Executive Licensing Panel - minutes

Centre 0109 (King's Hewitt Fertility Centre) Renewal Inspection Report

Friday 16 June 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Hannah Verdin (Chair) Howard Ryan Ian Peacock	Head of Regulatory Policy Report Developer Systems Manager
Members of the Executive	Bernice Ash	Secretary
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 King's Hewitt Fertility Centre is based in London and holds a Treatment and Storage licence. The centre provides a full range of fertility services and has two transport centres, Epsom and St Helier NHS Trust (centre 0259) and Kingston Hospital Associated Conception Unit (centre 0270).

1.3. The panel noted that the centre has been licensed by the HFEA since July 1992.

1.4. The panel noted that, in the 12 months to 28 February 2017, the centre provided 1,423 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

1.5. An inspection was carried out at the centre on 11 and 12 April 2017.

1.6. The panel noted that at the time of the inspection there was one critical and seven major areas of practice that required improvement concerning storage of gametes and embryos, egg donor screening, import and exports, Quality Management System, equipment and materials, process validation, record keeping and payment of HFEA fees.

1.7. The panel noted the centre also had six 'other' areas of non-compliance regarding safety and suitability of premises and facilities, medicines management, patient feedback, website, obligations and reporting requirements and disclosure of information, held on the HFEA Register, for use in research.

1.8. The panel noted that the PR has given a commitment to fully implementing all recommendations, but currently, all remained outstanding.

1.9. The panel noted the centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided.

1.10. The panel noted that the Executive had referred to HFEA's 'Guidance on Licensing' and whether a licence of less than four years is warranted due to the number of recommendations made. Taking into consideration the centre's success rates, patient feedback provided directly to the HFEA, the centre's compliance history and the actions already taken by the PR in response to this report, the executive were satisfied that a licence of four years was suitable.

1.11. The panel noted the inspectorate's recommendation to renew the centre's Treatment and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

1.12. The panel noted that the centre's inspector will continue to closely monitor the centre's progress with the required actions and the implementation of this report's recommendations within the required timescales. Any failure to implement these recommendations in a timely and effective manner may result in a further submission to ELP and regulatory action may be considered.

2. Decision

2.1. The panel expected the PR to continue being proactively engaged with the centre's inspector, to address and fully implement all the recommendations made in the report. The panel noted that significant improvements are required for the centre's practices to be suitable, recognising that three areas of non-compliances evident in the report are repeat non-compliances, also identified at the last inspection.

2.2. The panel noted that the inspector will continue to closely monitor the centre's progress and any failure to implement these recommendations in a timely and effective manner may result in a further submission to ELP and regulatory action may be considered.

2.3. The panel noted that required actions are due for submission by 12 July 2017 and 12 October 2017. The panel requested the Executive to submit a summary of all the required outcomes to a further meeting by the end of November 2017.

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's Treatment and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

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3. Chair's signature

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

Signature

Name

Hannah Verdin

Date

27 June 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 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: 11 and 12 April 2017

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.

Inspectors: Louise Winstone, Karen Conyers, Shanaz Pasha, Cathy Hodgson, Hannah Demuren and Danya Harris (observer).

Executive Licensing Panel: 16 June 2017

Centre name	King's Hewitt Fertility Centre
Centre number	0109
Licence number	L/0109/13/b
Centre address	King's College Hospital, Denmark Hill, London, SE5 9RS, United Kingdom.
Person Responsible	Mr Michael Savvas
Licence Holder	Mrs Leonie Penna
Date licence issued	1 October 2013
Licence expiry date	30 September 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

King's Hewitt Fertility Centre has held a licence with the HFEA since July 1992.

The centre provides a full range of fertility services and has two transport centres, Epsom and St Helier NHS Trust (0259) and Kingston Hospital Assisted Conception Unit (0270).

The centre provided 1,423 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2017. In relation to activity levels this is a large centre.

The centre's licence was varied in November 2016 to reflect a change of Licence Holder, and in November 2015 to reflect a change of centre name.

The centre is currently undergoing a change of ownership; however, the PR has confirmed that this will not affect the day to day running of the centre. The centre has plans to relocate premises later in the year and to change the centre name.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 December 2015 to 30 November 2016 show the centre's success rates are in line with national averages.

In 2016, the centre reported ten cycles of partner insemination with two pregnancies. This is in line with the national average.

Multiple births[2]

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

Between 1 December 2015 and 30 November 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%: 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, Statutory Licence Conditions (SLC) and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- 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 several areas of practice that required improvement, including one critical, seven major and six 'other' areas of non compliance. The PR has given a commitment to fully implementing all recommendations.

