Executive Licensing Panel – minutes

Centre 0148 (Shropshire and Mid-Wales Fertility Centre)

Renewal Inspection Report

Friday, 11 August 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Anna Quinn Ian Peacock	Director of Strategy and Corporate Affairs Policy Manager Systems Manager
Members of the Executive	Dee Knoyle	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 since the last licence renewal.

1.2. The panel noted that Shropshire and Mid-Wales Fertility Centre is part of The Shrewsbury and Telford Hospital NHS Trust. The centre provides a full range of fertility services.

1.3. The panel noted that the centre has been licensed by the HFEA since 1994.

1.4. The panel noted that in the 12 months to 31 May 2017, the centre provided 546 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium-sized centre.

1.5. The panel noted that for IVF and ICSI, HFEA-held register data for the period March 2016 to February 2017 showed the centre's success rates were in line with national averages.

1.6. The panel noted that in 2016, the centre reported one cycle of partner insemination with no pregnancy, which was in line with the national average.

1.7. Between March 2016 to February 2017 the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 17%. This represented performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

1.8. The panel noted that at the time of the renewal inspection on 13 and 14 June 2017 there were four major areas of non-compliance identified. The panel noted that since the inspection the PR has addressed two major areas of non-compliance and given a commitment to fully implement the outstanding recommendations.

1.9. The panel noted that the centre has a Quality Management System (QMS) and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients.

1.10. The panel noted that the inspectorate recommends the renewal of the centre's treatment and storage licence for a period of four years with no additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales.

2. Decision

2.1. The panel had regard to its decision tree.

2.2. The panel was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

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

2.4. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge their duty under section 17 of the HFE Act 1990 (as amended).

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years with no additional conditions, subject to the recommendations made in the report 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

18 August 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: 13 and 14 June 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, Douglas Gray and Grace Lyndon.

Executive Licensing Panel: 11 August 2017.

Centre name	Shropshire and Mid-Wales Fertility Centre
Centre number	0148
Licence number	L/0148/13/a
Centre address	Royal Shrewsbury Hospital North, Mytton Oak Road, Shrewsbury, Shropshire, SY3 8XQ, United Kingdom.
Person Responsible	Jason Kasraie
Licence Holder	Medical Director, Shrewsbury and Telford Hospital NHS Trust Board.
Date licence issued	01 December 2013
Licence expiry date	30 November 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Shropshire and Mid-Wales Fertility Centre is part of The Shrewsbury and Telford Hospital NHS Trust. The centre has held a Treatment and Storage licence with the HFEA since 1994.

The centre provides a full range of fertility services to NHS and self-funding patients.

The centre provided 546 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2017. In relation to activity levels this is a medium sized centre.

Pregnancy outcomes[1]

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

In 2016, the centre reported one cycle of partner insemination with no pregnancy, which is in line with the national average.

Multiple births[2]

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

Between March 2016 to February 2017 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%: 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 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 four major 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 process for freezing and thawing sperm is validated.
- The PR should ensure that an adequate audit of legal parenthood consent is performed.

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

Major areas of non compliance:

- The PR should ensure that the procedures for the management of medicines are compliant with all regulatory requirements and guidance.
- The PR should ensure that there is effective written consent in place for all gametes that are in storage.

Recommendation to the Executive Licensing Panel

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

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/live birth rates meet the target. The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to monitor and improve their success rates and the quality of the service provided to patients.

The inspection team recommends the renewal of the centre's Treatment and Storage licence for a period of four years without additional conditions subject to 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 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)
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.

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

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

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 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 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 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 partially 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 therefore requirements related to its use were not relevant at 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 the 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 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;
- 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 compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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 any transport and satellite agreements 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 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 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 partially 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.

