Executive Licensing Panel - minutes

Centre 0197 (Salisbury Fertility Centre)

Renewal Inspection Report

Tuesday, 26 March 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dan Howard Helen Crutcher	Director of Strategy and Corporate Affairs Chief Information Officer Risk and Business Planning Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Joanne Anton Danielle Vincent Yvonne Akinmodun	Licensing Manager Policy Manager Communications Manager Head of Human Resources

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 four years.

1.2. The panel noted that Salisbury Fertility Centre is located in Salisbury District Hospital and has held a treatment and storage licence with the HFEA since 2002.

1.3. The panel noted that, in the 12 months to 30 September 2018, the centre provided 437 cycles of treatment (excluding partner intrauterine insemination). In relation to activity this is a small centre.

1.4. The panel noted that, between July 2017 and June 2018, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

1.5. The panel noted that, for IVF and ICSI, HFEA held register data, for treatments in the year to 30 June 2018, show the centre's success rates are in line with national averages.

1.6. The panel noted that the clinic has not submitted information to the HFEA about the outcomes of treatment relating to a significant number of patients. As such, the performance information will be affected and a consequence of this is that the data is likely to show a lower pregnancy rate than is actually being achieved.

1.7. The panel noted that, in 2017, the centre reported 26 cycles of partner insemination with one pregnancy, which although low, is still in line with the national average.

1.8. An inspection was carried out at the centre on the 13 and 14 November 2018.

1.9. The panel noted that at the time of the inspection, there were four major areas of non-compliance regarding laboratory accreditation, the Quality Management System (QMS), storage of gametes, and obligations and reporting. There were also five 'other areas of non-compliance concerning medicines management, equipment and process validation, staffing, consent and, record keeping and document control. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations relating to laboratory accreditation, the QMS, obligations and reporting, medicines management, equipment and process validation, staffing, consent and record keeping and document control, and has committed, where required to audit the effectiveness of these actions within the required timescales. The PR has given a commitment to fully implementing the non-compliance concerning the storage of gametes.

1.10. The panel noted that the PR is engaging with the executive and seeking legal advice regarding the storage of gametes past the statutory storage period. The executive will continue to liaise with the centre about these stored samples and does not consider this on-going process impacts on the consideration of the centre's licence renewal.

1.11. The panel noted that the multiple pregnancy rate was high at the last inspection, but with the introduction of extended embryo culture and regular review, this has reduced significantly.

1.12. The panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a robust QMS and the PR is encouraged to use it to best effect to improve the service provided to patients.

1.13. The panel noted that the inspection team 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 the report being implemented within the prescribed timescales.

1.14. The panel noted that there has been a delay in renewing this licence due to other competing commitments of the HFEA Compliance Directorate. As a result, this application is being

considered late and will not allow sufficient time for the licensing administrative process to conclude prior to the expiry of the centre's licence. The executive recommends that Special Directions are issued to the PR under Section 24 (5A)(b) of the H&E Act 1990 (as amended) to permit the continuation of licensed activity from 1 May 2019 to 31 July 2019 (or earlier, if a licence has been granted).

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 their 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 and storage only licence for a period of four years, without additional conditions, subject to the recommendations in the report being implemented within the prescribed timescales.

2.5. The panel agreed that Special Directions are issued to the PR under Section 24 (5A) (b) of the HF&E Act 1990 (as amended) to permit the continuation of licensed activity from 1 May 2019 to 31 July 2019 to enable sufficient time for the licensing administrative process.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

2 April 2019

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 13 and 14 November 2018

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: Mhairi West, Sara Parlett and Kathryn Mangold

Date of Executive Licensing Panel: 26 March 2019

Centre name	Salisbury Fertility Centre
Centre number	0197
Licence number	L/0197/10/c
Centre address	Salisbury District Hospital, Odstock Road, Salisbury, Wiltshire, SP2 8BJ, United Kingdom
Person Responsible	Dr Aarti Umranikar
Licence Holder	Salisbury NHS Foundation Trust
Date licence issued	1 May 2015
Licence expiry date	30 April 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Salisbury Fertility Centre (SFC) is located in Salisbury District Hospital and has held a Treatment and Storage licence with the HFEA since 2002.

The centre provides a full range of fertility services and provided 437 treatment cycles (excluding partner intrauterine insemination) in the twelve months to 30 September 2018. In relation to activity levels this is a small centre.