Critical area of non compliance:

- **The PR should ensure that there is effective written consent in place for all gametes and embryos that are in storage.**

Major areas of non compliance:

- The PR should ensure that egg donors are screened in accordance with regulatory requirements and professional body guidelines.
- The PR should ensure that all imports and exports of gametes and embryos comply with the requirements of General Direction 0006.
- The PR should ensure that the centre's quality management system (QMS) and auditing processes are effective, that they include an audit against regulatory requirements and professional guidance, and, that audits, including proposed corrective actions, are consistently documented.
- The PR should ensure that all critical equipment is validated and that only CE marked medical devices are used wherever possible.
- The PR should ensure that all critical processing procedures are validated.
- The PR should ensure that the identity of a patient is reliably confirmed and documented.
- The PR should take appropriate action to ensure that all HFEA invoices are paid within the timescales specified by the Authority.

'Other' areas that require improvement:

- The PR should ensure that staff are aware of health and safety requirements when using liquid nitrogen.
- The PR should ensure that the procedures for the management of medicines are compliant with all regulatory requirements and guidance.
- The PR should ensure there is an appropriate mechanism in place to review and act upon patient feedback.

- The PR should review the contents of the centre's website to ensure success rates are presented in accordance with guidance.
- The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are accurately recorded on the HFEA register.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Recommendation to the Executive Licensing Panel

The centre has one critical and seven major areas of concern. Significant improvement is therefore required.

The executive has referred to HFEA's 'Guidance on Licensing' and whether a licence of less than four years is warranted due to the number of recommendations made. Taking into consideration the centre's success rates, patient feedback provided directly to the HFEA, the centre's compliance history and the actions already taken by the PR in response to this report, the executive were satisfied that a licence of four years was suitable.

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

The centre's inspector will continue to closely monitor the centre's progress with these actions and the implementation of this reports recommendations within the required timescales. Any failure to implement these recommendations in a timely and effective manner may result in a further submission to ELP and regulatory action may be considered.

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 patients receive treatment using the correct gametes or embryos.
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)** 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. The centre's procedures for screening donors are partially compliant with HFEA requirements. **Payments for donors (Guidance note 13; General Direction 0001)** The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused. **Donor assisted conception (Guidance note 20)**

It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non-identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better

Screening of donors (Guidance note 11)
The centre does not recruit sperm donors and occasionally provides treatment using egg donors. The inspection team reviewed two records of treatments involving egg donation. The following non compliances were observed:

- One egg donor had not had a karyotype test performed prior to donating. Centre staff had identified on a check list that the test results were missing, however this was not followed up. There was no live birth following this treatment. (SLC T52i and CoP Guidance 11.22)
- Blood samples taken from the egg donors for screening purposes were not obtained within a timeframe specified by the Authority, nor is an appropriate timeframe for taking such blood samples stated in the centre's SOP for egg donation. The centre team did not appear to understand the requirements to screen donors 'at the time of donation', or to provide a rationale as to why the screening performed ensured a level of safety equivalent to that provided if the donor had been screened 'at the time of donation', in accordance with the requirements of the European Union Tissues and Cells Directive 2006/17/E; explained within the Clinic Focus article on 28 March 2013 (SLC T53b).
- In addition to the above observations, there is no consideration of the risk of infection with Ebola based upon recent travel history (SLC T52h).

See recommendation 2.

Suitable premises and suitable practices
Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements

Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

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

The centre has 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 premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to processes gametes and/or embryos in an environment of appropriate air quality.

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

Infection control (Guidance note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management (Guidance note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are broadly compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy and this area of regulation is therefore not relevant to this inspection.

Pre-operative assessment and the surgical pathway (Guidance note 25)
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and

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

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

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 note 15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are partially compliant with HFEA requirements.

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

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)
It is important to ensure that activities performed by transport and satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements. The centre has systems in place to manage transport and satellite activities that are partially compliant with HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. All 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 partially compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
Validation ensures that critical processes are effective and do not render gametes or embryos clinically ineffective or harmful to the recipient. The centre's procedures are partially compliant with HFEA requirements to validate critical processes.

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)
During the inspection two members of staff were observed carrying a tray with liquid nitrogen without the use of personal protective equipment (for example safety goggles and gloves).

CoP guidance 25.17; see recommendation 9.

Medicines management (Guidance note 25)
A review of the controlled drugs register identified that in at least three instances the amount of controlled drug administered had not been recorded.

SLC T2, Misuse of Drugs Regulations 2001, Schedule 19(b); see recommendation 10.

Imports and exports (Guidance note 16; General Direction 0006)

The centre was unable to provide evidence that recent imports and exports of gametes and embryos met the requirements of General Direction 0006. In addition, the centre had not submitted a gamete out form for one sperm export.

General Direction 0006; schedule 2b, c, e, f and g; see recommendation 3.

