Executive Licensing Panel - minutes

Centre 0008 (Midland Fertility Service) Renewal Inspection Report

Friday, 19 May 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Juliet Tizzard (Chair) Anjeli Kara Hannah Verdin	Director of Strategy & Corporate Affairs Regulatory Policy Manager Head of Regulatory Policy
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 for the last three years.

1.2. The panel noted that Midland Fertility Services, centre 0008, is located in Tamworth. The centre has been licensed by the HFEA since 1992. The centre currently holds a treatment and storage licence and provides a full range of fertility services.

1.3. The panel noted that the centre's current licence is due to expire on 31 July 2017.

1.4. The panel noted that since the last inspection, Midland Fertility Services has become part of IVI UK, a global fertility group. It is expected over the next year that changes will be made to the centre to bring it in line with IVI corporate policies.

1.5. The panel noted that, in the 12 months to 31 January 2017, the centre provided 726 cycles of treatment (excluding partner insemination). In relation to activity levels this is a medium-sized centre.

1.6. The panel noted that in 2016, the centre reported 13 cycles of partner insemination with one pregnancy. This was in line with the national average.

1.7. The panel noted that for IVF and ICSI, HFEA-held register data for the period November 2015 to October 2016 showed the centre's success rates were in line with national averages with the following exceptions:

- success rates following IVF treatments involving fresh embryos created from patient eggs in women under 38 years old are higher than average at a statistically significant level.

1.8. Between November 2015 and October 2016 the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 8%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

1.9. The panel noted that an inspection was carried out at the centre on 7 and 8 March 2017.

1.10. The panel noted that at the time of the inspection there were six major and five other areas of non-compliance identified. The panel noted in particular the areas of non-compliance relating to donor screening, consent and reporting treatment data to the HFEA. The panel noted that the Person Responsible (PR) has started to address the non-compliances and has committed to implementing the remaining recommendations within the required timescales.

1.11. The panel noted that improvement is required in order for the centre to reflect suitable practices. 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.

1.12. The panel noted that the inspectorate had considered making a recommendation to reduce the length of licence, however the inspectorate considers that there is no ongoing risks to patient safety and there is not enough concern to suggest a reduction. Therefore, the inspectorate recommended 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.

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 Person Responsible (PR) are such as is required for the supervision of licensed activities and that the PR will discharge their duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel had regard to its guidance on periods for which new or renewed licences should be granted. The panel had some concerns about the non-compliances, particularly those relating to donor screening, consent and reporting of treatment data to the HFEA. The panel carefully considered whether it would be appropriate to offer a licence for a period shorter than four years. However, the panel was reassured by the inspectorate that there is no ongoing risk to patient safety. Also, due to the change of ownership to IVI UK and the forthcoming change of PR over the next year, changes will be made to the centre's processes and procedures which will help with improvements. The panel agreed that a four-year licence would be appropriate for this renewal.

2.5. The panel noted that the inspectorate will continue to monitor the centre's performance and the implementation of the outstanding recommendations.

2.6. The panel recommended that the inspectorate also conducts an interim inspection within 12 months of the renewal licence coming into force, to make sure that the non-compliances have been fully addressed.

3. Chair's signature

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

Signature

Name

Juliet Tizzard

Date

30 May 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: 7 and 8 March 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: Lesley Brown (lead), Douglas Gray and Janet Kirkland.

Date of Executive Licensing Panel: 19 May 2017

Centre name	Midland Fertility Services
Centre number	0008
Licence number	L/0008/15/c
Centre address	Tamworth House, Ventura Park Road, Tamworth, B78 3HL, United Kingdom
Person Responsible	Dr Gillian Lockwood
Licence Holder	Mrs Susan Barlow
Date licence issued	1 August 2013
Licence expiry date	31 July 2017
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

Midland Fertility Services has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 726 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2017. In relation to activity levels this is a medium centre.

