non compliance:

- the PR should ensure that witnessing is recorded at all critical points of the clinical and laboratory process.
- the PR should ensure that all licenced treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

'Other' areas of poor practice that require improvement:

- the PR should establish and maintain a summary log of cases where multiple embryos have been transferred to a patient who meets the criteria for elective single embryo transfer (eSET).

The PR has provided a response confirming his commitment to undertaking the following recommendation:

'Other' areas of poor practice that require improvement:

- the PR should ensure that all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, are audited against compliance, namely:
    - confidentiality and privacy
    - submission of data to the HFEA.

Implementation of these recommendations will be subject to on-going monitoring by the centre's inspector.

Recommendation to the Executive Licensing Panel

Some improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides. The inspection team is satisfied that activities carried out at the centre are necessary in order to provide licensed treatment services.

The PR should ensure that the quality management system is used to best effect to monitor and reduce their multiple pregnancy rates in line with the current target, and in doing so improve the quality of the service offered to patients.

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

Section 2: Inspection findings

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

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

1. Protection of the patient, and children born following treatment

Witnessing and assuring patient and donor identification (Guidance note 18)

What the centre does well.

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

What the centre could do better.

Standard Licence Condition (SLC) T71 requires that witnessing checks are completed and recorded at the time the relevant clinical or laboratory procedure takes place. During the inspection the scientific inspector was able to observe witnessing procedures during egg collections, insemination and gamete disposal. Whilst activities were appropriately witnessed by a second person, the witnessing of transfer of eggs between dishes was not documented.

See recommendation 2

Patient and donor selection criteria and laboratory tests

- Screening of patient and / or donors prior to procuring, processing and / or transporting gametes and embryos (Guidance notes 11 and 15)
- Payments for donors (Guidance note 13)
- Donor assisted conception(Guidance note 20)

What the centre does well.

Screening of patients and / or donors

The centre does not recruit donors and therefore donor screening is not performed. Procedures for screening patients are broadly compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross

infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors
The centre does not recruit donors but treatment may be provided with donor gametes transferred from an external donor bank.

Donor assisted conception
People born as a result of donation are entitled to request and receive their donor's name and last known address, once they reach the age of 18. Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre is fully compliant with the requirements of the HFEA to ensure the donor conceived will be able to receive this information.

What the centre could do better.

Patient screening:
The centre does not carry out additional tests depending on the patient's travel and exposure history. e.g. for RhD, Malaria, CMV and T.cruzi (SLC T50d).

See recommendation 6

Good clinical practice

What the centre does well.

The centre's licence renewal application indicates that the centre wishes to conduct egg freezing, vitrification and pronucleate embryo freezing as proposed new activities. Prior to the inspection the PR confirmed that these activities may be conducted at a later point. The PR confirmed that prior to these activities commencing, SOPs, patient information and evidence of staff training in these techniques will be provided to the centre's inspector.

Multiple births (Guidance note 7)
The single biggest risk of fertility treatment is a multiple pregnancy.

The centre has been partially effective in adapting their multiple birth minimisation strategy to meet the HFEA's multiple birth rate target.

Process Validation (Guidance note 15)
The centre has fully validated all critical processing procedures to ensure that these procedures are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Traceability (Guidance note 19)
The centre's procedures are broadly compliant with HFEA requirements to ensure it has the ability -

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

Quality management system (Guidance note 23)
The centre has a quality management system in place that is broadly compliant with HFEA requirements. The centre uses its quality management system to ensure optimum outcomes and improve the quality and safety of the treatment and services it provides to patients.

Third party agreements (Guidance note 24)
The centre has agreements in place which cover the :
(a) procurement, testing or processing of gametes or embryos on behalf of the licensed centre, and
(b) supply of any goods or services (including distribution services) to the licensed centrewhich may affect the quality or safety of gametes or embryos.

Equipment and materials (Guidance note 26)
Equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

Premises (Guidance note 25)
The centre conducts all the licensed activities in an appropriate environment, in line with good clinical practice. All diagnostic testing is carried out in a suitable accredited laboratory.

Adverse incidents (Guidance note 27)
The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all of the adverse incidents that have occurred and shares the lessons learned in order to continuously improve the services it offers.