Quality management system (QMS) (Guidance note 23)
The following was noted regarding the centre's audits:

- whilst the centre had audited some aspects of the counselling service as part of a broad audit of consent, the inspectors considered the scope was too narrow and did not for example review if the offer of counselling had been made prior to consent;
- the centre has not audited records of manual witnessing steps;
- the centre had audited the presence of legal parenthood consents in patient records, but this was part of a general consent audit and did not specifically look at whether the consent forms had been completed correctly, signed before treatment and that counselling had been offered prior to signing the consent forms;
- the centre has not audited its transport service within the last two years;
- audits that have identified and documented non-conformances do not consistently record corrective actions and the implementation of those actions. For example, the gamete and embryo storage audits identified errors with data entry on IDEAS, including storage expiry dates, however the audit report provided did not show what the corrective actions were and whether these had been implemented;
- the centre has not effectively audited processes against regulatory requirements for example, the SOP for egg donor screening does not describe the requirement to screen at the time of donation.
- centre staff were unaware of the new PBR consent form, updates to CoP and Ebola advice on the Clinic Portal, suggesting that the recent Chair's letter CH (17)01 describing several changes to the Code of Practice and new consent forms had not been acted upon. This suggests a failure to audit effectively against regulatory requirements and that the centre's systems for implementation of new regulatory requirements or guidance are not robust.

The following was noted regarding the centre's SOPs:

- some SOPs had passed their review dates without review;
- some SOPs and patient information, for example 'embryos for use in training and research', contain regulatory requirements and other information which has been superseded, suggesting the audit of SOPs against the regulatory requirements is not effective;
- SOPs to direct the use of embryos in training and research do not state the training activities that embryos can be used for, that embryos used in training must not be used in treatment or to ensure there is no conflict of interest;
- the SOP to direct vitrification and/or warming does not fully reflect practices observed during the inspection.

SLC T32, T33b and T36; see recommendation 4.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has not audited its two transport services as discussed above, to ensure that the services are compliant with HFEA requirements.

SLC T36, CoP 24.3a and c; see recommendation 4.

Equipment and materials (Guidance note 26)
The centre was unable to provide documented evidence of the validation of the suction pump(s) used during egg collection (SLC T24).

The centre supplement CE marked culture media with CE marked human serum albumin for use when culturing vitrified embryos after they have been removed from storage. This is against the manufacturer's instructions and may invalidate the CE mark of both products.

SLC T30; see recommendation 5.

Process validation (Guidance note 15)
The centre introduced a new culture procedure for warming vitrified embryos after they have been removed from storage, but this had not been validated or documented in a SOP.

SLC T72, T33b; see recommendation 6.

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 compliant with HFEA requirements to have suitably qualified and competent staff**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

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

What the centre could do better

Staff (Guidance note 2)
Over the course of the inspection and following discussions with staff, the inspectors were made aware that there is currently a staff shortage at the centre. Several staff have recently left or have plans to leave which has been prompted by the change in ownership of the centre. Of concern was the counsellor who has recently dropped her hours from 27 to 7 hours per week. There are however, plans to recruit an additional counsellor. The PR explained that due to the uncertainty of ownership of the centre,

there was a freeze on the recruitment of new staff. This is now resolved and the PR can progress with making business cases for the recruitment of new staff. The PR also confirmed that key members of staff meet regularly to review activity levels and should the need arise, activity levels will be capped. The PR has provided assurance that he will continually monitor staffing levels in line with clinical activity to ensure service provision is safe. The inspectors considered that no further recommendation is required at this stage and the centre's inspector will remain in close contact with the PR to monitor the situation.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

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

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
Embryo testing is not provided at this centre.

What the centre could do better
Not applicable.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit, an inspector spoke to one patient who provided feedback on their experiences. This feedback was positive and the patient complimented the care received. A further four patients also provided feedback directly to the HFEA in the time since the last inspection. In these instances, feedback was positive, with three of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

What the centre could do better

The centre does not effectively collect or analyse patient feedback. There is a box in the waiting area for posting patient comments, however staff did not know who was responsible for emptying this box, monitoring, analysing or responding to this feedback. The inspection team were concerned that the centre does not have an effective system for reviewing and responding to patient feedback and identifying how the patient experience can be improved especially given the changes to the centre and the shortage of staff.

SLC T32 and CoP guidance 23.17; see recommendation 11.

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 and prior to consenting to legal parenthood.

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

Egg and sperm sharing arrangements are not provided at this centre.

Surrogacy (Guidance note 14)
The centre has not undertaken any surrogacy treatments in the time since the last licence renewal inspection. The centre does however have procedures for treatment involving surrogacy that are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to be responsive to patient complaints. This is important to ensure that the centre uses 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)
It is important that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions. The centre's procedures for providing information to patients and/or donors are broadly compliant with HFEA requirements.

