Executive Licensing Panel - minutes

Centre 0031 (Assisted Reproduction Unit (ARU) University Hospital of Hartlepool)

Renewal Inspection Report

Friday, 1 December 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Anna Coundley Helen Crutcher	Director of Strategy and Corporate Affairs Information Access and Policy Manager Risk and Business Planning Manager
Members of the Executive	Siobhain Kelly Erin Barton Caylin Joski-Jethi	Secretary Policy Manager (Observer) Head of Intelligence (Observer)
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

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

1.2. The panel noted that The Assisted Reproduction Unit (ARU), University Hospital of Hartlepool has held a treatment and storage licence with the HFEA since July 1992. The centre provides a full range of fertility services.

1.3. The panel noted that in January 2016, North Tees and Hartlepool NHS Foundation Trust announced that the centre was to stop providing licensed fertility services on 31 March 2016. Hartlepool Borough Council applied for a judicial review of this decision. A court order was received by the Trust on 14 March 2016 that no further steps were to be taken to facilitate the closure of the centre until the court considered the matter further. In April 2016, the Trust agreed to enter into a three month engagement and consultation exercise with key stakeholders about the future of the ARU. In July 2016, the Trust agreed to extend service provision until January 2017.

1.4. The panel noted that the Trust and the Hartlepool and Stockton on Tees Clinical Commissioning Group (CCG) announced the cessation of licensed activities at the centre on the 6 January 2017, except for the continued storage of cryopreserved gametes and embryos. The Person Responsible (PR) advised the HFEA that the last licensed treatment took place on 16 December 2016 and that the CCG would liaise with other regional licensed fertility units regarding alternative models of fertility service provision for the region. The PR advised the HFEA on 9 June 2017 that he wished to renew the centre's licence but that a 'storage only' licence was needed. This will allow the storage of gametes and embryos to continue, while the CCG re-establishes a regional fertility service and arranges funding for the transport of stored gametes and embryos and patient records to other licensed centres.

1.5. The panel noted that, due to on-going uncertainties, in the 12 months to 31 July 2017, the centre provided only 28 cycles of treatment (excluding partner intrauterine insemination). The centre has now stopped providing licensed treatments.

1.6. The panel noted that HFEA held register data, in the period between 1 May 2017 and 30 April 2017, showed the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.7. An inspection was carried out at the centre on 12 September 2017.

1.8. The panel noted that at the time of the inspection, there were three major and two 'other' areas of non-compliance. Since the inspection the Person Responsible (PR) had fully implemented the major area of non-compliance regarding staffing alongside the 'other' areas of non-compliance concerning premises and facilities and obligations and reporting requirements. The PR had given a commitment to fully implementing the recommendations concerning the Quality Management System (QMS) and equipment and materials.

1.9. The panel noted that the centre has not provided licensed treatments since December 2016 but continues to store cryopreserved material. The centre has applied to renew its licence as a 'storage only' licence. Therefore, the inspection report focused on the compliance of activities specific to a storage-only licence.

1.10. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The PR is encouraged to review the centre's QMS system to ensure it can then be used to best effect to monitor and improve the service provided to patients. The panel noted that the inspectorate will continue to monitor the centre's performance and ensure that the report's recommendations are implemented within the prescribed timescales. Failure to

implement the recommendations within the prescribed timescales will result in the submission of a further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

1.11. The panel wanted the PR to ensure that defective equipment, such as the cryogenic storage dewar, did not take as long to fix as was noted on this inspection.

1.12. The panel noted the inspectorate recommends the issue of a storage only licence for a period of four years, without additional conditions, subject to the recommendations being implemented within the prescribed timescales.

2. Decision

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

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

2.3. The panel endorsed the inspectorate's recommendation to issue the centre with a storage-only licence for a period of four years, without additional conditions, subject to the recommendations being implemented within the prescribed timescales.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

8 December 2017

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 licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 12 September 2017

Purpose of inspection: Renewal of a licence.

The centre has applied for the following changes: The centre currently holds a Treatment and Storage licence. The centre has applied for a Storage Only licence.

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

Inspectors: Lesley Brown (Lead), Andrew Leonard.