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

Medicines management (Guidance Note 25)
On inspection, the following issues were noted:

- Two drugs (Ibuprofen (PO) and Cefuroxime (IV)) had past their expiry date by three and four months. The inspectors were concerned that there is no mechanism in place to check the drugs contained in the controlled drugs cupboard.
- The disposal of the waste portion of controlled drug drawn up but not administered is not witnessed or recorded in the controlled drugs register.
- The controlled drugs were not checked by a second member of staff prior to administration.

SLC T2. Misuse of Drugs Regulations 2001, schedule 27; see recommendation 1.

Process validation (Guidance note 15)
The process for freezing and thawing sperm is not validated.

SLC T72; see 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 biological sciences 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, in sufficient number**,** 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
Nothing identified at this inspection.

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)
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 visit the inspectors spoke to three patients who provided feedback on their experiences. A further three patients also provided feedback directly to the HFEA in the time since the last inspection. The centre's most recent patient survey responses were also reviewed. Feedback was positive with all the individuals providing written feedback giving compliments about the care that they received.

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

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

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

Treating patients fairly
Counselling
Egg 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 sharing arrangements (Guidance note 12; General Direction 0001)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind;
- egg providers are fully assessed and medically suitable; and

- the benefit offered is the most suitable for the egg provider and recipient(s).

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's procedures for providing information to patients and / or donors 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'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 centre's 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 one couple was affected by legal parenthood consent anomalies. The centre sought legal advice and were advised that the centre's in-house consent forms cover legal parenthood consent. The couple have left strict instructions that they do not wish to be contacted again regarding this matter.

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 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.

In summary, the inspection team considers the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements except for the observation noted below.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This 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.

What the centre could do better

Legal parenthood (Guidance note 6)

During this inspection, it was noted that since the 2014 audit of consent to legal parenthood requested by the HFEA, the centre has audited the presence of legal parenthood consent forms in patient records as part of a general consent audit but 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 could undermine 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.

SLC T36; see recommendation 3.

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

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 one patient. The samples had been in storage for a period of 10 years with effective consent, but had breached the statutory storage period without consent being renewed. It is noteworthy that a medical practitioners statement was however in place.

Schedule 3, 8(1) HF&E Act 1990 (amended); see recommendation 4.

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. 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)
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 compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

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

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, two areas of major non compliance and two 'other' areas of non compliance.

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

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

This 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. Medicines Management On inspection, the following issues were noted: • Two drugs (Ibuprofen (PO) and Cefuroxime (IV)) had past their expiry date by three and four months. The inspectors were concerned that there is no mechanism in place to check the drugs contained in the controlled drugs cupboard. • The disposal of the waste portion of controlled drug drawn up but not administered is not	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 procedures for the management of medicines at the centre. A summary of this review including details of any actions taken should be provided to the centre's inspector by 14 September 2017. Three months after the implementation of corrective actions, the centre should perform an audit to ensure that these corrective actions have been effective. A summary of the	Out of date drugs were identified on inspection however these were not controlled drugs and were not in the controlled drugs cupboard, (which is checked every time we use controlled drugs). The out of date drugs were stored in a different (i.e. not controlled drugs) cupboard, which was checked when non-controlled drugs are reordered (periodically). The drugs in question are not routinely used in the department. 1 ampoule of Cefuroxime was out of date, two were present in the cupboard.	The Executive acknowledges that the PR has provided clarification regarding the location of the out of date medicines and that they are of course not controlled drugs. The Executive considers that the measures taken since the inspection meet the requirement of this recommendation but should ensure that the 'count' of all controlled drugs held in stock against the running total in the controlled drugs register is recorded for reference. The Executive awaits the outcome of the scheduled audit.

witnessed or recorded in the controlled drugs register. • The controlled drugs were not checked by a second member of staff prior to administration. SLC T2. Misuse of Drugs Regulations 2001, schedule 27.	audit should be provided to the centre's inspector by 14 December 2017.	We have begun checking the non-controlled drugs cabinet at the start of every month and recording this in order that this could not happen again. The controlled drugs book has three lines for each patient. For each drug we record the amount drawn up, the amount used and the amount disposed of. The Doctor who administers the drug(s) checks the ampoule(s) prior to injecting, and at the end of the procedure checks the volumes/dosages tally and signs once in the controlled drugs book, with the nurse countersigning. In future we will ensure that the drugs are always drawn up in front of the doctor and that both the doctor and the nurse check and sign twice if any of the drug is disposed of after the procedure. This is in line with practice across our organisation. Protocols are being updated to reflect these changes.	Further action is required