This current licence has been varied to reflect the following changes:

- change of Licence Holder in November 2016
- change of Person Responsible (PR) in August 2018.

The centre treats both NHS Trust (Wiltshire, Hampshire and Dorset) and self-funding patients.

Other licensed activities at the centre include the storage of gametes and embryos.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data in the 12 month period to 30 June 2018 show the centre's success rates are in line with national averages.

It is noted that the clinic has not submitted information to the HFEA about the outcomes of treatment relating to a significant number of patients. The report details this in the obligations and reporting requirements section. As such the performance information will be affected and a consequence of this is that the data is likely to show a lower pregnancy rate than is actually being achieved.

In 2017, the centre reported 26 cycles of partner insemination with one pregnancy, which although low is still in line with the national average.

In 2017, the centre also reported one cycle of GIFT, which did not result in a pregnancy. The centre is no longer performing GIFT.

Multiple births[2]

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

Between July 2017 and June 2018 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 16%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

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

Summary for licensing decision

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

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged 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 no areas of 'critical' non compliance, albeit several areas of practice where improvement is required, including four major and five 'other' areas of non compliance.

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

Major areas of non compliance:

- The PR should ensure that all laboratories used by the centre are accredited with an appropriate body for the tests performed.
- The PR should ensure that the centre's quality management system (QMS) is robust and fit for purpose.
- The PR should ensure information about treatments is submitted to the HFEA on time.

'Other' areas that require improvement:

- The PR should ensure that the centre's practices for the management of medicines are compliant with regulatory requirements and professional body guidance.
- The PR should ensure that all equipment and processes are accompanied by documented evidence of validation.
- The PR should ensure that a formal assessment of workforce requirements is performed.
- The PR should ensure all imported gametes and embryos are accompanied by appropriate consents completed by the gamete provider.
- The PR should ensure that the centre's document control procedure ensures that only current versions of documents are in use.

The PR has provided a commitment to implement the following recommendation:
Major areas of non compliance:

- The PR should ensure storage of gametes and embryos is only extended beyond the statutory storage period when there is compliance with the relevant storage regulations.

Recommendation to the Executive Licensing Panel

The centre has no critical areas of concern but has four major areas of concern.
The PR is engaging with the executive and seeking legal advice regarding the storage of gametes past the statutory storage period. The executive will continue to liaise with the centre about these stored samples and does not consider this on-going process impacts on the consideration of the centre's licence renewal.

The inspection team notes that the success rates are consistent with the national average and its multiple clinical pregnancy rate meets the target. The multiple pregnancy rate was high at the last inspection but with the introduction of extended embryo culture and regular review this has reduced significantly.

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 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.

There has been a delay in renewing this licence due to other competing commitments of the HFEA Compliance Directorate. As a result, this application is being considered late and will not allow sufficient time for the licensing administrative process to conclude prior to the expiry of the centre's licence. The executive recommends that Special Directions are issued to the PR under Section 24 (5A)(b) of the H&E Act 1990 (as amended) to permit the continuation of licensed activity from 1 May 2019 to 31 July 2019 (or earlier, if a licence has been granted).

Centre 0197 has not been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

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 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 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 NHS Foundation Trust's laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are partially compliant with HFEA requirements for accreditation 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 broadly compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

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

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

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

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

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

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

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements, with an exception noted in the consent section of this report. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are compliant with HFEA requirements, with an exception noted in the consent section of this report.

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

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have any transport or satellite arrangements, therefore this area of practice was not relevant to this inspection.

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 staff.

The centre is broadly 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 broadly compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)

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

What the centre could do better

Laboratory accreditation (Guidance note 25)
Laboratory services are provided by Salisbury NHS Foundation Trust within Salisbury District Hospital, for diagnostic and investigative testing. No evidence was provided that the laboratory was accredited by UKAS for the tests performed (SLC T21; see recommendation 1).

Medicines management (Guidance Note 25)
A review of the controlled drugs (CD) register showed that alterations made by staff were made by 'overwriting' rather than using the required method, that is, using a margin note or footnote (Misuse of Drugs (safe Custody) Regulations 2001; see recommendation 5).