What the centre could do better.

Multiple Births (Guidance note 7)
It was noted that the centre has a log of all cases where multiple embryos were transferred, however the centre does not maintain a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer (General Direction 0003).

See recommendation 5

While it is acknowledged that the centre's clinical multiple birth rate / pregnancy rate indicates performance not likely to be different from the relevant targets, the effectiveness of the centre's current strategy was discussed on inspection in

consideration of the 10% live birth rate target that became effective on 1 October 2012. If the centre's current multiple pregnancy rate trajectory continues, the centre may not meet this current target (SLC T123). It is suggested that the centre continues to closely monitor the effectiveness of their multiple birth minimisation strategy.

Quality management system (Guidance note 23)
Audits of the procedures and processes for submitting data to the HFEA and for maintaining patient confidentiality have not been conducted within the last two years (SLC T36).

See recommendation 4

Traceability (Guidance note 19)
Aspirate tubes used to collect follicular fluid are not labelled with the patient's full name and a further unique identifier or a uniquely identifying donor code (SLC T101).

See recommendation 7

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance note 1)
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and
- that the conditions of the licence are complied with.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

The PR has successfully completed the HFEA PR Entry Programme (Prep no. T/1253/7).

Staff (Guidance Note 2)
The centre has suitably qualified and competent staff to carry out all of the licensed activities and associated services.

What the centre could do better.

Nothing noted at time of inspection.

Welfare of the child(Guidance note 8)
What the centre does well. The centre's procedures for taking into account the welfare of the child are compliant with HFEA requirements. The centre takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth.
What the centre could do better. Nothing noted at time of inspection.

2. The experience of patients

Patient feedback

What the centre does well.

During the inspection visit the inspectors spoke to two patients who provided feedback on their experiences. A further 19 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was very positive with 13 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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

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

What the centre could do better.

Nothing noted at time of inspection.

Treating patients fairly

What the centre does well.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements, ensuring that counselling support is available to patients before and during the consenting process and treatment.

Gamete sharing arrangements (Guidance note 12)
The centre does not facilitate egg sharing.

Surrogacy (Guidance note 14)
The centre does not undertake treatment that requires surrogacy.

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

Treating patients fairly (Guidance note 29)
The centre treats prospective and current patients fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

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

What the centre could do better.

Confidentiality and privacy (Guidance note 30)
The inspection team considers that the confidentiality audit (June 2013) reviewed on inspection does not constitute an audit of procedures employed by the centre to ensure the confidentiality and privacy of patients. The focus of the audit was on consent to disclosure documentation only (SLC T36).

See recommendation 4

Information

What the centre does well.

The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients sufficient, accessible and up-to-date information to enable them to make informed decisions.

Provision of a costed treatment plan (Guidance note 4)
The centre provides an individual costed treatment plan to all of its self-funded patients. This ensures that patients know the full cost of their proposed treatment before deciding on whether to proceed or not.

What the centre could do better.

Nothing noted at time of inspection.

Consent

What the centre does well.

The centre's procedures for obtaining consent are partially compliant with HFEA requirements, with the exception noted in the section 'Storage of gametes and embryos'. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity or storage of gametes and embryos.

Disclosure of information, held on the HFEA Register, for use in research
The Register started operating in August 1991 and is a rich source of information about assisted reproductive technologies (ART), its outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about

the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA is permitted to disclose non-identifying information to researchers it can only provide identifying information with the consent of patients. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA. The centre's procedures for doing this ensure that the HFEA holds an accurate record of the patients consent, so that it only releases the patients identifying information, to researchers, with their consent.
What the centre could do better. See section 'Storage of gametes and embryos' and recommendation 1.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well.

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

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

What the centre could do better.

Nothing noted at time of inspection.

Storage of gametes and embryos

What the centre does well.

The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers, with the two exceptions noted.

What the centre could do better.

Although the centre's bring forward system appeared robust, on day one of the inspection, the centre was storing the embryos of two patients several months beyond the consented storage period. This situation was discussed with the PR and on day two of the inspection, the inspection team were informed that the embryos had been allowed to perish; documentation to support this was seen (Schedule 3, 8 (2) HF&E Act 1990 (as amended)).