The centre's licence was last renewed following an inspection in February 2013. In August 2014 the centre's licence was varied to change the location. The licence was amended on 14 November 2016 to reflect a change in Licence Holder. Since the last inspection, Midland Fertility Services has become part of IVI UK. IVI is a global fertility group, of which IVI London (centre 0354) is a newly licensed centre. It is expected over the next year that changes will be made to the centre to bring it in line with IVI corporate policies. A request has also been made to vary the centre's name from 'Midland Fertility Service' to 'IVI Midland', although the Executive are awaiting a suitably completed application form.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period November 2015 to October 2016 show the centre's success rates are in line with national averages with the following exceptions:

- success rates following IVF treatments involving fresh embryos created from patient eggs in women under 38 years old are higher than average at a statistically significant level.

In 2016, the centre reported 13 cycles of partner insemination with one pregnancy. This is in line with the national average.

Multiple births[2]

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

Between November 2015 and October 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 8%: 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 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 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, six major and five 'other' areas of non compliance.

The PR has fully implemented the following recommendation:

Major areas of non compliance:

- The PR should ensure that welfare of the child (WOC) forms are completed appropriately when providing surrogacy treatments.

The PR has provided a commitment to implementing the remaining recommendations within the required timescales:

Major areas of non compliance:

- The PR should ensure a valid medical practitioner's statement is available for all samples that have been stored beyond 10 years.
- The PR should ensure donors of gametes and embryos are screened, within required timeframes and in accordance with current professional guidance produced by the relevant professional bodies.
- The PR should ensure critical procurement and processing procedures are validated.
- The PR should ensure that import and export procedures satisfy the requirements of General Direction 0006.
- The PR should ensure the liquid nitrogen generator is validated.

'Other' areas that requires improvement:

- The PR should establish quality indicators and objectives for all licensed activities and for other activities carried out in the course of providing treatment services that do not require a licence, and carry out audits of activities every two years.
- The PR should ensure the ability of all third parties to meet the required standards is evaluated.
- The PR should ensure that written patient information relating to intralipid treatment specifies that it is being prescribed 'off-label'. The PR should also ensure data presented to patients via the centre website meets HFEA requirements.

- The PR should ensure that the disclosure consent information supplied to the HFEA accurately reflects that given and recorded on disclosure consent forms.
- The PR should ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Direction 0005.

Recommendation to the Executive Licensing Panel

The centre has more than five major of areas of concern. Improvement is required in order for the centre to reflect suitable practices. The centre has a quality management system (QMS) and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

The inspection team notes that the success rates are consistent with, or above, the national average. Their multiple clinical pregnancy is below the target; a significant improvement from a multiple clinical pregnancy rate of 25% in 2014.

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

The inspection team has considered the non-compliances, and acknowledges that there are some concerns related to quality of service. However, it is not considered that there is any ongoing risk to patient safety. On the balance of evidence and after consideration of HFEA's 'Guidance on Licensing', the inspection team does not consider there is enough concern to suggest a reduction in licence length and therefore recommends the renewal of the centre's treatment and storage licence for a period of four years without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

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 partially 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

Screening of donors (Guidance note 11)

In one set of notes reviewed during the inspection, a donor who had provided eggs in an egg sharing arrangement had not been screened for Chlamydia (CoP 11.22). A review of one set of notes alongside discussions with staff revealed egg donors are screened for syphilis as part of the initial donor recruitment process but this test is not repeated at the time of donation. (SLC T53). See recommendation 3.

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 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/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 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.

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

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;
- if 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 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.

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 are broadly compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not provide transport or satellite activities.

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, with one exception. 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. Validation 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

Prescription of intralipid 'off label'
Written information provided to patients offered intralipid therapy is not compliant with guidance. It does not specify that, if prescribed to this group of patients, the drug is being prescribed 'off label'. Nor does the written information explain the reasons for prescribing intralipid medicines off-label when there is little evidence to support its use (SLC T58). See recommendation 9.