What the centre could do better

Information (Guidance note 4; Chair's Letter CH (11)02)
In 2011, all PRs were asked to ensure that information provided to patients on their centre's website was reliable and accurate. A review of the centre's website against guidance showed:

- data relating to live birth rates is more than three years old;
- live birth rate per treatment cycle in each age/treatment category is not given.

This was cited as non-compliant at the previous inspection.

CoP guidance 4.5; see recommendation 12.

Consent
Legal parenthood 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's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out 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 its effectiveness and, in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that no couples were affected by legal parenthood consent anomalies.

At the inspection on 15 July 2015, we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. Actions had been taken in response to the audit findings.

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.

During this inspection, it was noted that the centre had not undertaken an adequate audit of consent to legal parenthood since the audit requested by the HFEA in 2014. The centre had audited the presence of legal parenthood consent forms in patient records but this was part of a general consent audit and did not specifically look at whether the consent forms had been completed correctly, signed before treatment and that counselling had been offered prior to signing the consent forms. This undermines the PR's reassurance, provided in October 2015, that 'effective audit procedures are in place to ensure on-going compliance with consent taking requirements.' It also leaves the centre exposed to a risk that consenting processes may not have been robust at times since 2014 and further cases of anomalous consent to legal parenthood may be present.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was

required. Effective consent to legal parenthood with a prior offer of counselling was seen to be in place before treatment in all cases. It was noted however, that in two sets of records page 3 of the PP form had been signed at a later date than the previous pages, but had been signed prior to treatment. Whilst this does not have any potential impact on effective consent to legal parenthood, this was discussed with the PR. The PR gave assurances that all pages of the forms are now signed at the same time.

In summary, the inspection team considers that the centre's current processes for obtaining effective consent to legal parenthood are compliant with HFEA requirements, with the exception of those observations noted above.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
It is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing assisted reproductive treatments (ART) and those born following ART treatment.

The centre's procedures for taking consent to disclosure to researchers are broadly compliant with HFEA requirements.

What the centre could do better

Legal parenthood (Guidance note 6)
The centre has not completed an adequate audit of legal parenthood since 2014, as described above.

SLC T36; see recommendation 4.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Seven discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. Therefore the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure. This failing leads to a risk that the HFEA may release patient identifying information to researchers, without consent.

CH(10)05 and General Direction 0005; see recommendation 13.

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;
- 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 and
- 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.

Storage of gametes and embryos (Guidance note 17)
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. It is important 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 centre's procedures for storing gametes and embryos are not compliant with HFEA requirements.

What the centre could do better

Storage of gametes and embryos (Guidance note 17)
On the day of inspection, centre staff informed the inspection team that they did not have written effective consent for the storage of cryopreserved gametes for 21 patients and cryopreserved embryos for six patients.

Schedule 3, 8(1) HF&E Act 1990 (amended); see recommendation 1.

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 procedures for using embryos for training staff are compliant with HFEA requirements, however see 'quality management system' regarding embryos used for training SOP and patient information. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

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)
Good medical records are essential for the continuity of the patient's care. The centre's procedures for keeping records are partially compliant with HFEA requirements to ensure that accurate medical records are maintained.

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.

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

Record keeping and document control (Guidance note 31)
The centre uses photographic identification to reliably identify its patients and donors but does not maintain a record of how, and by whom, the patient/donor has been reliably identified.

SLC T46b and T47; see recommendation 7.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
26% (35/134) of the IVF and 34% (24/70) of the donor insemination (DI) treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005. The centre has been informed of some minor data quality issues which the centre need to correct.

General Direction 0005; see recommendation 14.

Section 3: Monitoring of the centre's performance

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

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales. However, the following areas of non-compliance described in this inspection report have been noted at previous inspections of this centre. These are:

- consent to storage,
- the late payment of licence fees and
- the centre's website.

Payment of HFEA fees
The centre has a historic issue with the late payment of HFEA fees. Invoices over the last year have been paid on average of 54 days. The HFEA payment terms is 28 days (SLC T09(d); see recommendation 8).

On-going monitoring of centre success rates

No risk tool alerts have been issued to this clinic regarding success rates.

Areas of practice requiring action

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

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Storage of gametes and embryos The centre does not have written effective consent for the storage of all cryopreserved sperm and embryos. Schedule 3, 8(1) HF&E Act 1990 (as amended). This area of practice was cited as a non compliance at the previous inspections.	The PR should ensure that there is effective written consent in place for all gametes and embryos that are in storage. The PR should establish an action plan for resolving the cases where sperm and embryos are in store beyond the consented storage period. A copy of the plan should be provided to the HFEA when responding to this report. The PR should provide monthly updates to the HFEA on progress in implementing the proposed actions.	It is acknowledged that there are a number of gametes and embryos in storage at King's in the absence of effective written consent. An action plan (Attachment 1.1) has been written to confirm how many samples are currently in storage without consent so that the scale of the non compliance can be established (attachmnet 1.2). A strict frozen sample management protocol will be implemented. This will encompass monthly	The PR has provided a suitable action plan to address this area of non compliance and a clear commitment to provide monthly updates on their progress. The centre's inspector will continue to closely monitor the centres progress. Further action is required.