See recommendation 1

Distribution and / or receipt of gametes and embryos

What the centre does well.

The centre's procedures for distributing and / or receiving gametes and embryos are broadly compliant with HFEA requirements. This ensures that all gametes / embryos sent to other licensed centres within or outside the UK are appropriately labelled and relevant information is sent to the other centre to ensure the continued quality and safety of the gametes and embryos. The centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in a way that does not compromise their quality and safety.

What the centre could do better

The centre's gamete and embryo distribution SOP does not specify the transport conditions for shipping containers used to transport gametes and/or embryos, and does not specify the temperature and time limits required during transportation (SLC T107).

See recommendation 8

Use of embryos for training staff (Guidance note 22)

What the centre does well.

The centre's licence renewal application states that embryos will be used for training staff in vitrification techniques and assisted hatching. On inspection the PR confirmed that embryos are not currently being used for training staff but that the centre may wish to do so at some point. Assurance was provided by the PR that prior to this commencing, evidence of SOPs and information to be provided to patients asked to consider consenting to the use of their embryos for training will be provided to the HFEA.

What the centre could do better.

Nothing noted at time of inspection.

4. Information management

Record keeping and submitting information to the HFEA

What the centre does well.

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

Obligations and reporting requirements (Guidance note 32)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a result of their donation. In order to maintain this Register, clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities, to the Authority are broadly compliant with HFEA requirements and ensure the HFEA can supply accurate information to a donor-conceived person and their parents.

What the centre could do better.

During an audit of register submissions conducted on inspection, it was noted that 36% (four of 11) of the DI treatments reviewed had not been reported at all, to the HFEA, as required by General Direction 0005, SLC T9(e) and SLC T41.

See recommendation 3

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2011, recommendations for improvement were made in relation to one area of critical non-compliance, one area of major non-compliance and eight 'other' areas of non-compliance.

The PR provided information and evidence that corrective actions to implement all the recommendations were completed within acceptable timescales for all recommendations with the exception of:

- Undertake an audit of confidentiality and privacy procedures at least every 2 years, against compliance with the approved protocols, regulatory requirements and quality indicators. Refer to 'treating patients fairly' section of this report.

Risk based assessment tool (RBAT) alerts

The centre has not been issued with any success rate performance alerts within the last 12 months.

Areas of practice requiring action

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

Critical area of non compliance

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

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

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. On the day of the inspection the centre was storing the embryos of two patients beyond the consented storage period. (Schedule 3, 8(2) HF&E Act 1990 (as amended))	The PR should ensure that gametes and embryos are stored in accordance with the gamete provider's consent.		On the second day of inspection the inspection team were informed that the embryos had been allowed to perish and documentation to support this was seen. The PR has confirmed that the process for managing this eventuality has been changed to ensure that where consent is not extended or contact with gamete providers is lost, gametes or embryos will be allowed to perish in accordance with the HF&E Act. No further action required.
2. Witnessing checks are not documented when transferring eggs between dishes.	The PR should take immediate action to ensure that witnessing is recorded at all critical points of the clinical and laboratory process. The HFEA		10 September 2013 The PR has submitted a revised 'Record of Witnessing' worksheet that includes a

(SLC T71)	should be advised of the measures taken to ensure that this happens by the time this report is considered by the ELP. By 5 December 2013		prompt to record the transfer of eggs between dishes. Within three months of the implementation of this procedure, the centre should conduct an audit of witnessing and a summary report of the findings of the audit should be provided to the HFEA.
3. 36% of the DI treatments reviewed at inspection had not been reported to the HFEA as required by Direction 0005. (SLC T9(e) / T41 Direction 0005)	The PR must ensure that all licenced treatment activity is reported to the Authority within the timeframe required by Direction 0005. The DI treatments whose reporting was outstanding at the time of inspection should be reported to the HFEA immediately. The systems and processes used for licensed treatment data submission should be reviewed to enable the reasons for non-reporting of DI cycles are identified and addressed. Corrective action should be taken and reported to HFEA. Within three months of the implementation of this procedure, the centre should conduct an audit of data submission to the HFEA and a summary report of the findings of the		4 October 2013 The centre has confirmed that all DI cycles from 2008 onwards have been updated onto the Register. The centre has also reviewed their processes for submitting such information and will audit in December 2013. This will be subject to on-going monitoring.