Imports and exports (Guidance note 16; General Direction 0006)
A review of one import and one export showed that documented evidence to satisfy the requirements of General Directions 0006 was not always available. Some documentation provided was in a different language with no translation or confirmation that its suitability had been assessed by centre staff (General Directions 0006). See recommendation 5.

Quality management system (QMS) (Guidance note 23)
The centre has not established quality indicators or objectives relevant to the following activities: donor recruitment, assessment and screening, and storage of gametes (SLC T36).

The centre's audit of witnessing does not cover alerts issued by its electronic witnessing system, whether the reason for the alert has been recorded, nor whether there is any learning (SLC T35)

The centre's audit schedule runs on a two year cycle. Individual audits are not performed at fixed points within this cycle, meaning audits are not always performed within required timescales. At the time of inspection the following audits had not been completed within a two year time period of the last audit; provision of information, donor recruitment, assessment and screening, submission of data to the HFEA, electronic witnessing mismatch, and import/export (SLC T36). See recommendation 7.

Third party agreements (Guidance note 24)
A review of the centre's third party agreements highlighted that the centre had not evaluated the ability of one third party supplier (ad hoc theatre services) to meet the requirements of HFEA licence conditions and the guidance set out in the CoP since 2010 (SLC T112). See recommendation 8.

Equipment and materials (Guidance note 26)
The nitrogen generator has not been validated to ensure the suitability of the gas used during the culture of gametes/embryos (SLC T24). See recommendation 6.

Process validation (Guidance note 15)
Whilst the centre is satisfied the critical processes used are safe and effective based on their monitoring of key performance indicators, there are no documented validations of those critical procurement and processing procedures (SLC T72). See recommendation 4.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

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

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

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, 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, were compliant with HFEA requirements save for one recommendation made elsewhere in this report relating to surrogacy.

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

Welfare of the child (Guidance note 8)
For detail see the surrogacy section of this report and recommendation 2.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

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

What the centre could do better
Not applicable.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit an inspector spoke to one patient couple who provided positive feedback on their experiences. A further 12 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with eight of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- 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 partially 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) (where relevant).

Surrogacy (Guidance note 14)
It is important to protect the surrogate and any children born as a result of the treatment. The centre's procedures for treatment involving surrogacy are partially compliant with HFEA requirements.

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

Egg sharing arrangements (Guidance note 12; General Direction 0001)
For detail see the donor screening section of this report and recommendation 3.

Surrogacy (Guidance note 14)
A review of two sets of notes showed that in one set a WOC assessment had not been performed for the husband of the surrogate, while in the other an assessment had not been completed for either the surrogate or her partner (SLC T56). See recommendation 2.

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 broadly 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
In relation to the centre's website

- the national success rate are not provided.
- data reportedly from the HFEA website has been converted to a per embryo transfer percentage and is not clearly traceable back to HFEA data.
- the website does not state clearly that success rates have limitations as the basis for comparison or personal choice CH(11)(02) (CoP 4.5).

See also the intralipid section of this report. See recommendation 9.

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 centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre sent the report of the audit to the HFEA within the required timeframe. The audit showed that six couples were affected by legal parenthood consent anomalies.

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

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

During the inspection the PR provided an update on the current status of affected patients. In all instances where anomalies were identified, the centre contacted the affected patients. Of six couples identified as having legal parenthood anomalies, four responded to centre contact. Counselling and support has been offered to these patients. The centre has facilitated contact between the four patient couples and solicitors practicing in family law. All four families chose to seek court declarations, with the centre paying all legal fees and associated travelling costs. The final couple is aware of the anomaly and support provided by the centre.

To provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed three 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 to be compliant HFEA requirements.

