Executive Licensing Panel - minutes

Centre 0139 (Bath Fertility Centre)

Interim Inspection Report

Tuesday, 9 July 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Clare Ettinghausen (Chair) Anna Coundley Dan Howard	Director of Strategy and Corporate Affairs Policy Manager Chief Information Officer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel noted that Bath Fertility Centre has held a treatment and storage licence with the HFEA since 1994 and provides a full range of fertility services. Other licensed activities at the centre include storage of gametes and embryos. The centre was taken over by the CARE group in February 2019, although there were no implemented changes as a result of this at the time of the inspection. The centre has recently established satellite services in Bristol (November 2018) and Swindon (February 2019).

1.2. The panel noted that, in the 12 months to 31 December 2018, the centre had provided 905 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre.

1.3. The panel noted that, IVF and ICSI, HFEA register data, for the period December 2017 to November 2018, show the centre's success rates are in line with the national averages.

1.4. The panel noted that, in 2018, the centre reported 16 cycles of partner insemination, with one pregnancy.

1.5. The panel noted that, HFEA register data, for the year ending November 2018, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6%. This represents performance that is not likely to be statistically lower than the 10% multiple live birth rate target for this period.

1.6. The panel noted that the inspection took place on 12 March 2019.

1.7. The panel noted that at the time of inspection there were five major areas of non-compliance concerning medicines management, infection control, safety and suitability of premises, the Quality Management System (QMS) and legal parenthood. Since the inspection, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendations regarding medicines management, infection control, the safety and suitability of premises and legal parenthood, and has committed, where required, to audit the effectiveness of those actions within the required timescales. The PR has given a commitment to fully implement the actions concerning the QMS.

1.8. The panel noted that the inspectorate recommended the continuation of the centre's treatment and storage licence, particularly noting the progress made by the centre in meeting the HFEA multiple birth rate targets.

2. Decision

2.1. The panel was satisfied the centre was fit to have its treatment and storage licence continued, subject to the outstanding audits and actions being completed within the required timescales.

3. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

16 July 2019

Interim Licensing Report

Centre name: Bath Fertility Centre
Centre number: 0139
Date licence issued: 1 September 2017
Licence expiry date: 31 August 2021
Additional conditions applied to this licence: None
Date of inspection: 12 March 2019
Inspectors: Mhairi West, Sandrine Oakes, Polly Todd
Date of Executive Licensing Panel: 9 July 2019

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an unannounced interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence. In particular we note the progress made by the centre in meeting the HFEA multiple birth rate targets.

The ELP is asked to note that this report makes recommendations for improvement in relation to five major areas of non compliance as follows:

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

Major areas of non compliance**:**

- The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements.
- The PR should ensure that clinical waste is stored in line with regulatory requirements.
- The PR should ensure that compressed gases are stored in line with regulatory requirements, and that resuscitation equipment is regularly serviced.
- The PR should ensure that the marital status of all patients is established and is then clearly and accurately documented in the records.

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

Major areas of non compliance:

- The PR should ensure that there is an effective and robust audit process in place, to improve the quality and effectiveness of the service provided in accordance with standard licence conditions and HFEA practice guidance.

Information about the centre

Bath Fertility Centre has held a treatment and storage licence with the HFEA since 1994 and provides a full range of fertility services. Other licensed activities at the centre include storage of gametes and embryos. The centre was taken over by CARE group in February 2019, although there were no implemented changes as a result of this at the time of the inspection.

The centre has recently established satellite services in Bristol (November 2018) and Swindon (February 2019).

The centre provided 905 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2018. In relation to activity levels this is a medium centre.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period December 2017 to November 2018 show the centre's success rates are in line with national averages.

In 2018, the centre reported 16 cycles of partner insemination with 1 pregnancy.

Multiple births[2]

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

HFEA held register data for the year ending November 2018 shows the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 6.0%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed during the inspection: laboratory preparation for embryo transfer and active patient identification in theatre. The procedures observed were witnessed using both a manual and electronic witnessing system in accordance with HFEA requirements. The inspection team discussed witnessing procedures with staff, and reviewed witnessing documentation in patient records.