	audit should be provided to the HFEA. By 5 December 2013		

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. The centre has not conducted an audit within the last two years for the following procedures: • confidentiality and privacy • submission of data to the HFEA (SLC T36)	The PR should ensure that all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence, are audited against compliance with approved protocols, regulatory requirements and quality indicators. The PR should ensure that procedures are audited for: • confidentiality and privacy • data submission to the HFEA The PR is to provide the lead inspector with a copy of the audit findings by 5 March 2014.		14 November 2013 The PR has provided a response to this recommendation, confirming his commitment to undertaking it within the required timescales. This will be subject to on-going monitoring.
5. The centre does not keep a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for eSET.	The PR should establish and maintain a summary log of cases where multiple embryos have been transferred to a patient who meets the criteria for eSET with immediate effect. Confirmation of the establishment of the log		14 November 2013 The PR has confirmed that an eSET summary log has been established and has committed to providing a copy of the log to the centre's inspector within 3 months.

(General Direction 0003)	should be provided to the HFEA by the time this report is considered by the ELP. By 5 December 2013 Within three months of the establishment of the log the PR should provide a copy of the log to the lead inspector.		
6. The centre does not have a mechanism in place to identify where additional screening may be required depending on the patient's travel and exposure history and the characteristics of the tissue or cells donated (e.g., Rh D, Malaria, CMV, T.cruzi). (SLC T50(d))	The PR should ensure that there is a mechanism in place to identify when additional screening tests are required, dependent on the patient's medical history. By 5 December 2013		4 October 2013 The PR has implemented a revised procedure and has submitted an assessment criteria form for additional screening; 'Confirmation of HTLV1, Malaria, CMV, RhD and T.Cruzi Testing'. No further action required.
7. At egg collection, tubes used to collect follicular fluid are not labelled with the patients / donor's full name and a further unique identifier or a uniquely identifying donor code. (SLC T101)	The PR is to ensure tubes used to collect follicular fluid during egg collection are labelled with the patients / donor's full name and a further unique identifier or a uniquely identifying donor code. By 5 December 2013		The PR has taken immediate action by reviewing the process and given assurance that from 6 September 2013 all tubes will be labelled with the patient's full name and a further unique identifier. No further action required.

8. The centre's gamete and embryo distribution SOP does not specify the transport conditions of shipping containers used to transport gametes and/or embryos and does not specify the temperature and time limits. (SLC T107)	The PR should ensure that the temperature and time limits for use of shipping containers are specified within the relevant SOPs, and that individuals using the containers understand the significance of these limits in maintaining the viability of gametes/embryos. The HFEA should be advised of the measures taken to ensure that this happens by the time this report is considered by the ELP.		10 September 2013 The PR has submitted a revised SOP: 'Safety Guidelines For Use Of Liquid Nitrogen Shipper For Transport Of Gametes And Embryos'. No further action required.

Reponse from the Person Responsible to this inspection report

The PR and the ARU team would like to thank the inspection team for their thorough inspection.
The team has noted the findings and corrective actions have been taken on all points.
The staffing lebels of the ARU and the medical cover of the unit was discussed during the inspection.
The PR expressed his concerns that the result of the work force planning done by the trust is not yet available and he expressed his cocerns about any decisions that might involve reducing the number of the nurses or the HCAs. The PR will inform the HFEA inspection team with the results as soon as they are available.
The PR is currently providing out of hours cover alone on voluntry basis and he believes that after careful consideration of the pattern of work in the trust across two sites with emergency admission at the North Tees site (about 15 miles away from the ARU) and with the on call team has no access to the fertility notes which are stored in the ARU; Providing out of hour cover through a designated telephone service is the safest model of cover. The trust is yet to recognise this and to incorporate this in the job plans of the medical team.
The PR will continue to negotiate with the Trust management team and inform the HFEA inspection team with the outcome.
The medical cover for the ARU activities during the working hours (9-5) is finalised, and a plan was put forward to the Clinical director and the business manager to incorporate the unit cover as a part of the job plans of the medical team.