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

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

What the centre could do better

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)

One discrepancy was found between 10 completed patient disclosure consents on the patient files and the related consent data submitted for inclusion on the register. The patient had provided consent to disclosure prior to a treatment cycle in 2014. The patient updated their consent in 2017, indicating they no longer consented to the disclosure of information. This change in consent was not reflected in data submitted for inclusion on the register. Therefore the centre's procedures have failed to ensure that the HFEA holds an accurate record of consents to disclosure. This failing leads to a risk that the HFEA may release patient identifying information, to researchers, without consent (CH(10)05 and General Direction 0005). See recommendation 10.

3. The protection of gametes and embryos

Respect for the special status of the embryo

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.

It is important to ensure that gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, that 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)
A review of three sets of patient notes, chosen at random, in which the patient(s) had stored gametes or embryos beyond 10 years, showed: in one set of notes there was no medical practitioner's statement to cover the first four years of extended storage over the 10 year statutory storage period; in the second there was no statement for the first year of extended storage; and in the third, there was no statement at all and the samples had been stored for four years over the 10 year period. In all files reviewed, the gamete

provider had provided consent to store beyond 10 years. (Human Fertilisation and Embryology (Statutory Storage Period for Gametes and Embryos) Regulations 2009, paragraph 3(3)(b)) (SLC T79). See recommendation 1.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are compliant with HFEA requirements. 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 broadly 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 some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Obligations and reporting requirements (Guidance note 32; General Direction 0005)

One of the 115 IVF cycles reviewed had not been reported to the HFEA (General Direction 0005). All 51 DI treatments in our sample had been reported to the HFEA.

26% (29/112) of the IVF and 76% (39/51) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Direction 0005 (SLC T41). See recommendation 11.

Section 3: Monitoring of the centre's performance

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

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

On-going monitoring of centre success rates

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

Areas of practice requiring action

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

Critical area of non compliance

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
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. **Storage** A review of three sets of patient notes, showed periods of storage beyond the statutory storage period that were not covered by a medical practitioner's statement. Human Fertilisation and Embryology (Statutory Storage Period for Gametes and Embryos) Regulations 2009, paragraph 3(3)(b), SLC T79	The PR should ensure storage is only extended beyond the statutory storage period when there is compliance with the 2009 storage regulations, both in relation to patient consent and evidence of either premature infertility or of likely premature infertility in the future. The PR should complete a full audit of all samples in storage that have been stored beyond the statutory storage period to establish if there are further cases in which storage has been extended but there has not been compliance with the 2009 storage regulations. A summary of this audit should be provided by 8 June 2017.	The PR seeks guidance as to the implications of including, 'their partner' in the written medical opinin concerning the eligibility of the gamete provider to extend beyond 10 years. CoP 17D 17.17 e.g. a social egg freezer would not be eligible to extend beyond 10 years if she 'froze' her eggs at 35 years if her partner was normally fertile, but would if he had incipient testicular failure. This has been completed	The executive awaits a summary of the centre's audit due by 8 June 2017. We also request the PR provides a summary of their proposed actions with respect to those patients whose storage beyond the statutory storage period was not adequately covered by a medical practitioner's statement. The PR has taken appropriate action to investigate the cause of this non compliance, and we await the outcome of their audit due a year after implementing corrective actions.

	In all cases where there has been a failure to comply with the 2009 storage regulations, the PR should seek independent legal advice on how to proceed, including whether affected patients ought to be informed. Proposed actions in response to this advice should be forwarded to the HFEA for review prior to any action being taken. The PR should investigate how this non compliance has occurred, identifying the barriers to ensuring medical practitioner's statements are in place, and should review processes accordingly. The PR should also ensure all relevant staff members understand the requirements of the 2009 storage regulations. The outcome of this investigation, including the centre's intended actions and the timescales for their implementation should be submitted to the HFEA by 8 June 2017. Given the need to seek a medical practitioner's statement occurs infrequently, the centre should conduct an audit within one year of the implementation of corrective	The 'mismatch' in timing between the medical practitioner's statement and the request to extend storage that has been identified in a few cases has not been identified before at previous inspections. Patients living at a distance who were identified as being candidates for extension (such as pre-chemo patients) were often telephoned to ascertain their wishes, by a member of the admin team and the doctor would then phone the patient and identify the medical grounds for extension. This is a complex area as patients who have had chemo may be at low risk of becoming prematurely infertile, but actually have become spontaneously pregnant and yet still wish to extend storage. Social egg freezers may freeze because they have a family history of relatively early menopause, but premature ovarian	The executive will discuss separately with the PR her questions.