Date of Executive Licensing Panel: 1 December 2017

Centre name	Assisted Reproduction Unit (ARU), University Hospital of Hartlepool
Centre number	0031
Licence number	L/0031/15/a
Centre address	University Hospital of Hartlepool, North Tees & Hartlepool NHS Trust, Holdforth Road, Hartlepool, Cleveland, TS24 9AH, UK.
Person Responsible	Dr Mohamed Hany Mostafa
Licence Holder	Dr Iona MacLeod
Date licence issued	1 March 2014
Licence expiry date	28 February 2018
Additional conditions applied to this licence	None

Contents

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 July 1992. The centre is currently licensed to provide a full range of fertility services.

In January 2016, North Tees and Hartlepool NHS Foundation Trust announced that the centre was to stop providing licensed fertility services on 31 March 2016. Hartlepool Borough Council applied for a judicial review of this decision. A court order was received by the Trust on 14 March 2016 that no further steps were to be taken to facilitate the closure of the centre until the court considered the matter further. In April 2016, the Trust agreed to enter into a three month engagement and consultation exercise with key stakeholders about the future of the ARU. In July 2016, the Trust agreed to extend service provision until January 2017.

The Trust and the Hartlepool and Stockton on Tees Clinical Commissioning Group (CCG) announced the cessation of licensed activities at the centre on the 6 January 2017, except for the continued storage of cryopreserved gametes and embryos. The Person Responsible (PR) advised the HFEA that the last licensed treatment took place on 16 December 2016 and that the CCG would liaise with other regional licensed fertility units regarding alternative models of fertility service provision for the region. The PR advised the HFEA on 9 June 2017 that he wished to renew the centre's licence but that a 'Storage Only' licence was needed. This will allow the storage of gametes and embryos to continue, while the CCG re-establishes a regional fertility service and arranges funding for the transport of stored gametes and embryos and patient records to other licensed centres.

Because of the on-going uncertainty regarding the centre's existence, it provided only 28 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2017. The centre has now stopped providing licensed treatments.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 May 2016 to 31 April 2017 show the centre's success rates are in line with national averages.

In 2016, the centre reported 11 cycles of partner insemination with one pregnancy. This is in line with the national average.

Multiple births[2]

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

Between 1 May 2016 and 31 April 2017 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]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. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of 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 a number of areas of practice that required improvement, including, three major and two 'other' areas of non compliance.

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

Major areas of non compliance:

- The PR should ensure that the staffing level is adequate for the activities being undertaken.

'Other' areas that requires improvement:

- The PR should ensure that there is a safe working environment for all staff.
- The PR should ensure that all licensed treatment is reported to the HFEA within the required timeframe.

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

Major areas of non compliance:

- The PR should ensure that suitable resources and processes are in place to maintain the compliance of the quality management system (QMS).
- The PR should ensure that equipment is subject to suitable monitoring and maintenance and is repaired in a timely manner.

Recommendation to the Executive Licensing Panel

The centre has not provided licensed treatments since December 2016 but continues to store cryopreserved material and has applied to renew its licence as a 'Storage Only' licence. This inspection report therefore focussed on the compliance of activities specific to a Storage-Only licence.

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

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The PR is encouraged to review the centre's QMS system to ensure it can then be used to best effect to monitor and improve the service provided to patients.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations. Failure to implement the recommendations within the prescribed timescales will result in the submission of a further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

The inspection team recommends the issue of a Storage Only licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

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

1. The protection of the patient, 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

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that when patients require treatment, the correct gametes or embryos are removed from storage and transported to the licensed treatment centre which will provide the treatment.

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

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos. This guidance note was reviewed in relation to gametes and embryos remaining in storage.

Payments for donors (Guidance note 13; General Direction 0001)
The centre does not recruit donors or provide treatment with donor gametes, therefore this area of practice is not applicable to this inspection.

Donor assisted conception (Guidance note 20)
The centre no longer provides treatment with donor gametes therefore this area of practice is not applicable to this inspection.

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

Suitable premises and suitable practices

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

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

The centre no longer processes gametes or embryos for treatment purposes, therefore HFEA requirements to process gametes and/or embryos in an environment of appropriate air quality are not applicable to this inspection.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided. This guidance note was reviewed in relation to gametes and embryos remaining in storage.

Infection control (Guidance Note 25)
The centre no longer provides licensed treatments, therefore this area of practice is not applicable to this inspection.

Medicines management (Guidance Note 25)

The centre no longer provides licensed treatments, therefore this area of practice is not applicable to this inspection.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. The centre no longer provides licensed treatments, therefore this area of practice is not applicable to this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre does not perform surgical procedures as part of its licensed activities therefore this area of practice is not applicable to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre no longer provides licensed treatments, therefore this area of practice is not applicable to this inspection.