Quality management system (QMS) (Guidance note 23)
A selection of audits undertaken by centre staff were reviewed by the inspection team. The audit of screening practices was found to be clear in scope with findings clearly documented. However, it was not clear what, if any, corrective action had been taken (SLC T36; see recommendation 2).

An audit of consent to legal parenthood has not been performed since 2015. The audit of patient records performed by the inspection team indicated compliance, and staff appeared to be knowledgeable. It was noted that the audit submitted in 2015 was thorough, showing a proper understanding of issues related to consent to legal parenthood, and the inspection team at the interim inspection in 2016 were satisfied with the centre's practices. However, the inspection team was concerned that the lack of audit reflects limited understanding of the importance of this critical area of consent. In addition, the centre could not provide a documented procedure detailing actions to take when a patient or partner withdraws their consent to be treated as the legal parent. The centre explained that no one had ever withdrawn their consent, and so it had not been considered (SLC T33b, T64 and T65; see recommendation 2).

During the inspection it became apparent that laboratory staff were unaware of an alert issued by the HFEA to all PRs by email in August 2018. This relates to the safe distribution and receipt of special mixed gas cylinders, following a serious incident at another centre. It is acknowledged that the centre does not use mixed gas cylinders, but the alert required the centre to inform all staff and review any relevant processes. The alert had been received and marked for attention, but no further action had been taken. There is a standard item on the centre's multidisciplinary team meeting agenda for items related to any HFEA guidance or communications, but the alert was not added to any agenda (SLC T32; see recommendation 2).

Equipment and materials (Guidance note 26)
Equipment validation for a new benchtop incubator has been performed but not formally documented (SLC T24; see recommendation 6).

Process validation (Guidance note 15)
Process validation for the introduction of vitrification has been performed but not formally documented (SLC T72; see recommendation 6).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

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

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

Staff (Guidance note 2)
The centre is broadly 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)
The centre has a low staff turnover and with uncertainty about patient numbers in the future, due to a reorganisation of the commissioning process, it is not actively recruiting. However the centre has not performed a formal workforce assessment since 2016. Most of the senior staff, who represent a wide range of expertise and specific knowledge, are part-time. This has resulted in pressure on their time, which the inspection team felt was apparent in some of the inspection findings. It is important to note that the inspection team was not of the opinion that patients or care were at risk, but felt that improvement and development of processes is potentially being limited in some areas of the clinic as staff do not have the time to dedicate to it. It was also noted that unexpected staff absences may cause some difficulties (SLC T12; See recommendation 7).

Welfare of the child and safeguarding

What the centre does well

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

Safeguarding (Guidance Note 25)

The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.
What the centre could do better Nothing identified at this inspection.

Embryo testing Preimplantation genetic screening Embryo testing and sex selection
What the centre does well **Preimplantation genetic screening (Guidance note 9);** **Embryo testing and sex selection (Guidance note 10)** The centre does not perform embryo testing therefore requirements relating to this are not relevant to this inspection.
What the centre could do better Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

Patient experience
The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. 21 patients 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 they had paid what they expected to.

Several patients provided individual comments to the HFEA complimenting the staff at the clinic.

The centre's own most recent patient survey responses were also reviewed. Feedback was comparable to that provided to the HFEA.

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

Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

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

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

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

- care is taken when selecting egg providers donating for benefits in kind
- egg providers are fully assessed and medically suitable, and
- the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

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 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 broadly 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.

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 last inspection in 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 audited five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. 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, with exceptions noted in the quality management system section of this report.

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

Consent (Guidance note 5;6)
A review of consent forms accompanying an import of donor sperm showed that, on the HFEA Consent to Disclosure form, the last page had not been signed by the donor. All other pages of the form had been completed appropriately (SLC T57; see recommendation 8).

Legal parenthood (Guidance note 6)
An audit of consent to legal parenthood had not been performed since 2015 and the centre could not provide a documented procedure detailing actions to take when a patient or partner withdraws their consent to be treated as the legal parent (see QMS section and recommendation 2).

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 17)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Storage of gametes and embryos (Guidance note 17)

The centre provides a service for fertility preservation for men prior to undergoing chemotherapy and/or radiotherapy. It has a large oncology bank of sperm samples from 644 patients.