	The PR is reminded of guidance issued by the HFEA in CH (03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.	administration duties to highlight all samples requiring annual review, all samples approaching consent expiry (bring forward policy trigger) and all samples where contact with the patient(s) has lapsed. Immediate actions will be identification of samples where consent has expired with actions to extend storage or discard as appropriate under guidance from Consultant Embryologist and PR. This will also include scanning and storing the most recent storage consents to the patient database (IDEAS) to allow more efficient future review. Action logs will be recorded in the form of electronic 'Medical record' events on each patient file. The summary plan(1.1) is attached as a document that includes a timetable of completion. Also included is the instruction of monthly progress reviews with the PR to allow updates to be forwarded to the HFEA inspection team.	

Major area of non compliance

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Egg donor screening The inspection team reviewed two records of treatments involving egg donation. The following non compliances were observed: • One egg donor had not had a karyotype test performed prior to donating. • Blood samples taken from egg donors for screening purposes were not consistently obtained within a timeframe specified by the Authority, nor is an appropriate timeframe for taking such blood samples stated in the	The PR should ensure that egg donors are screened in accordance with regulatory requirements and professional body guidelines. The PR should provide the centre's inspector with confirmation of revised donor screening practices, evidence of relevant staff training and a summary of the changes made to the egg donation and any related SOPs when responding to this report. The PR should audit the treatments carried out with egg donors in the centre since the last renewal inspection in 2013 to assess the number of	Our donor screening practices have been revised. The screening check list for male and female donors have been ammended and are attached (Attachment 2.1 and 2.2). The tests recquired are listed. The tests will be requested at the first doctors consultation and the person taking the tests will sign and confirm that the test has been taken. The results will be entered on the sheet by the donor co-ordinator before the second doctor's consultation, the doctor will review the results at that consultation and virology screening will be repeated at the nurse consent appointment, this means that	The Executive acknowledges the PR's response and commitment to ensuring that this area of non-compliance is fully addressed. The PR has provided the revised screening checklist and confirmation of staff training. The PR has confirmed that the audit of all treatments carried out with egg donors in the centre since the last renewal inspection in 2013 will be submitted by 12 July 2017 and the re-audit by 12 October 2017. Further action is required.

centre's SOP for egg donation. • In addition to the above observations, there is no consideration of the risk of infection with Ebola based upon recent travel history. SLC T52, T52i and CoP Guidance 11.22 and T53.	recipients affected by the use of donors where screening has not been compliant. A summary of the findings of the audit should be provided to the centre's inspector by 12 July 2017. In view of the small number of treatments provided with egg donors, the PR should audit the effectiveness of changes introduced in this area of practice within six months. A copy of the audit should be provided to the centre's inspector by 12 October 2017.	these blood test will be repeated within a few weeks of the donation. The doctors involved in seeing such patients and the egg donation coordinator have been made aware of these changes and have confirmed that they will follow the new process(attachment 2.3) We will audit all the egg donors seen at this centre since the last renewal inspection. the results will be provided to the inspector by 12 July 2017. An Ebola information sheet and consent form have been created and are attached (2.4). This will be given to patients at their first doctors visit to read and complete. they will have the opportunity to ask any questions when they see the doctor.	
3. Import and exports	The PR should ensure that all imports and exports of gametes and embryos comply	The current SOP and documentation for national and international import /	The Executive acknowledges the PR's response and commitment to ensuring that

The centre cannot provide evidence that they have complied with all the requirements of General Direction 0006. General Direction 0006; schedule 2b, c, e, f and g.	with the requirements of General Direction 0006. The PR should conduct a review against the requirements of General Direction 0006 of all gametes and embryos imported or exported by the centre since the last inspection. A summary of the report should be sent to the centre's inspector by 12 July 2017. The PR should review the centre's processes for import and export to ensure compliance with regulatory requirements and General Direction 0006. A summary of the findings of the review and corrective actions taken should be provided to the centre's inspector by 12 July 2017.	export of gametes / embryos will be reviewed and amended to ensure that it reflects all HFEA / EUTCD requirements. Namely, scrutiny of receiving centre to ensure that treaments that would not be permitted in the UK are intended, that they have traceability and QM systems in place, and also provision of full information to patients prior to sample import / export. Consent and information forms will be reviewed and amended to reflect the necessary considerations from both patient and King's ACU prior to approving any import or export as well as ensuring that personnel are aware of the situations requiring submission of gamete in / out reports via EDI. A summary of the findings of the review and corrective actions will be submitted to the inspector by 12 July 2017	this area of non-compliance is fully addressed and awaits the summary of the findings of the review and corrective actions by 12 July 2017. Further action is required.
4. Quality Management System The following was noted regarding the centre's audits:	The PR should ensure that the centre's QMS and auditing processes are effective, that they include an audit against regulatory requirements and	Our QMS will be reviewed to ensure that all required audits are scheduled to be performed and reviewed within the suggested time frames or	The Executive acknowledges the PR's response and commitment to ensuring that this area of non-compliance is fully addressed. The PR has