	actions, to assess the compliance of samples in storage beyond the statutory storage period. A summary report of the findings of the audit should be provided to the HFEA by 30 June 2018. The PR is reminded of guidance issued in CH(03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions to take should there be a possibility of legal challenge to the disposal of cryopreserved material.	insufficiency is hard to predict, though easy to diagnose. 'Social' egg freezers in particular are reluctant to accept the 'norms' of female reproductive agingand cite the reduced risk of miscarriage and chromosomal abnormality in pregnancies achieved with 'younger' vitrified eggs. The PR would welcome guidance on how to explain to a woman that she may have treatment with 'donor' eggs at 50, but she cannot keep her own eggs in extended store to have treatment with her own eggs at the same age. In a centre like ours which does a lot of pre-oncology oocyte and sperm freezing, the need to seek a medical practitioner's statement occurs quite often.	

2. **Surrogacy** A records audit performed on the day of the inspection indicated that in one file a WOC assessment had not been performed for the husband of a surrogate in one case, and had not performed for either the surrogate or their partner in another case. SLC T56	The PR should take immediate action to ensure that no treatments are provided before an appropriate WOC assessment has been conducted, documented and the findings of the assessment considered. The HFEA should be advised of the measures taken to ensure that this happens by 8 June 2017. The PR should undertake an audit of surrogacy records to identify whether the inspection observations represent a systemic failure or a rare occurrence. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 8 June 2017.	An immediate audit of 'current' surrogacy couples found no additional missing WOC consents and addtiional training on the new Surrogacy consents has been organised for relevant staff	The PR has taken appropriate action in response to the recommendation. No further action.

	The PR should ensure an audit of WOC assessment procedures in surrogacy arrangements is included in the centre's scheduled audit program.		
3. **Donor screening** Egg donors are not screened in accordance with current professional guidance produced by the relevant professional bodies. A review of one set of notes showed that a donor who had provided eggs in an egg sharing arrangement had not been screened for Chlamydia. The centre do not repeat screening for Syphilis at the time of donation. CoP Guidance 11.22,11.23, SLC T52 and T53	The PR should ensure that egg donors are screened in accordance with regulatory requirements and professional body guidelines. The PR should seek the advice of an infectious disease expert to assess the risk to patients who have received treatment with eggs or embryos created with donated eggs, from donors where the screening has not been compliant with regulatory requirements. The PR should inform the centre's inspector of the timeline for obtaining this expert advice when responding to this report. The PR should provide the centre's inspector with confirmation of revised screening practices, a copy of the updated donor screening SOP and	The pre-treatment checklists have been modified to ensure that all gamete donors are screened in accordance with requirements and guidelines Consultant Virologist Dr H Osman has been contacted to undertake this risk assessment exercise These time frames will be adhered to	We request an update following the consultant virologist's assessment when responding with their revised SOP and audit due in June 2017.

	evidence of relevant staff training by 8 June 2017. The PR should conduct an audit of the centre's screening practices and procedures for egg donors to ensure that they are compliant with regulatory requirements and professional body guidelines. The PR should provide the centre's inspector with a copy of this audit report, including corrective actions identified, by 8 June 2017. Within six months of the implementation of revised practices, the centre should carry out an audit of egg donor screening to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the findings of the audit should be provided to the centre's inspector by 8 September 2017.		
4. **Process validation** The centre has not validated all critical	The PR should provide a list of all procurement and processing procedures that are considered	Critical procuring and processing procedures include :	We await completion of the centre's process validations.