The centre's processes for managing the storage of these samples are clear. However, the centre currently does not have written consent for the samples of ten patients, all of which have been in storage for longer than the 10 year statutory storage period. Despite many efforts, contact with these patients has been unsuccessful. The sample which has been in storage longest reached 10 years in May 2017. These were stored at a time when the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 ('The 1991 Regulations') were in force. However, whether the gametes are currently being stored in compliance with the 1991 Regulations is something the clinic must investigate and clarify in relation to each patient.

The centre explained that the HFEA MS consent forms were completed by these patients prior to storage and all consented to ten years storage. However, the patients also completed an in-house consent form, which describes storage to the patient's 55th birthday. The centre is of the view that the patients may have understood that they were consenting to storage until their 55th birthday, albeit on an in-house consent form, and are discussing the cases with their Trust lawyers.

Centre staff also asked the inspection team for clarification regarding the 'interpretation of mandatory requirements 17C' section of the Code of Practice that states: 'Gametes first placed in storage between 1 August 1991 and 1 October 2009, and which are being kept lawfully, may continue to be stored beyond the statutory maximum storage period without the written consent of the gamete provider (if the conditions in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 are satisfied)……'. Centre staff considered that this may mean that these ten samples are being kept lawfully. Schedule 3 of the HF&E Act 1990 (as amended) sets out that a person's gametes must not be kept in storage unless there is an effective consent by that person to their storage. Additionally, at the moment the centre has not demonstrated that there is full compliance with the 1991 Regulations for the individual patients concerned.

The 1991 Regulations clearly document the circumstances that must be met in order to extend the statutory storage period of gametes. This includes a written opinion of a registered medical practitioner that the fertility of the gamete provider since providing the gametes has, or is likely to become, significantly impaired. It is not clear if these circumstances have been met for any of the ten patients.

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

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 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 inspection team found 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)** Document management is via an electronic database, accessible by all staff, who print any documents from that location. The database details review dates and hyperlinks to documents. One of the records was linked to an out of date version of a document. This was attributed to a training issue around the procedure for document review. It was also observed that two laminated documents on display in the centre in multiple locations were out of date for review (SLC T34; see recommendation 9). **Obligations and reporting requirements (Guidance note 32; General Direction 0005)** The HFEA's Risk Tool indicated that the centre has failed to submit a significant number of early outcome forms via the HFEA electronic (EDI) system over the last 12 months. The HFEA's register team has investigated and provided data indicating that 198 forms of various types have not been received between December 2016 and the day of the inspection. The centre was not aware of this issue until it was raised by the inspection team. The quality manager informed the inspector that their IT system was unable to retrieve the EDI error report and was awaiting an upgrade. The centre was unclear if the forms had been submitted but not received by the HFEA, or had not been submitted at all (General Direction 0005; see recommendation 4). Since the inspection the centre has made efforts to resolve the issues with access to the EDI error report, and has also submitted most of the forms identified on that report.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2016, recommendations for improvement were made in relation to four areas of major non compliance and one 'other' area of non compliance.

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

On-going monitoring of centre success rates

No alerts related to success rates at the centre have been issued since the last inspection.

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.

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 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.

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. Laboratory accreditation Evidence could not be provided that the laboratory used by the centre is accredited by UKAS, or an equivalent body, to carry out the tests performed. SLC T21.	The PR should ensure that all laboratories used by the centre are accredited with an appropriate body for the tests performed. The PR should provide evidence of accreditation to the centre's inspector when responding to this report.	Tests undertaken at Salisbury fertility centre: 1.All biochemistry - Salisbury NHS foundation Trust - lab has UKAS accreditation - evidence attached 2.Genetics - At Wessex Regional Genetics lab at Salisbury Hospital- Accredited- evidence attached 3.Virology/Microbiology - CPA accreditation until 1st October 2018. UKAS inspection of microbiology lab occurred on	The executive acknowledges the PR's response and implementation of this recommendation. The executive is assured that the centre has adequately risk assessed the need to rescreen the patients who had blood screening in the virology/microbiology laboratory after the lapse of accredited status and before the screening service was reassigned to an accredited laboratory.