These activities indicate that witnessing procedures are compliant with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, reports of audits of all stored gametes and of the accuracy of gamete and embryo storage logs and consent records were reviewed, and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were

[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%.

able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Quality Management System (QMS)

It is important that centres audit all their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: medicines management; infection control; legal parenthood; witnessing; consent to storage; traceability.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements. This was because:

- The centre's audit of medicines management was not sufficiently robust and did not contain any methodology or performance indicators. The audit did not state whether any anomalies had been found, or if any corrective or preventative actions had been implemented.
- The centre's audit of gamete storage records and locations described several areas of inaccuracy, including multiple inaccurate storage records resulting from incorrect storage expiry dates and incomplete disposal of samples. The findings had been collated and problems corrected but there was no documented evidence of root cause analysis, the corrective or preventative actions taken, or evidence of the dissemination of any relevant actions to staff.
- The documented scope of the audit of consent to legal parenthood was incomplete because it did not include audit of an offer of counselling or whether the consent had been withdrawn. Evidence was provided subsequently that these areas had been audited, and no non compliance found.

See recommendation 4.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture, then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- patient support
- extension of storage consent
- consent
- the use of CE marked medical devices
- the content of the centre's website
- the centre's audit of legal parenthood
- HFEA Clinic Focus articles regarding equipment failure

The centre is partially effective in implementing learning from guidance from the HFEA. The centre's documentation of marital status is not robust (see Legal Parenthood section of this report), and there was no evidence that the recent HFEA alert regarding the wrong medical gas being connected to an embryo culture incubator has been considered.

See recommendations 4 and 5.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be partially compliant with guidance because:

- The controlled drugs (CD) keys are kept locked with the rest of the nursing team keys when not in use. This location is accessible by all staff at the centre rather than only those authorised to have access to controlled drugs.
- The carry over of controlled drugs from one page to another, was not recorded or witnessed.
- The 'drug proprietary name' was not recorded, where relevant in all instances and the unit of the controlled drug administered was not recorded in all cases.
- The discard of controlled drugs was not witnessed in all cases.
- Alterations in the controlled drug register were not made according to regulatory guidance.
- A list of signatories was not available.
- The Controlled Drugs Accountable Officer (CDAO) is not registered with the CQC or HFEA and is unaware whether the centre is exempted or not.
- Adrenaline, kept on the resuscitation trolley, is not stored in a tamper-proof container.

See recommendation 1.

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.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be partially compliant with guidance. Access to the clinical waste area outside was not locked and was accessible to the members of the public. Within that area, three large bins awaiting collection, containing clinical waste bags and sharps bins, were overloaded and not locked, and there were several individual sharps bins, standing in front of the larger bins rather than within. Three unlabelled sharps bins were seen in use in the centre; in a consultation room, the medicine cupboard and in theatre. The recovery and scanning rooms do not have sealed floors, as the centre do not class these as clinical areas. The inspection team consider that there is a risk of bodily fluid spillage in these areas and therefore a risk of infection.

See recommendation 2.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed during the inspection: a selection of media, consumables and plasticware. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

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. Only five patients have provided feedback in the last 12 months, giving an average five star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, this will be followed up at the next inspection.'

The centre's own most recent patient survey responses were therefore reviewed. Feedback was comparable to that provided to the HFEA. The website also gives the ability for patients to comment on the cost of treatment. Most of the patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting staff at the clinic.

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 during 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.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is compliant with HFEA requirements, except regarding the following issues:

- The inspection team observed four small oxygen cylinders unsecured against the wall in the patient recovery area. Unsecured gas cylinders in the outside gas store were cited in the last renewal inspection report.
- The defibrillator machine present in the centre has not been serviced since 2017.

See recommendation 3.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2017, recommendations for improvement were made in relation to two critical, eight major and three 'other' area(s) of non compliance. The PR subsequently provided information and evidence that all the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Since the last renewal inspection in March 2017, the centre has received two risk tool alerts related to performance, in September 2017 and January 2019, to which the PR has responded appropriately, providing evidence and information that the issues have been resolved.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

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.

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

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. However, at the renewal inspection in March 2017, the inspection team found that the centre had not performed an audit of consent to legal parenthood since 2014, despite reassurances from the PR to the HFEA in October 2015. This resulted in a critical non compliance in the renewal inspection report.

At that time, it was considered that, in his response, the PR engaged fully with the HFEA in addressing all the areas of concern identified in the report, and that the centre had provided the requested assurances regarding the centre's processes for checking consents prior to treatments.

At the current inspection, to provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of the centre's most recent consent to legal parenthood audit. The team also reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required.

