Executive Licensing Panel - minutes

Centre 0057 (Wessex Fertility Limited)

Renewal Inspection Report

Tuesday, 7 April 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Kathleen Sarsfield-Watson Helen Crutcher	Director of Strategy and Corporate Affairs Communications Manager Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

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:

- 9th 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 five years.

1.2. The panel noted that Wessex Fertility Limited is located in Southampton and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services. Other licensed activities at the centre include storage of gametes and embryos and embryo testing.

1.3. The panel noted that, in the 12 months to 31 October 2019, the centre provided 994 cycles of treatment (excluding partner intrauterine inseminations). In relation to activity this a medium sized centre.

1.4. The panel noted that, IVF and ICSI, HFEA held register data, for the period between 1 November 2018 and 31 October 2019, show the centre's success rates are in line with national averages, with the following exception:

- Success rates following ICSI in women under 38 years old are lower than average at a statistically significant level.

1.5. The panel noted that, since the last interim inspection in January 2018, the centre has received three performance related risk tool alerts in relation to pregnancy rates per cycle for ICSI treatments in patients aged under 38 years. The centre was asked to review procedures for the provision of ICSI treatments. The Person Responsible (PR) responded to these requests, advising the inspection team that the centre undertakes a high number of 'freeze-all' treatments for patients who have a good prognosis. The centre believes this negatively affects pregnancy rates per cycle for ICSI treatments in patients aged under 38. The PR provided a commitment to keep success rates in this group of patients under review.

1.6. Following discussion with the PR, the inspection team decided that it was not proportionate to make recommendations, in relation to ICSI treatments in patients under 38 years old, at this point in time, noting there is a facility in the EDI system to prevent 'freeze all' cycles from being considered as failed fresh cycles; this will be relayed to the PR by the centre's inspector, who will also continue to monitor the success rate for ICSI treatments in patients aged under 38 years. The inspections report states that if success rates fail to improve and normalise, with the sector average, by 30 June 2020, the PR will be required to commission an external review of the centre's ICSI practice. The panel noted that this report was written and submitted prior to treatments ceasing, due to COVID-19; the deadline for this issue has now been extended to 30 December 2020.

1.7. The panel noted that, in 2015, the centre reported 15 cycles of partner insemination, with one pregnancy.

1.8. The panel noted that, HFEA register data, between November 2018 and October 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.9. An inspection was carried out at the centre on the 14 and 15 January 2020.

1.10. The panel noted that at the time of the inspection, there were five major area of non-compliance concerning medicines management, transport and distribution of gametes and embryos, imports and exports, staff and the storage of gametes and embryos. There were also two 'other' non-compliances relating to the quality management system (QMS) and record keeping and document control. Since the inspection, the PR has provided evidence that actions have been taken to implement the recommendations regarding the storage of gametes and embryos and record

keeping and document control, and where required, to audit the effectiveness of those actions within the required timescales. The PR has given a commitment to implementing the recommendations relating to medicines management, imports and exports, staff, the QMS and transport and distribution of gametes and embryos.

1.11. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients. The panel noted that the centre is well led and provides a good level of patient support.

1.12. The panel noted that the inspection team recommends the renewal of the centre's treatment (including embryo testing) 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.

1.13. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

2. Decision

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

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

2.3. 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 his duty under section 17 of the HFE Act 1990 (as amended).

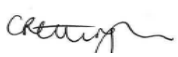
2.4. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (including embryo testing) and storage licence for a period of four years, without additional conditions. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

2.5. The panel endorsed the inspectorate's recommendation to renew the centre's ITE certificate in line with the centre's licence.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

16 April 2020

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: 14 and 15 January 2020

Purpose of inspection: Renewal of a licence to carry out Treatment (including embryo testing) 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: Nicola Lawrence (lead), Julie Katsaros, Victoria Brown and Angela Belotti (observer)

Date of Executive Licensing Panel: 7 April 2020

Centre name	Wessex Fertility Limited
Centre number	0057
Licence number	L/0057/18/b
Centre address	Wessex Fertility Limited, The Freya Centre, 72 - 74 Anglesea Road, Southampton, Hampshire, SO15 5QS, United Kingdom
Person Responsible	Dr Sue Ingamells
Licence Holder	Mrs Laurel Hird
Date licence issued	1 August 2016
Licence expiry date	31 July 2020
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Wessex Fertility Limited is located in Southampton and has held a treatment and storage licence with the HFEA since 1992.

The current licence was varied to reflect a change of Licence Holder in December 2016 and October 2019.