		8/9th Nov 2018 -formal report notifying further work needed for UKAS accreditation received on 19th November 2018. HFEA report received on 21st January 2019. We were formally notified by microbiology quality manager on 28th January 2019 regarding further work needed for accreditation.The issues raised by their inpectors were mostly around administrative tasks. There were no issues regarding the actual tests done, their accuracy or with results reporting.(Confirmation of this received via email from Microbiology consultant at Salisbury.) Following actions were undertaken: 1.Hospital incident report logged. 2.Also on the hospital risk register. 3.HFEA incident form done-details on the incident form.	The executive has received a copy of the revised process for ensuring that laboratories used by the centre are accredited. No further action required.

		Decision taken to undertake all screening blood tests at an accredited lab ie at Bristol lab PHE(evidence attached) until our microbiology lab receive their accreditation. A risk assessment has been undertaken at the fertility centre and a plan of action has been outlined.(attached) This has been discussed over the phone with our inspector Mhairi West. Risk assessment is attached separately	
2. QMS The centre's processes for acting on findings from its audits are not evidenced and therefore not effective. SLC T36.	The PR should ensure that the QMS is robust and fit for purpose. The PR should review the process for performing audits to ensure documentation of the implementation of corrective action. The PR should submit a summary of their review of the audit process and schedule, and provide a copy to the	1. Attached Audit on legal parenthood (PP,WP,PBR)undertaken from 2016,2017,2018. Details attached. 100% compliance achieved on a repesentative selection of patients from 2016,2017 and 2018. no immediate action needed as results show full compliance. Plan - to check all relevant cases within this time period over the next 3 months.	The executive acknowledges the PR's response and implementation of this recommendation. The centre has supplied the executive with a reviewed audit process and schedule. No further action required. The executive acknowledges information supplied by the centre which details how centre staff perform a witnessed check of consent to

An audit of consent to legal parenthood has not been performed since 2015. The centre could not provide a documented procedure detailing actions to take when a patient or partner withdraws their consent to be treated as the legal parent. SLC T33b, T64, T65. The clinic's processes are not effective in relation to responding to HFEA alerts. SLC T32.	centre's inspector by 14 February 2019. The PR should ensure that an audit of consent to legal parenthood is performed, and should supply a copy of this to the clinic's inspector by 14 February 2019. The PR should ensure that the process for managing legal parenthood to ensure it includes the procedure to be followed when a patient or partner withdraws their consent to be treated as the legal parent is documented. A copy of this procedure should be provided to the centre's inspector by 14 February 2019. The PR should ensure that any alerts received from the HFEA are acted on in an appropriate time frame, and the information disseminated to the centre team. The PR should review the process for dealing with alerts and any guidance issued	Added to our audit schedule for annual audit. Details of audit attached separately with an action plan. 2. Our centre has a policy on legal parenthood when patient or partner withdraws consent- See policy written on the legal parenthood audit. Attached . 3. All HFEA alerts are discussed at team meetings and minutes are taken with an action plan where necessary. Team meeting minutes are emailed to all staff. Our Governance lead is responsible for checking HFEA alerts regularly along with the PR. The alerts are included in an agenda item titled HFEA matters at the team meeting. Following the gas cylinder alert, although the incident did not involve our lab, corrective actions were taken by using posters to highlight increased	legal parenthood forms for every relevant case. An audit of consent to legal parenthood has been performed for a sample of eligible cases. No further action other than submission of a full audit of all relevant cases to the centre's inspector by 14 May 2019. The centre has supplied their policy for withdrawal of consent to legal parenthood. No further action required. The centre has supplied a new process for dealing with communications received from the HFEA, to ensure that all items are added to meeting agendas, discussed and any relevant information disseminated to centre staff. No further action required.