procurement and processing procedures. SLC T72	critical including the date of validation or the planned date by which validation is expected to be complete. The list should be provided to the centre's inspector when responding to this report. It is expected that validation will be prioritised on the basis of risk associated with the procedure and that all validations will be complete by 8 September 2017. On completion of the validation programme the HFEA will ask for a sample of validation documents to be submitted for review.	Oocyte retrieval Semen preparation for ivf, ICSI and IUI IVF insemination ICSI injection Freezing and vitrification of eggs, embryos and blastocysts Sperm freezing Thawing and warming of sperm, egg and embryos SSR Embryo assisted hatching Embryo transfer	We request the PR provides an update in July 2017.
5. **Import/Export** A review of one import and one export showed that documented evidence to satisfy the requirements of General Directions 0006 was not always available. SLC T36, General Directions 0006	The PR should review import and export processes to ensure the required evidence is always available. A summary of actions should be provided to the HFEA, along with any amended documentation by 8 June 2017. An audit of import/export records should be completed within six months and a copy forwarded to their centre's inspector. The PR should ensure future audits are completed at least every two years.	A review of existing and potential suppliers is being undertaken to address these issues	We await a further update and amended documentation due June 2017.

6. **Equipment** The liquid nitrogen generator has not been validated. SLC T24	The PR should validate the liquid nitrogen generator to provide evidence that the quality of gas is not detrimental to the quality and safety of gametes/embryos, and provide a copy of the validation document to the centre's inspector by 8 June 2017.	We have contacted Wirak who are the engineers for NobleGen who are the manufacturers to provide this evidence. This equipment is used in other centres and hospitals	We request the PR forwards a copy of their validation once available.

Other areas of practice that requires improvement

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

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
7. **Quality Management System** The centre has not established quality indicators or objectives relevant to the following activities: donor recruitment, assessment and screening, storage of gametes and. The centre has not audited how far all licensed activities and other activities carried out in the course of providing treatment services that do not require a licence comply with the approved protocols, the regulatory requirements and quality indicators within the past two years. The centre's audit of witnessing does not cover	The PR should ensure the establishment of quality indicators or objectives for these procedures. Documentation demonstrating the establishment of the quality indicators or objectives for those endpoints cited in this report should be provided to the centre's inspector by 8 September 2017. The PR should review the centre's audit schedule to ensure all licensed activities or activities carried out in the course of providing treatment services are audited at least every two years. A copy of this schedule should be provided to the HFEA by 8 September 2017. The PR should complete an audit of electronic witnessing	Our present QMS is based on the requirements of BSI as this was the basis of our ISO accreditation. We are currently converting to the IVI QMS which includes quality indicators for these activities	We acknowledge the centre's transition to an IVI QMS, and request that an update on all points in this recommendation is provided by 8 September 2017.

alerts issued by its electronic witnessing system, whether the reason for the alert has been recorded, nor whether there is any learning. SLC T35, SLC T36	system alerts. A copy of the audit summary should be submitted to the HFEA within six months. The PR should ensure future audits of witnessing include this aspect.		
8. **Third Party Agreements** The centre has not evaluated the ability of all third parties to meet the required standards. SLC T112	The PR should evaluate the ability of relevant third parties to meet the required standards. The HFEA should be advised of the proposed actions and timescale when responding to this report. It is expected that the programme to evaluate relevant third parties will be complete by 8 September 2017. On completion of the programme, the HFEA will ask for a sample of evaluation documents to be submitted for review.	The relevant third parties in this context are the two hospitals where we occasionally require a urological surgeon to undertake a testicular biopsy under general anaesthetic. We plan to set up inspection visits in the near future	We await completion of the PR's inspection, and a summary of their actions by 8 September 2017.
9. **Patient Information** Patient information does not explain the reasons for prescribing intralipid medicines off-label where	The PR should review the information about reproductive immunology treatments provided to patients to make sure it follows the guidance	Intralipid is no longer available at this clinic to patients (with the exception of patients who have had previous success after receiving Intralipid	The PR has taken appropriate action in response to the recommendation regarding intralipid therapy.