• whilst the centre had audited some aspects of the counselling service as part of a broad audit of consent, the inspectors considered the scope was too narrow and did not for example review if the offer of counselling had been made prior to consent; • the centre has not audited records of manual witnessing steps; • the centre has not completed an adequate audit of legal parenthood since 2014; • the centre has not audited its transport service within the last two years; • audits that have identified and documented non-conformances do not consistently record corrective actions and the implementation of those actions.	professional guidance, and that audits, including proposed corrective actions, are consistently documented. The PR should develop an action plan to ensure that all the centre's processes are reviewed against regulatory requirements and provide a copy of the plan to the centre's inspector by 12 July 2017. The PR should review the centre's audit programme to ensure that it is compliant in the range of audits performed, the methodology used and the documentation of corrective and preventative actions and their implementation. The PR should provide the centre's inspector with a copy of the review and an action plan for the implementation of this recommendation by 12 July 2017. The PR should provide copies of the audits and SOPs identified in this report as non-	more frequently as results suggest. These will be recorded on Q Pulse with any corrective action logged. All processes will be audited aginst regulatory requirments to ensure that comprehensive and current SOPs and guidance documents (including patient information) are in place and accessible via Q Pulse. This will required extensive planning and team delegation. The plan for this will be formalised by the PR and submitted to the inspection team by 12 July 2017. Areas of audit that were not deemed broad enough will be expanded to be more comprehensive with an audit schedule confirmed and submitted to the inspection team by 12 july 2017. Audits and SOPs identified as non compliant at inspection will be reviewed and updated or completed by 12 October 2017.	confirmed that a copy of the action plan and audits identified in this report will be submitted by 12 July 2017 and further audits and SOPS by 12 October 2017. Further action is required.

• the centre has not effectively audited processes against regulatory requirements. The following was noted regarding the centre's SOPs: • some SOPs had passed their review dates without review. • some SOPs and patient information, for example 'embryos for use in training and research', contain regulatory requirements and other information which has been superseded, suggesting the audit of SOPs against the regulatory requirements is not effective; • SOPs to direct the use of embryos in training and research do not state the training activities that embryos can be used for, that embryos used in training must not be used in treatment or to	compliant, by 12 October 2017.	The transport centre at kingston Hospital was inspected in 2015 and the report is attached (Attachment 4.1). A further inspection is planned for 30 June 2017 the PR will submit an inspection repert by 12 July 2017. The other transport centre at St Hellier Hospital now has it's own laboratory and we are currently seeing very few referrals from them, it is expected that this will stop completely in due course. The PR will arrange a visit to inspect the facilities and provide the inspector with a report of the findings by 12 October 2017.	

ensure there is no conflict of interest; • the SOP to direct vitrification and/or warming does not fully reflect practices observed during the inspection. SLC T32, T33b and T36.			
5. Equipment and materials The centre was unable to provide documented evidence of the validation of the suction pump(s) used during egg collection. SLC T24. The centre supplement CE marked culture media with CE marked human serum albumin for use when culturing vitrified embryos after they have been removed from storage. This is against the manufacturer's instructions and invalidates the CE mark of the media. SLC T30.	The PR should ensure that all critical equipment is validated and that only CE marked medical devices are used. It is expected that validation of this item will be complete by 12 July 2017. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this, the PR should identify a suitable CE marked alternative product by 12 July 2017. It is expected that all medical devices should be CE marked by 12 October 2017.	The equipment of note was a Cook aspiration pump used for TVOR. Service / calibration reports will be obtained from the Trust medical engineering department and filed electronically on the Q Pulse asset register log. In addition the relevant SOPs will be amended to ensure pre use checks are performed, the equipment will be labelled to clearly indicate acceptable pressure range for use during TVOR (to safeguard against potential oocyte damage) and a validation report will be generated to demonstrate that the device is fit for purpose. This will comprise of retrospective KPI analysis as well as suggested prospective	The Executive acknowledges the PR's response and awaits the validation documentation and confirmation of their intentions regarding CE marking by 12 July 2017. The PR is reminded of relevant CE marking guidance issued in the September 2016 issue of Clinic Focus. Further action is required.