The centre provides a full range of fertility services and provided 994 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2019. In relation to activity levels this is a medium sized centre. Other licensed activities at the centre include storage of gametes and embryos and embryo testing.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period 1 November 2018 - 31 October 2019 show the centre's success rates are in line with national averages with the following exception;

- Success rates following ICSI in women under 38 years old are lower than average at a statistically significant level.

In 2015 the centre reported 15 cycles of partner insemination with one pregnancy.

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

Between November 2018 and October 2019 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. 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) and standard licence conditions (SLCs), 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 her 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 the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including five major and two 'other' areas of non compliance.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non compliance:

- The PR should ensure that effective consent to storage is in place for all stored gametes and embryos.

'Other' areas that requires improvement:

- The PR should ensure that the staff member who verifies a patient's identity is documented in the patient's records.

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

Major areas of non compliance:

- The PR should ensure that medicines management practice is compliant with regulatory requirements.
- The PR should ensure that the procedures for transport and distribution of gametes and embryos meet the mandatory requirements of licence conditions and the Code of Practice.
- The PR should ensure that the import and export of gametes and embryos is compliant with General Directions.
- The PR should ensure that staff are suitably trained and assessed as competent to undertake their roles.

'Other' areas that requires improvement:

- The PR should ensure that the centre's quality management system processes are effective.

Recommendation to Executive Licensing Panel

The centre has no critical areas of concern but does have five major and two 'other' areas of concern.

Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system and the PR is encouraged to use it to best effect to monitor and improve the service provided to patients.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales.

The centre is well led and provides a good level of patient support.

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.

Centre 0057 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

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)
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
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 premises of the centre's satellite/transport facilities and 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 process gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and 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

UKAS, the national accreditation body for the UK, or another accreditation body recognised as 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 a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered to be suitable, however, it was noted that staff who administer intralipids did not have documented assessment of their competency to undertake this task (See 'Staff' section and recommendation 4).

Written information provided to patients offering intralipid therapy is compliant with guidance.

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 partially compliant with HFEA requirements. This is important to ensure that all gametes/embryos sent to other licensed centres within or outside the UK are:

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

Receipt of gametes and embryos (Guidance note15)
The centre'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.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. The centre has been allocated an ITE import certificate and imports of

gametes and embryos from TCSs outside the EU/EEA have been made since the introduction of the ITE import certification scheme on 1 April 2018. No imports have been made from TCSs which are not specified on the centre's ITE import certificate. The centre is therefore compliant with General Direction 0006.

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 broadly 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, including those associated with ITE/TCS import certificates, are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage transport and satellite activities that are compliant with HFEA requirements. This 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.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

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

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

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all 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)

The following issues were noted during inspection of the controlled drugs (CD) register:

- The centre is using a ward CD register, rather than a theatre CD register, so is not appropriate for the practices undertaken and does not have the facility to record separately the supply, administration or discard of controlled drugs.
- Only one patient identifier is recorded, contrary to best practice/ professional guidelines
- In the CD register the carry-over of stock levels from one page to the next were completed, however these levels were not signed by either the registered nurse or a witness to the carry-over.
- The numbers of stock entries of drugs received were not written in words as per guidance.
- There are several entries where the date of administration is recorded in the wrong place.
- There are several entries where the time of discard of drugs was not recorded.
- In one record a drug was prepared but not given, and there was no documentation of the discard of the drug.
- Several entries were crossed through with 'written in error' documented, however, there was no explanation for the error. This is contrary to the centre's standard operating procedure (SOP) which states that the reason for the error should be clearly noted.

Further concerns were noted in the centre's management of controlled drugs:

- Staff were observed administering a CD to a patient during an egg collection procedure in theatre. The CD register was not completed prior to the patient leaving the theatre. The inspector was advised by the nurse that the CD register would be completed later. This is not in line with regulatory requirements, best practice guidance or the centre's own SOP.
- Denaturing kits were used for the destruction of unused CD stock, however, any leftover CDs prepared but not administered to patients, were dispersed onto a paper towel rather than a denaturing kit and discarded in a yellow clinical sharps bin. The centre's SOP does not clearly document the process for the discard of left over CD medication that is not administered.
- The centre's audits of medicines management are not robust and failed to identify the non compliances noted by the inspection team or to lead to the implementation of effective corrective action. For example, in a previous audit of the CD register, a non conformity had been documented for the carry-over of stock levels not being signed or witnessed, however, in a subsequent audit, the controlled drugs accountable officer (CDAO) had removed this section from the audit and therefore it was no longer being checked.

See recommendation 1.