	from the HFEA or other bodies, to ensure that any requested actions are taken, and the information is disseminated to the rest of the team. The PR should submit the review of the process to the centre's inspector, along with any corrective actions, by 14 February 2019.	awareness amongst lab staff. (Attached)	
3. Storage of gametes The centre does not have effective written consent for the storage of cryopreserved sperm for ten patients. Centre staff consider there is some uncertainty whether storage of samples can continue based on the in-house consent completed by the sperm providers and the guidance in the CoP: 'interpretation of mandatory requirements 17C'. Schedule 3, 8(1) HF&E Act 1990 (as amended).	The PR should ensure storage of gametes is only extended beyond the statutory storage period when there is compliance with the relevant storage regulations. The PR should seek legal advice on whether continued storage of these ten sets of samples is compliant with the 1991 Regulations. A detailed review should be performed for each patient's case. This should include the consents given, to establish whether effective consent to storage is in place, and whether the conditions of the 1991 Regulations have been	A detailed case analysis of 8 cases has been undertaken by 2 PR's(past and current), sperm bank co-ordinator and the quality manager. All cases were under the 1991 regulations. All the 8 cases have been confirmed to have an MPS certificate completed by a registered medical practitioner. All 8 cases have been reviewed and trust legal advice sought. Athough all the 8 cases were beyond the 10 year statutory period, they were young men with sperm freeze prior to chemotherapy for cancer. Based on their individual	The executive acknowledges the PR's response and commitment to implementing this recommendation. The original non-compliance relates to the storage of cryopreserved sperm for ten patients, noted on the day of inspection. Since then two of those patients no longer have sperm in storage and the centre has provided the executive with a case-by-case analysis of the remaining eight patients' consent to storage. However, the executive considers that it remains unclear if patient consent to

	satisfied in each case, to allow storage for longer than the statutory storage period. A copy of this review and any resulting action plan should be provided to the centre's inspector by 14 May 2019.	clinical history, there is a continued risk of permanent infertility and none of them have been noted to have children based on information obtained through the NHS database.. These were all prior to the 2009 storage regulations. On a case by case basis the team found it was appropriate to continue storage based on individual circumstances in each of these cases. A similar situation is unlikey to result in future as the requirements have changed following 2009. The trust legal team are aware and are supportive of our decisions based on the individual case details. (Following our inspection in November 2018, our inpector has forwarded contact details of the HFEA solicitor who we plan to get in touch for further advice.) Findings attached.	storage past 10 years is in place and crucially, whether the relevant statutory provisions for storage beyond 10 years have been met in each of the 8 cases. Whilst the clinic has indicated that it its view it considers that ongoing storage 'is appropriate', further actions are required to demonstrate that, in relation to all 8 cases, the relevant statutory provisions have been satisfied such as to enable lawful storage for longer than the statutory storage period. The PR will be required to demonstrate that staff understand the legal requirements for storage, and for storage beyond 10 years, for patients who have stored embryos or gametes, relevant to the regulations in place at the time of storage. The executive will continue to liaise with the centre about these stored samples and their processes for dealing

			with extending storage consent, but does not consider this on-going process impacts on the consideration of the centre's licence renewal.
4. Obligations and reporting The centre failed to submit 198 forms, mostly reporting early pregnancy outcomes, to the HFEA EDI system, between Dec 2016 and the day of the inspection. The centre reported that it was unable to run an error report and were unaware of the problem. GD 0005.	The PR should ensure information about treatments is submitted to the HFEA on time. The PR should ensure that all missing forms are submitted and update the centre's inspector when responding to this report. The PR should determine if the forms have not been received by the HFEA because of an IT problem, or because they haven't been submitted at all. The PR should consult with the third party responsible for the operation of their EDI system to ensure that it is able to view error reports regularly, and update the centre's inspector when responding to this report.	All data submission has been undertaken correctly by the centre.No processes have been changed within the unit. There have been technical issues integrating the IT departments of Salisbury NHS Foundation trust, Mellow wood and IT dept at HFEA. The issue has since been resolved as a backlog of 400 forms that were submitted correctly by our team were received by the HFEA team on 23rd January 2019. I have been assured that all the 3 IT units are working to resolve this issue We have instigated a monthly request to the registry team to find out whether we have missed any submissions. This function should be available via the Ideas database.	The executive is aware that the centre has been working to address this issue, but is now awaiting the required HFEA IT support before being able to resolve it fully. The PR should clarify here the events since the inspection, and how it is intending to manage data submission. **Update February 2019**: The problems contributing to the failures in the data submission process have been identified by the centre as a combination of lack of form submission by staff, but mainly an IT issue, involving a problem with transmission between the centre and the HFEA, and also the lack of ability to run a report to identify this. The IT issues have been resolved and the centre's inspector has received a report of the

	The PR should review the centre's processes for ensuring that data submission to the HFEA is compliant, making any changes necessary, and submitting a copy of the process to the centre's inspector by 14 February 2019. The centre should audit three months after implementation of any changes, to determine effectiveness and submit a copy of the audit to the centre's inspector by 14 May 2019.		process, and a method to identify forms which have not been submitted. No further action other than submission of an audit of data submission by 14 May 2019.