		KPI analysis / service frequency. This will be summarised and submitted to the PR by 12 July 2017 and fowarded to the inspection team. With respect to off label use of G-TL culture medium for embryo culture post warming, a validation report will be generated to suppport this process. This will comprise of potential risks vs benefits and will be supported by media supplier information as well as KPI analysis relating to FET success rates prior to and post change to the Vit -warming SOP. A decision will be made as to suspending supplementation of G-TL with additional serum, continuing the practice or sourcing an alternative CE product by 12 July 2017. The report and recommendations will be reviewed by the PR and submitted to the inspection team by 12 October 2017.	
6. Process validation	The PR should ensure that this procedure is validated.	With respect to off label use of G-TL culture medium for embryo culture post warming,	The Executive acknowledges the PR's response and awaits the validation documentation

The centre introduced a new culture procedure for warming vitrified embryos after they have been removed from storage, but this had not been validated or documented in a SOP. SLC T72.	It is expected that validation will be complete by 12 July 2017.	a validation report will be generated to suppport this process. This will comprise of potential risks vs benefits and will be supported by media supplier information as well as KPI analysis relating to FET success rates prior to and post change to the Vit -warming SOP. This validation will be completed and submitted to the PR and subsequently the inspection team by 12 July 2017.	to be submitted by 12 July 2017. Further action is required.
7. Record keeping The centre does not maintain a record containing how, and by whom, the patient/donor has been reliably identified. SLC T46b and T47.	The PR should ensure that the identity of a patient is reliably confirmed and documented. The PR should undertake a review of the centre's processes for establishing the identity of patients. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 12 July 2017. Within three months, the centre should carry out an audit of records to ensure that the proposed corrective	An SOP will be created to confirm responsibilities and actions when confirming patient identity. This will include staff responsible for this event as will as documnentation and record retention to ensure accessibiliyt to all staff who may be required to verifiy patient identitiy prior to, during and post treatment. Staff will be advised of the process and trained appropriately. A summary review and changes implemented will be provided by 12 July 2017. An audit of the of records will be compolted within three months	The Executive acknowledges the PR's response and awaits a summary of the review by 12 July 2017 and a summary of the follow up audit by 12 October 2017. Further action is required.

	actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 12 October 2017.	to ensure that corrective actions are effective. Audit findings to be submitted by 12 October 2017.	
8. Payment of HFEA fees The centre has a historic issue with the late payment of HFEA fees. Invoices over the last year have been paid on average of 54 days. The HFEA payment terms is 28 days. This was an issue identified during the previous two inspections. SLC T09(d).	The PR should take appropriate action to ensure that all HFEA invoices are paid within the timescales specified by the Authority. An action plan to address this should be sent to the centre's inspector when responding to this report.	We recognise that the trust has been slow in making these payments despite the PR's request efforts to speed up the process. The trust has assured me that payments will be made on time. As the PR I will continue to monitor this and and exert any influence I have.	The Executive acknowledges the PR's response and commitment to ensuring that this area of non-compliance is fully addressed. The Executive will continue to monitor this issue closely. Further action is required.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
9. Safety and suitability of premises and facilities During the inspection, two members of staff were observed carrying a tray with liquid nitrogen without the use of personal protective equipment (for example safety goggles and gloves). CoP guidance 25.17.	The PR should ensure that staff are aware of health and safety requirements when using liquid nitrogen. The procedure used for the transfer of liquid nitrogen between laboratories must be reviewed and risk assessed and precautions put in place to minimise potential hazards to laboratory staff. A summary of this review including confirmation of staff training should be sent to the centre's inspector by 12 July 2017.	Laboratory staff have all been enrolled on a liquid nitrogen safety training course. Renewal date will be reviewed and the course will be repeated if necessary. Initial action proposed is to raise the importance of using appriate PPE at a team meeting and also to confirm suitable PPE is available and accessible. The lab manager will be reposnsible for monitoring compliance when decanting and moving LN2. If further non compliance is obsvered then remedial training and ultimatley disciplinary action may be taken. It will be sytressed that this is for individual as well as Trust protection.A summary of the review and actions taken will be provided by 12 July2017	The Executive acknowledges the PR's response and awaits a summary of the review by 12 July 2017. Further action is required.