SLC T2; The Misuse of Drugs Regulations 2001 20(c); 'Controlled drugs in peri-operative care' (2019) The Association of Anaesthetists of Great Britain & Ireland; Department of Health (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The label used by the centre when transporting gametes and embryos did not include all the information specified and required by SLC T107; neither did the centre's relevant SOP state the need for the label to include this required information.

The centre did not have a documented procedure describing the process used to recall gametes or embryos and to manage gametes and embryos that were returned to the centre.

See recommendation 2.

SLC T107; CoP Interpretation of Mandatory requirements 15C.

Imports and exports (Guidance note 16; General Direction 0006)
The centre has exported gametes to Poland and Ukraine under the authorisation provided by General Direction (GD) 0006, without obtaining evidence and assuring themselves that all requirements of this GD have been met. These requirements are, specifically, for the export to Poland, schedule 2 section 1(a) ('the centre to which the gametes or embryos are to be exported is accredited, designated, authorised or licensed under the laws or other measure of Gibraltar or the EEA state concerned, in accordance with the first, second and third Directives (2004/23/EC, 2006/17/EC and 2006/86/EC)) and, for the export to Ukraine, schedule 4 section 1(a) ('the receiving centre is accredited, designated, authorised or licensed under the quality and safety laws or other measures of the country in which it is situated'). The inspection team note that once this concern was identified to the PR, evidence of accreditation of the clinics to which the gametes were exported, was obtained by the centre and provided to the inspection team during the course of the inspection.

See recommendation 3.

GD 0006.

QMS (Guidance note 23)
The following concerns within the QMS were noted on inspection:

- The controlled drugs audit was not robust, in that it did not identify numerous non-conformities which were noted by the inspection team.
- The only audit of witnessing was a mismatch report generated by the electronic witnessing system. A witnessing audit should include (but not be limited to) an assessment whether witnessing practices are compliant, i.e. whether all necessary witnessing steps took place for all patients in accordance with HFEA requirements and the clinic's SOP guidance. Such an assessment cannot be completed only on consideration of the mismatch audit.
- The audit of traceability was not robust because it did not cross check that the batches of media which were in use in the laboratory were the same as those

listed as 'active' on the traceability system. Indeed an inspector noted that the batch number for one media item in use in the laboratory was not listed as active within the traceability system.
- An audit of non-controlled drugs has not been performed in the last two years.
- The last audit of pre-implantation genetic screening (PGS) practices was performed in 2017 and the PGS audit scheduled in November 2019 has not yet been performed.
- The SOP for drug fridge monitoring does not direct staff as to what actions should be taken in the event that the fridge temperatures fall outside the recommended levels.
- The centre does not systematically document the timescales for implementation of corrective and preventative actions identified by audits, or the dates on which those actions are completed.

See recommendation 6.

SLCs T33 and T36.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
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.

Leadership
The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

Staff (Guidance note 2)
The centre is partially compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has 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)
There was no evidence of training or assessment of competence for staff who undertake the following procedures;

- The taking of patient consent for the storage of gametes
- Recruitment of sperm donors
- Traceability procedures
- Administration of intralipid infusions

See recommendation 4.

SLCs T12 and T15a.

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's procedures for performing embryo testing are compliant with HFEA requirements. This ensures that:

- no embryo is transferred to a woman where that embryo or material removed from it, or the gametes that produced it, has been subject to genetic testing unless expressly authorised by the HFEA
- no information derived from tests conducted has been used to select embryos of a particular sex for social reasons
- no embryo is tested unless the statutory tests are met i.e. that the embryos is at a significant risk of having a series genetic condition.

The centre ensures that people seeking embryo testing are given written information, are given every opportunity to discuss the implications of their treatment and have access to clinical geneticists, genetic counsellors and infertility counsellors where required.

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

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Evidence was provided that the centre actively promotes this facility to patients and 57 have provided feedback in the last 12 months, giving an average 4.5 star rating to the clinic. The website also gives the ability for patients to comment on the cost of treatment. All patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting staff at the clinic.

The centre's most recent patient survey responses for the period of September - November 2019 were also reviewed. A total of 46 responses were received, all of which provided feedback that was extremely positive.

During the inspection the inspectors spoke to two patients who also provided positive feedback on their experiences.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
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.

Patient support (Guidance note 3)
New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

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)
The centre does not undertake egg and sperm sharing; therefore this area of practice is not relevant to this inspection.

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy 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 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 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 the effectiveness of the consent and in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

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.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in February 2016, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Five sets of records where treatment with donor sperm had recently been provided, in circumstances where consent to legal parenthood was required, were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005) The centre'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 ART and those born following ART treatment.
What the centre could do better Nothing identified at this inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

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

- licensed activities only take place on licensed premises;
- 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 and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

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 additional invasive procedures.