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.

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
5. Medicines management Alterations in the CD register do not follow professional guidelines. Misuse of Drugs (safe Custody) Regulations 2001.	The PR should ensure that the centre's practices for the management of medicines are compliant with regulatory requirements and professional body guidance. Confirmation of this should be provided when responding to this report. Within three months of the implementation of corrective actions, the centre should carry out an audit of medicines management procedures to ensure that the corrective actions have been effective in ensuring compliance. A summary report of the audit should be supplied to the centre's inspector by 8 May 2019.	Report from Sam Breech DSU theatre sister - will be sent.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The executive has received a report confirming compliance with regulatory medicines management requirements and professional body guidance. No further action, other than submission of an audit of medicines management procedures to the centre's inspector, by 8 May 2019.

6. Equipment and Process validation Equipment validation for a new benchtop incubator, and process validation for the introduction of vitrification has been performed but not formally documented. SLC T24 and T72.	The PR should ensure that all equipment and processes are accompanied by documented evidence of validation. Evidence of validation of the incubator, and of the vitrification process should be submitted to the centre's inspector by 14 February 2019.	Report from B Barker-Governance lead will be submitted.	The executive acknowledges the PR's response and implementation of this recommendation. The executive has received evidence of validation of the incubator and the vitrification process. No further action required.
7. Staffing The centre has not performed a formal assessment of workforce requirements since 2016. SLC T12.	The PR should ensure that a formal assessment of workforce requirements is performed. This should be submitted to centre's inspector by 14 February 2019.	A formal work force assessment has been carried out by the PR, Business manager, deputy medical director and 2 of our senior embryologists in January 2019. Staffing deficiencies were identified within the nursing/ admin team and the embryology team. A nurse assistant post has been approved by the trust and has been advertised to support our nurses and the admin team. The need for 2 further posts in the lab have been identified--	The executive acknowledges the PR's response and implementation of this recommendation. The centre's inspector has received the assessment of workforce requirements. Deficiencies have been identified and a restructuring of the quality management system recommended. No further action required.

		a laboratory quality manager and a laboratory administrator. A succession planning exercise has been undertaken to identify any gaps in staffing. A full report along with a business case will be submitted to the trust. Paul Wylie report	
8. Consent A review of consent forms accompanying an import of donor sperm showed that, on the HFEA CD form, the last page had not been signed by the donor. All other pages of the form had been completed appropriately. T57.	The PR should ensure all imported gametes and embryos are accompanied by appropriate consents completed by the gamete provider. The PR should review the processes used to assess the suitability of patient/donor documentation before accepting imports of gametes or embryos. This review should be supplied to the centre's inspector along with any changes, by 14 February 2019. The PR should attempt to obtain a completed CD form from the donor, although it is	The missing page 6 of the consent form has been followed up . The correct version has been emailed to the inspector. The centre has updated checking process to ensure we request and check the CD forms accompanying import of donor sperm.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The centre has supplied the executive with a review of the process used to assess suitability of gametes or embryos for import, with an added step for checking that any consent forms are correct and complete. No further action required.

	acknowledged that this may present some difficulties. The PR should update the centre's inspector if any progress is made with this.		
9. Record keeping and document control The centre's processes for managing document control are not effective. Documents with an expired review date were on display in the clinic, and the centre's database hyperlink system linked to a version of a document that had been superseded. This was attributed to a training issue around the procedure for document reviewing. SLC T34.	The PR should ensure that the centre's document control procedure ensures that only current versions of documents are in use. The PR should review the processes for managing document control, including staff training requirements, to ensure that printed copies of documents are kept up to date, and documents do not appear to be active when they have been superseded. The PR should submit a summary of this review, including any resultant changes, by 14 February 2019.	The centre's quality management system is being reviewed as a whole. Deficiencies have been identified and plans are in place for the entire system to be replaced following appointment of a new quality manager. The staffing of the quality team is also being reviewed. All processes related to the quality team including document control and the audit schedule (in line with the new code of practice) will be undertaken at the monthly quality meetings.	The executive acknowledges the PR's response. The executive has received evidence of review of the processes around document control, with a program of training and redevelopment of the structure of the quality management team. No further action required.

Reponses from the Person Responsible to this inspection report