10. Medicine management A review of the controlled drugs register identified that in at least three instances the amount of controlled drug administered had not been recorded. SLC T2, Misuse of Drugs Regulations 2001, Schedule 19(b).	The PR should ensure that the procedures for the management of medicines are compliant with all regulatory requirements and guidance. The PR should review the centre's procedures to ensure that the amount of controlled drug administered is recorded in the controlled drugs register A summary of the review should be sent to the centre's inspector by 12 July 2017. Within three months of having implemented any corrective actions, the centre should audit the record of administration of controlled drugs in the controlled drugs register to ensure that actions taken are effective. A summary of the report of the audit should be sent to the centre's inspector by 12 October 2017.	We will review our procedures for the management of medicines to ensure that that we are compliant with regulations and guidance. Once the review is complete we will implement corrective actions as required. A summary of the review findings an dcorrective action taken will be privided to the inspector by 12 July 2017. An audit will then be carried to ensure that the steps taken have resuilted in th erequired changes. A summary of the audit will be submitted by 12 October 2017	The Executive acknowledges the PR's response and awaits a summary of the review including corrective actions by 12 July 2017 and a summary of the follow up audit by 12 October 2017. Further action is required.
11. Patient feedback The centre was unable to provide assurance of appropriate mechanisms to	The PR should ensure there is an appropriate mechanism in place to review and act upon patient feedback.	This has been highlighted internally. Although there is a Trust patient feedback mechanism, this is not highly visible to ACU staff or even	The Executive acknowledges the PR's response and awaits a summary of the actions taken by 12 July 2017.

respond to and act upon patient feedback. SLC T32 and CoP guidance 23.17.	The PR should inform the centre's inspector of the actions taken to comply with this recommendation by 12 July 2017.	patients. The intention is to generate a short but useful patient feedback questionnaire that will be distributed and collected regularly from patients in the waiting areas / post TVOR and post ET. The results will be collated and presented at QM meetings and team meeting as appropriate. A summary of the changes will be provided by 12 July.	
12. Website Success rates on the centre's website are not presented in accordance with HFEA guidance. Code of Practice, Guidance Note 4.5. This was also identified during the previous inspection.	The PR should review the contents of the centre's website to ensure success rates are presented in accordance with guidance. The PR should audit the centre's website against the regulatory requirements and promptly arrange for any amendments required. The PR should inform the centre's inspector of actions that have been taken when responding to this report.	The success rates on the web site are out of date. We will provide corporate communications with more recent data so that the website can be amended. We aim for these changes to be completed within 4 weeks.	The Executive acknowledges the PR's response and awaits confirmation that the website is compliant within four weeks. Further action is required.
13. Disclosure of information, held on the HFEA Register, for use in research	The PR should ensure that patient/partner consents to disclosure of identifying information to researchers are	We have corrected the submissions that have been identified.	The Executive acknowledges the PR's response and awaits the summary of the review by 12 July 2017 and a summary

Seven discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register. CH(10)05 and General Direction 0005.	accurately recorded on the HFEA register. The PR should correct the submissions that have been identified as being incorrect and confirm this has been completed when responding to this report. The PR should review the centre's procedures to ensure that the disclosure consent information supplied to the HFEA accurately reflects that given and recorded on patient's consent forms. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector by 12 July 2017. Within six months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be	The procedure for obtaining consent to disclosure has been reviewed and a summary of the findings and corrective actions taken will provided by 12 July. The leaflet entitled " How to fill WOC and CD forms" has been revised to give the patient /partner clearer information on how to complete these forms (attached). This instruction leaflet will be given to patients when they arrive for the first doctors visit. Patients will be asked to complete these forms and will have the oppurtunity to ask the doctor for any clarification. At this point the doctor will ensure that the forms have been completed correctly. An audit will be undertaken to ensure that the corrective actions taken are effective and the findings will be provided by 12 October 2017.	of the follow up audit by 12 October 2017. Further action is required.

	provided to the centre's inspector by 12 October 2017.		
14. Obligations and reporting requirements 26% (35/134) of the IVF and 34% (24/70) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005. General Direction 0005.	The PR should ensure that all licensed treatment activity is reported to the HFEA within the timeframe required by General Direction 0005. The PR should review the centre's procedures used to submit licensed treatment data to identify and address the reasons for poor quality submissions. A summary of the findings of the review including corrective actions and the timescales for implementation should be provided to the centre's inspector when responding to this report. Within six months, the centre should carry out an audit of records to ensure that the proposed corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 12 October 2017.	The memebrs of staff involved in the submission of data met to review our processes. The following challenges were identified: 1. Delays in returning notes from the lab after completion of treatment sometimes means the admin staff are delayed in sumbitting data 2. Outcome data is sometimes late from transport centres. 3 Some staff were not aware of time frames for data submission. Corrective actions: The team has been reminded of the HFEA time frames as detailed in Direcion 0005. The laboratory staff have been advsied of the need to return notes to the admin team as soon as a treatment is completed.	The Executive acknowledges the PR's response and awaits a summary of the follow up audit by 12 October 2017. Further action is required.

		The Transport partners have been reminded of the need to communicate treatment outomes speedily. It is anticipated that this will improve the data entry and submission via EDI. This will be audited within 6 months and the results forwarded to the PR and inspection team.	

Responses from the Person Responsible to this inspection report
I accept the comments made. I as the PR and the rest of the team are commited to proividng a high quality service and will make the necessary changes/improvements required.