Procurement of gametes and embryos (Guidance note 15)
The centre no longer procures gametes and embryos or uses them in treatment, therefore these requirements are not applicable to this inspection.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre does not receive distributed gametes or embryos from other centres, therefore this area of practice is not applicable to this inspection.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for export of gametes and embryos are compliant with HFEA requirements. The centre does not import gametes or embryos therefore this area of practice is not applicable to this inspection.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;

- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- 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 (QMS) (Guidance note 23)
The centre has a QMS that is partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of the services provided.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have transport and satellite links therefore this area of practice is not applicable to this inspection.

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

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient. This guidance note was reviewed in relation to gametes and embryos remaining in storage.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
The lead nurse described working alone in the centre, both with and without patients present, on occasions when no reception cover was available and access to the centre was unrestricted. Although the centre has wall mounted panic buttons, the inspection team considers this measure alone to be insufficient to constitute a safe working environment (Code of Practice 25.9; recommendation 4).

Quality management system (QMS) (Guidance note 23)

The centre could not provide assurance that suitable processes are in place to support the QMS and to review its performance to ensure continuous and systematic improvement. This is because although audits and quality indicator monitoring are performed, the centre management team does not meet to review the outcomes of these activities. Furthermore, the role of the quality manager is performed by the lead nurse but her recently updated job description does not include key responsibilities of the quality manager role: i.e. ensuring that the quality management system is implemented and maintained, reporting to centre management on how the QMS works and how effective it is, and coordinating awareness of centre users' needs and requirements (SLC T13, CoP Interpretation of mandatory requirements 23A, CoP guidance 23.4; recommendation 1).

The centre no longer provides treatment but does store gametes and embryos. When patients require treatment with their stored material, they request for their gametes or embryos to be transported to a licensed centre where treatment can be provided. The centre has not established quality indicators for responding to such requests for transport or for the transportation process (SLC T35; recommendation 1).

The standard operating procedure (SOP) for transporting samples does not document a recall procedure or the methods used to prime with liquid nitrogen and secure the dry shipper; it also directs staff to complete forms that are no longer in use (SLC T33b; recommendation 1).

Equipment and materials (Guidance note 26)
The storage dewar monitoring system was identified as defective in February 2017 because the temperature sensor in one dewar containing gametes and embryos had failed its annual validation. Six months elapsed before the system was repaired (SLC T23; recommendation 2).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

The PR has academic qualifications in the field of 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.

Staff (Guidance note 2)
The centre is partially compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Staff (Guidance note 2)
The centre is operating with one part-time, HCPC-registered embryologist supported by one healthcare assistant, to maintain the cryostorage facilities and to staff the 'on call' rota responding to dewar monitoring system alarms. The inspection team considered these staffing resources insufficient to effectively staff the on call rota with trained staff at all times (SLC T12 and CoP guidance 26.6c; recommendation 3). The centre cannot therefore provide assurance that critical parameters within the storage dewars will be maintained within acceptable limits at all times, including outside of normal working hours and when annual leave is taken.

The PR was unable to provide a work force assessment at the time of inspection (CoP 25.13; recommendation 3).

The inspection team was concerned that staffing levels may be inadequate for the activities being undertaken. This is based on staff feedback and the observation of non compliances attributable to inadequate staffing, noted above and elsewhere in this report (SLC T12; recommendation 3).

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre no longer provides licensed treatments therefore this area of practice is not applicable to this inspection.

Safeguarding (Guidance Note 25)
The centre no longer provides licensed treatments therefore this area of practice is not applicable to this inspection.

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
The centre does not perform embryo testing, therefore this area of practice is not applicable to this inspection.

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

2. The experience of patients

Patient feedback

What the centre does well

During the inspection no patients were available to speak with the inspectors about their experiences at the centre. The centre's most recent patient survey responses were reviewed. Feedback was positive, with 31 of the individuals providing written feedback giving compliments about the care that they had 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;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non discriminatory way.

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent. These requirements were reviewed in relation to the on-going gamete and embryo storage activities at the centre.

Egg [and sperm] sharing arrangements (Guidance note 12; General Direction 0001)

The centre does not provide treatment with donated gametes therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not provide treatment involving surrogacy therefore this area of practice is not applicable to this inspection.