there is little evidence to support its use. Nor does it specify that, if prescribed to this group of patients, the drug is being prescribed 'off label'. The centre's website does not provide the national success rate. Data reportedly from the HFEA website had been converted to a per embryo transfer percentage and is not clearly traceable back to HFEA data. The website does not state clearly that success rates have limitations as the basis for comparison or personal choice. SLC T58, CoP 4.5, Clinic Focus, July 2015	provided by the MHRA on the off-label use of medicines (Clinic Focus, July 2015). Copies of the revised patient information should be submitted to the centre's inspector by 8 June 2017. The PR should ensure that the centre's website complies with CoP guidance. Confirmation of compliance should be provided to the HFEA by 8 September 2017.	following repeated failures and who would be psychologically damaged by being denied a treatment even though the consensus opinion is that Intralipid is unhelpful.) All reference to Intralipid has been removed from the website I have looked at several clinic's websites and they all give topline data as pregnancy rate per embryo transfer rather than in the preferred HFEA format of 'per embryo transferred' eg see Nurture, Nottingham Most also give regional comparisons based on these data. A caveat stating that 'success rates have limitations etc' will be added to the new website	We will review the centre's website once amended and liaise with the PR should we continue to have concerns.
10. **Disclosure of information, held on the HFEA Register, for use in research**	The PR should correct the submission that has been identified as being incorrect and provide confirmation to	Please inform me of the patient clinic reference and I can ensure this is done	We will work with the PR on this observation.

One discrepancy was found between 10 completed patient disclosure consents on the patient files and the related consent data submitted for inclusion on the register. CH(10)05, GD 0005	their inspector by 8 June 2017. The PR should review the procedures for checking and submitting consent to ensure that consent to disclosure decisions made by patients are accurately reported to the HFEA. This should include any variations to consent previously given by patients. A summary of the findings and any corrective actions identified should be submitted to the centre's inspector by 8 June 2017. Three months after the implementation of corrective action, the centre should perform an audit to ensure that these corrective actions have been effective. This audit should be submitted by 8 September 2017. It is also recommended that the clinic undertakes a further representative retrospective sample audit of relevant records (i.e. where consent to non contact research has		

	been withdrawn upon return to the centre). The purpose of this audit is to identify whether the observation made on inspection represents a systemic failure of the recording of this consent in these circumstances. The PR should advise the HFEA of the findings of this audit by 8 September 2017. On completion of the audit it is recommended that the PR should liaise with the HFEA's register team to consider the most proportionate way to implement corrective actions to mitigate any risks identified by the audit.		
11. **Obligations and reporting requirements** One of the 115 IVF cycles reviewed had not been reported to the HFEA. General Direction 0005 26% (29/112) of the IVF and 76% (39/51) of the DI treatments reviewed at inspection had been	The PR should ensure that all licensed treatment activity is reported to the HFEA within the timeframe required by General Direction 0005. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for non-reporting and delayed submissions. The PR should	I shall inmvestigate the reason why so many DI treatments are reported late. It may be related to our DI-IUI cycles being carried out in natural cycles to minimise the MPR and therefore there is no 'trigger' to alert the data monitor..	We await a summary of the PR's investigation due June 2017.

reported to the HFEA outside the period required by General Direction 0005. General Direction 0005, SLC T41	confirm these recommendations have been implemented by 8 June 2017. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the HFEA by 8 December 2017.		

Reponses from the Person Responsible to this inspection report
I thank the Inspectors for their courteous, supportive and constructive inspection and report and am gratified that a positive recommendation for renewal is to be made.. I shall be stepping down as Person Responsible in the near future after 17 years as PR with the expectation that our current Consultant, Dr Radha Venkatakrishnan, will assume this role. i shall be remaining at IVI Midland on a part-time basis and will thus be in a good position to ensure all the report's recommendations and instructions are carried out within the required time -frame..