What the centre could do better

Storage of gametes and embryos (Guidance note 17)

The centre does not have effective consent for the storage of cryopreserved sperm from two patients and for one donor sperm sample. The centre is aware of this and have taken appropriate action.

In relation to the two sperm samples stored by the gamete providers, one patient has not responded to efforts to contact him. This has been raised as an incident and reported to

the HFEA. The second patient has commenced a legal challenge to the disposal of his sample.

In relation to the donor sperm sample, this was transported from another licensed centre without the appropriate consent forms, although the PR has been reassured that the consent forms were completed. At the time of inspection, the transporting centre had not yet provided this information.

See recommendation 5.

Schedule 3, 8(1) HF&E Act 1990 (as amended).

Use of embryos for training staff

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 and 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 broadly 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 **Record keeping and document control (Guidance note 31)** The centre does not document in patient records by whom a patient/donor has been reliably identified. See recommendation 7. SLC T46.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2018, recommendations for improvement were made in relation to one area of critical non compliance and one 'other' area of non compliance.

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

On-going monitoring of centre success rates

Since the last interim inspection in January 2018 the centre has received three performance related risk tool alerts in relation to pregnancy rates per cycle for ICSI treatments in patients aged under 38 years.

In response to these risk tool alerts, the centre was asked to review procedures for the provision of ICSI treatments. The PR responded to these requests, and during discussion at the time of the inspection, provided a commitment to keep success rates in this group of patients under review. The PR advised the inspection team that the centre undertake a high number of 'freeze-all' treatments for patients who have a good prognosis. The centre believes this negatively affects pregnancy rates per cycle for ICSI treatments in patients aged under 38 years. This is in part because there is a higher proportion of good prognosis patients at younger ages, who have freeze-all procedures, so those aged under 38 years having fresh ICSI embryo transfers tend to have poorer prognosis. In addition, when an ICSI treatment cycle is started, if there is no embryo transfer performed (because the embryos have been cryopreserved), the cycle will show as unsuccessful in data submitted to the register. If a subsequent FET cycle is performed and the patient becomes pregnant, this will be included in the centre's FET success rate data, not in the ICSI data. Indeed the centre's FET rates for patients aged under 40 are above average.

The inspection team decided that it was not proportionate to make recommendations at this point in time, though they note that there is a facility in the EDI system to prevent 'freeze all' cycles from being considered as failed fresh cycles. Information regarding this facility will be relayed to the PR by the centre's inspector, who will also continue to monitor the success rate for ICSI treatments in patients aged under 38 years. If success rates fail to improve and normalise with the sector average by 30 June 2020, the PR will be required to commission an external review of the centre's ICSI practice.

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 areas 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.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
None.			

Major areas 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.

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Medicines management Several concerns were noted on inspection related to medicines management practices and documentation; these are detailed in the main body of the report. SLC T2. The Misuse of Drugs Regulations 2001 20(c). 'Controlled drugs in peri-operative care' (2019) The Association of Anaesthetists of Great Britain & Ireland.	The PR should ensure that medicines management practice is compliant with regulatory requirements and best practice guidelines. The PR should review medicines management practice and provide a summary report of this review together with details of the corrective actions taken, to the centre's inspector by 14 April 2020. Three months after corrective actions have been implemented the PR should	The required theatre drug record book is in use now and the new recommendations for documentation in routine practice. A full review will be undertaken and additional information provided as required by April 14. An audit will be undertaken as suggested at the end of May.	The executive acknowledges the PR's actions to date and commitment to fully implementing this recommendation. Further action is required.

DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'.	audit medicines management practice to ensure actions taken have been effective in achieving compliance. A summary report of this review should be provided to the centre's inspector by 14 July 2020.		
2. Transport and distribution of gametes and embryos The label used by the centre when transporting gametes and embryos did not include all the information specified and required by SLC T107; neither did the centre's relevant SOP state the need for the label to include this required information. The centre did not have a documented procedure describing the process used to recall gametes or embryos and to manage gametes and embryos that were returned to the centre. SLC T107; CoP Interpretation of Mandatory requirements 15C.	The PR should ensure that the procedures for transport and distribution of gametes and embryos meet the requirements of licence conditions and the Code of Practice. The PR should ensure that the non compliances noted in this report are completed. A summary of the updated actions and processes should be provided to the centre's inspector when responding to the report.	This has already been undertaken with a new label being used and an SOP under the final stages of review with a completion date of march 31st anticipated.	The executive acknowledges the PR's actions to date and commitment to fully implementing this recommendation. Further action is required.