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

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

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

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre no longer provides licensed treatments therefore these requirements were reviewed in relation to the gamete and embryo storage activities at the centre. The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

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

What the centre does well

Consent (Guidance note 5;6)
The centre no longer provides licensed treatments therefore consenting requirements were reviewed in relation to the gamete and embryo storage activities at the centre. The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before their gametes or embryos are used in any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties

giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre has been inspected since 2014 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in September 2015, legal parenthood consenting processes were found to be robust.

As part of the HFEA's ongoing activities relating to legal parenthood, in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive

To provide assurance of the compliance and effectiveness of the centre's legal parenthood consenting procedures up to the cessation of licensed treatments in December 2016, the inspection team discussed these procedures with staff and reviewed the results of the centre's final legal parenthood consenting audit. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre no longer provides licensed treatments therefore this area of practice was not reviewed at this inspection.

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

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well
The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- licensed activities only take place on licensed premises;
- 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 identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos. This guidance note was reviewed in relation to gametes and embryos remaining in storage.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are compliant with HFEA requirements, notwithstanding concerns regarding the time taken to repair the dewar monitoring system and staffing the on call rota, noted elsewhere in this report. 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. 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.

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

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's does not use embryos for training staff, therefore this area of practice is not applicable to this inspection.

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

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

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

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are broadly compliant with HFEA requirements

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Obligations and reporting requirements (Guidance note 32 ; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres 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.

Whilst treatment reporting is timely (i.e. 99% of IVF and 67% of DI treatments are reported to the HFEA within the period required by General Direction 0005, 3% (2/76) of the IVF and 25% (1/4) of the DI treatments reviewed post inspection had not been reported to the HFEA (General Direction 0005 and SLC T41; recommendation 5).

Section 3: Monitoring of the centre's performance

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

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

Areas of practice requiring action

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

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
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. **Quality management system (QMS)** The centre could not provide assurance that suitable processes are in place to support the QMS and to review its performance. This is because audits and quality indicator monitoring reports are no longer reviewed by the centre management team. It is also not clear that the quality manager has time allocated for the role because her recently updated job description does not include key responsibilities of the quality manager (CoP Interpretation of mandatory requirements 23A, SLC T13, CoP guidance 23.4).	The PR should ensure that: • a suitable process is re-established to evaluate and act on the findings of audits and quality indicator monitoring; • the quality manager has allocated time to undertake the key responsibilities of the role, defined by CoP guidance 23.4, and that these responsibilities are specified in her job description; • quality indicators for the gamete and embryo transport process are established and monitored; • the SOP for transporting gametes and embryos is reviewed and updated to	The centre has a policy for an annual quality management review, this did not take place this year as the service model is still not clear. We could not discuss the volume and scope of work, staffing, premesis as we are awaiting for a decision about a satellite model of care which is yet to be decided by the trust and the CCGs. Quality management review meeting has been requested and minutes will be forwarded to the inspector. The GM explained in an e mail correspondance that, the quallity manager has 4 hours weekly incorporated in her jobplan to carry out the QM responsibility and this could	The Executive acknowledges the PR's response and his commitment to fully implementing the recommendation. The Executive is satisfied with the assurance that the quality manager has allocated protective time to complete their duties. The Executive has reviewed the submitted transport and recall SOP's. Although the SOP does now contain quality indicators and a recall procedure, the method used to charge the dry shipper and to lock/secure the dry shipper has not been documented.

The centre has not established quality indicators or objectives relevant to the transportation of cryostored materials (SLC T35). The SOP for transporting samples does not document a recall procedure or the methods used to charge the dry shipper and to lock/secure the dry shipper; it also directs staff to complete forms that are no longer in use (SLC T33b).	address the concerns identified in this report. All aspects of this recommendation should be implemented by 12 December 2017. The centre's inspector should be advised of the actions taken and provided with evidence in support of their implementation.	vary as needed. As the unit currently is not carring out any licenced treatment activities, this time allocation would be adequate. The SOP for gametes / embryos transportation has been revised and quality indicators were established. 100% of the transfer requests will be completed within two weeks. Audit of the current practice will be done in December 2017 and the result will be forwarded to the inspector. The revised SOP is attached to this reportand .	The PR has committed by email to update the documentation when the Embryologist returns from annual leave. The Executive awaits the minutes of the quality management review. Further action required.
2. **Equipment and Materials** The storage dewar monitoring system was identified as defective in February 2017 because the temperature sensor in one dewar failed its annual validation. Six months elapsed before the system was repaired. SLC T23.	The PR should take immediate action to ensure equipment is subject to maintenance and regular inspection, and that actions are taken in a timely manner to address any defects which are found. The HFEA should be advised of the actions taken to ensure that this happens by the time this report is returned. The PR should conduct a review to identify the barriers	The incident stated in the report was formally investigated following submision of a datix . Equipment management protocol was reviewed and updated to reflect the recommendations in the action plan (Copy attached).	The Executive acknowledges the PR's response. The PR has provided an updated Equipment Management protocol, detailing steps to take to avoid delays in completing required actions. The Executive awaits the copy of the requested review by 12 December 2017.