		We would be happy to discuss further with our pharmacy department if the HFEA can forward evidence that our revised practice is not in line with current standards. We hope that these actions address the first points. We will forward the 3 month audit in due course.	
2. Process validation The process for freezing and thawing sperm is not validated. SLC T72.	The PR should ensure that these procedures are validated. A copy of the validations should be forwarded to the centre's inspector by 14 September 2017.	Please see enclosed excerpt from updated process validation document which now includes semen cryopreservation and protocol for semen cryopreservation. We would point out that semen cryopreservation using the technique utilised in our centre has been performed successfully worldwide for over 40 years.	The PR has provided a validation document for the processes identified. No further action is required.
3. Legal Parenthood Since the comprehensive audit of legal parenthood conducted in 2014, the centre has not completed a focused audit of legal parenthood consent.	A full audit of legal parenthood consents was initiated by the centre during the inspection. A summary of this should be submitted when responding to this report if available, or by 14 September 2017 at the latest.	Please find enclosed a copy of the audit that was completed on the day of inspection. This audit has now been added to our annual audit list and will be repeated routinely going forwards as a full and	The PR has provided an audit of legal parenthood consents. The audit had been performed in accordance with the requirements stated in CE(14)01. No anomalies were identified. No further action is required.

SLC T36; CE(14)01.		separate audit (rather than being a part of another audit).	
4. Storage of gametes The centre does not have written effective consent for the storage of cryopreserved sperm from one patient. Schedule 3, 8(1) HF&E Act 1990 (as amended).	The PR should ensure that there is effective written consent in place for all gametes that are in storage. The PR should provide monthly updates to the centre's inspector until this is resolved.	As discussed with inspectors on the day of inspection, this is a complicated case. This patient originally stored sperm in 2007 and consented to 10 years storage using the old HFEA 'MS- consent to storage of sperm' form. In November 2010 the patient completed a new HFEA 'GS- your consent to the storage of your eggs and sperm' form and indicated consent to storage of sperm for 10 years. In January 2017 the patient returned our standard sperm storage review form having ticked the box indicating that he wished us to extend storage. He also signed and dated the form. At this stage a HFEA 'medical practitioners statement' was completed by the department.	The Executive acknowledges the PRs response and commitment to ensuring that consent for extended storage is obtained. The executive asks that the PR provides monthly updates to the centre's inspector. Further action is required.

		Unfortunately since this time we have been unable to contact the patient, although we have now managed to leave a message on his home phone and await a reply. We would ask the HFEA to consider what action would be considered reasonable (i.e. should we discard the sperm) when:- a) The patient has indicated in writing, with a signature and date, that they wish the sperm to remain in storage (i.e. is a form of consent already in place?). b) The patient signed a HFEA consent form in 2010 which indicated he consented to 10 years storage (i.e. could this infer a storage expiry of 2020?) We would appreciate advice from the HFEA. In the meantime we will endeavour to contact the patient in order	

		for him to complete the HFEA 'LGS- Your consent to extending the storage of your eggs or sperm beyond 10 years' form. We will update the HFEA further as requested by our inspector co-ordinator.	

Other areas of practice that requires improvement

Other 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
None			

Responses from the Person Responsible to this inspection report
On behalf of the team in Shrewsbury I would like to thank the inspection team for their professionalism and the lack of disruption that occurred on the days of the inspection. We always aim to ensure that we are open to constructive feedback and will, as always, endeavour to address any issues highlighted at inspection to ensure that we continue to be compliant with the HFEA code of practice.