3. Imports and exports The centre has exported gametes to Poland and Ukraine under the authorisation provided by GD0006, without obtaining evidence and assuring themselves that all requirements of this GD have been met. GD 0006.	The PR should ensure that the import and export of gametes and embryos is compliant with General Directions. The PR should update the centre's practices and SOP to ensure imports and exports undertaken under GD0006, are compliant with the relevant requirements. The PR should also retrospectively audit all gamete and embryo imports and exports undertaken under General Direction 0006, in the last two years, to assess the compliance of those import and exports with the requirements of GD0006. Details of the actions taken and a report of the audit, should be provided to the centre's inspector by 14 July 2020.	The full actions will be completed as requested by July 14 2020 and an audit undertaken and reported by then too.	The executive acknowledges the PR's commitment to fully implementing this recommendation. Further action is required.
4. Staff There was no evidence of training or assessment of competence for staff who	The PR should ensure that staff are suitably trained and assessed as competent to undertake their roles.	Competency training for the first three items is underway and the fourth item has been discontinued by the clinic with no further intralipid infusions	The executive acknowledges the PR's commitment to fully implementing this recommendation.

undertake the following procedures: • The taking of patient consent for the storage of gametes • Recruitment of sperm donors • Traceability procedures • Administration of intralipid infusions SLCs T12 and T15a.	The PR should review staff competencies and complete competency assessments where required. It is expected that all staff will have had their competency assessed by 14 April 2020, and evidence of completed assessments should be provided to the centre's inspector.	being undertaken so no training will be required	Further action is required.
5. Storage of gametes and embryos The centre does not have effective consent for the storage of cryopreserved sperm from two patients and for one donor sperm sample. Schedule 3, 8(1) HF&E Act 1990 (as amended).	The PR should ensure that effective consent to storage is in place for all gametes and embryos that are in storage. The PR should ensure storage is only extended beyond the statutory storage period when there is compliance with the 2009 storage regulations. The PR should confirm whether any further gametes or embryos are in storage without effective consent when responding to this report. In any cases where there has been a failure to comply with	All consents have been obtained and no embryos are in store without effective consent.	The executive acknowledges the PR's review of processes and action taken in implementing this recommendation. No further action required.

	the 2009 storage regulations, the PR should seek independent legal advice on how to proceed. The outcome of these reviews, including the centre's intended actions and the timescales for their implementation should be submitted to the centre's inspector by 14 July 2020.		

Other areas of practice that require improvement

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

An 'other' area of non compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
6. QMS Several non compliances within the QMS were noted on inspection; these are detailed in the main body of the report. SLCs T33 and T36.	The PR should ensure that the centre's QMS is effective, notably the audit programme and SOP content. The specific non compliances identified in this report should be reviewed and corrected. The PR should undertake a root cause analysis of the non compliances and should, if necessary, review and upgrade relevant areas of the QMS to ensure its effectiveness. The PR should provide a summary report of the corrective actions taken, as well as of the root cause analysis and any planned preventative actions, with	A review of the audit programme and SOP is underway. Non compliances are being corrected and a more effective audit process that is also more robust is being developed.	The executive acknowledges the PR's commitment to fully implementing this recommendation. Further action is required.

	timescales for implementation, to the centre's inspector by 14 April 2020. The PR should also review all audit reports generated in the last audit cycle, to ensure that audit reports have been fully completed to document the corrective actions taken and the date all non compliances were resolved. A copy of this review should be provided to the centre's inspector by 14 July 2020.		
7. Record keeping and document control The centre does not document in patient records by whom a patient/donor has been reliably identified. SLC T46.	The PR should ensure that the staff member who verifies a patient's identity is documented in the patient's records. The PR should inform the centre's inspector of the actions taken to address this non-compliance when responding to this report. Three months after corrective actions have been implemented, the PR should perform a records audit to ensure these actions have	Administrative staff have been advised of this new procedure and are recording the verification of identity as required. A records audit will be undertaken on June 1st to ensure that this has been fully implemented.	The executive acknowledges the PR's review of processes and action taken in implementing this recommendation. No further action required beyond submission of the audit due by 14 July 2020.

	been effective. A summary report of this audit should be provided to the centre's inspector by 14 July 2020.		

Reponses from the Person Responsible to this inspection report
Thank you for the inspection report and the thorough review of Wessex Fertility and our QMS system. Your advice will be followed, and the audits of the new practices put in place will be forwarded as requested on completion.