	that prevented a repair to the dewar monitoring system being performed in a timely manner. A copy of this review should be provided to the centre's inspector by 12 December 2017.		
3. **Staffing** The inspection team was concerned that staffing levels may be inadequate for the activities being undertaken. This is based on there being a clear shortfall in the number of trained and qualified staff to administer the on call rota responding to the storage dewar monitoring system, concerns regarding the resources and processes supporting the QMS, and potentially hazardous lone working practices. Furthermore a documented workforce assessment has not been recently completed by the PR. SLCs T12 and T13, CoP guidance 25.13.	The PR should assess the workforce requirements for the licensed activities and associated services currently being undertaken at the centre. The assessment should focus on suitable staffing levels and skills mix to ensure; the ongoing monitoring and maintenance of the cryostore - including out of hours provision, the timely transport of cryopreserved gametes and embryos to licensed treatment centres, the ongoing functions of the quality management system and safe working practices – including lone working. A copy of the assessment, including any necessary corrective actions, should be submitted to the centre's inspector by 12 December	Work force requirements has been assessed and additional cryo lab cover has been added to the work force. A band 6 BMS has joined the team to offer support for on call and leaves as required. Training and competencies assessment were completed. Attached is a copy of the work force planing document.	The Executive acknowledges the PR's response and receipt of the workforce planning document. No further action required.

	2017. The PR should ensure that corrective actions have been initiated by this time so that workload is maintained within the safe limits determined by the assessment.		

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. **Premises and Facilities** The lead nurse described working alone in the centre, both with and without patients present, on occasions where no reception staff are present and access to the centre is unrestricted. The centre has wall mounted panic buttons, but the inspection team do not consider this measure alone sufficient to constitute a safe working environment CoP guidance 25.9.	The PR should review the centre's current lone working arrangements to ensure there is a safe working environment for all staff. A copy of this review, along with corrective actions and the lone working SOP, updated as necessary, should be submitted to the centre's inspector by 12 December 2017.	following concerns raised by the HFEA inspection team, risk assessment has been submitted and current level is low risk with controls in place. The action was discussed with the GM and she agreed that ARU-H is a low risk area. Trust lone worker SOP, ARU SOP and risk assessment are attached to this report.	The Executive acknowledges the PR's response and his commitment to fully implementing the recommendation. The Executive notes that the risk assessment shows that procedures have changed since the inspection and supervisors now make regular contact with the lone worker and there is now and end of task/shift contact. No further action.
5. **Obligations and reporting requirements** 3% (2/76) of the IVF and 25% (1/4) of the DI treatments reviewed post	The PR is asked to correct the identified errors by the time this report is returned.	DI: Treatment and outcome forms have been completed and submitted to HFEA. IVF: [redacted] the patient had a frozen embryo transfer and was performed on the 11th of March 2016, EDI form was correctly	The Executive acknowledges the PR's response. The recommendation has been fully implemented. No further action.

inspection had not been reported to the HFEA. General Direction 0005.		submitted and the ref. number is:[redacted] There was a transcription error and the correct number is:[redacted] this patient had IVF on the 3rd of June 2016 and the EDI was correctly submitted on time (EDI ref. number:[redacted]	

Reponses from the Person Responsible to this inspection report
The PR has been working closely with the HFEA inspection team to update them about all the challenges since the decision of the trust to stop the licensed treatment. The PR and the remaining staff completed all the required audits and quality control measures to maintain the safety of the gametes. The PR engaged for the last two years in negotiaions with the trust management team to ensure the safety of the stored gametes, embryos and medical notes. The PR would like to stress that decisions about the staff is made by the trust management. on occasions , he requested the help of the HFEA inspection team to emphasise the right advice to the management team. The PR would like to commend the remaining members of staff in the ARU-H on their dedication and professionalism trying to provide the best possible care to patients despite this stressful time. The PR will continue to cooperate with the HFEA inspection team to ensure the safety of the stored gametes, embryos and the medical notes.