The inspection team considers that the process for documenting a patient's marital status is not robust. When patients declare themselves to be not married to the person with whom they are attending for treatment, the centre does not ascertain if either patient is married to anyone else. In addition, in one record marital status was recorded as 'same sex', which is irrelevant to marital status. Failure to identify a patient couple's marital status accurately and act on it appropriately while assisting couples providing consent to legal parenthood, may undermine the quality and effectiveness of the consents provided.

The inspection team concluded that the processes used to collect legal parenthood consent are partially compliant with HFEA requirements.

See recommendation 5.

Annex 1

Areas of practice that require the attention of the Person Responsible

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, 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 made.

Critical areas of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical 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	Inspection team's response to the PR's statement
Nothing found.			

‘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 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;
- which can comprise 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	Inspection team’s response to the PR’s statement
1. Medicines management The controlled drugs (CD) keys are kept locked with the rest of the nursing team keys when not in use. This location is accessible by all staff at the centre rather than only those authorised to have access to controlled drugs. There were numerous anomalies in the CD register – see main body of the report. The Controlled Drugs Accountable Officer (CDAO) is not registered with the CQC or HFEA and is unaware	The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements. The PR should ensure that controlled drugs are only accessed by authorised staff and the key to the controlled drugs cupboard is stored according to regulatory and best practice requirements. The PR should ensure that all resuscitation drugs must be stored in tamper-evident containers.	The PR has reviewed our practices and procedures relating to medicines management to ensure that they are safe and effective. The findings of the review are below. Awareness of medicines management has been raised across the nursing and clinical teams. Following inspection, accurate completion of the CD Register was raised immediately at the nurses' daily briefing and will also be discussed at the next formal	The Executive acknowledges the PR’s response and commitment to implementing this recommendation. The centre has already informed the centre’s inspector of the application to the CQC requesting de-registration. The centre should update the inspector with the outcome of this application and if it is refused, the inspector has already informed the current CDAO regarding the actions that will be required. The centre should keep the

whether the centre is exempted or not. Adrenaline, kept on the resuscitation trolley, is not in a tamper-proof container. DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'. The Controlled Drugs (Supervision of Management and Use) Regulations 2013 Resuscitation council 2016; Quality standards for cardiopulmonary resuscitation practice and training.	The PR should make an application to be included on the CQC's register of CDAOs. If the CQC confirm that the centre is exempt from CDAO registration, the PR must inform the HFEA so that they can included on the HFEA's register of CDAOs This should be confirmed to the centre's inspector by 12 July 2019. The PR should review practices and procedures relating to medicines management, including, but not exclusively, the issues identified in this report. A summary report of this review, including any corrective actions, staff training, with timescales, should be provided to the centre's inspector by 12 July 2019. Three months after the implementation of corrective actions the PR should audit medicines management	nurses' meeting on 21 May 2019. We have installed a key safe for the drug cupboard keys which is only accessible by the clinical team. We acknowledge the guidance from the Resuscitation Council which is designed to prevent public access to resuscitation drugs. Our resuscitation trolley is not in a public area and is stored in a corridor which is only accessible via staff key cards. Patients are escorted through this corridor and never left unattended. The adrenaline is in pre-filled syringes; the foil packaging inside each box is tamper-evident and the syringes themselves also have tamper-evident seals. We therefore feel the risks are well managed. The current system is efficient, allowing our nurses to easily check the stock levels and expiry dates of resuscitation drugs during routine checks.	inspector updated on the progress of this application. The PR should review the scope and methodology of the audit of medicines management, to ensure it considers the findings in this report. This audit should then be carried out and submitted to the centre's inspector by 12 September 2019.

	practice and procedures to ensure that corrective actions implemented, have been effective in achieving compliance. A summary report of this audit should be provided to the centre's inspector by 12 September 2019.	We are in the process of deregistering from the CQC. We have informed the HFEA that Helen Kendrew is the CDAO. We will carry out a further audit of medicines management practice and submit a summary report to our inspector by 12 September 2019.	
2. Infection Control The clinical waste bins stored outside were overfilled, unlocked and the area unsecured from public access. Unlabelled sharps bins were in use in the centre. The recovery and scanning rooms do not have sealed floors, as the centre do not class these as clinical areas, although the inspection team considered that there is a risk of bodily fluid spillage in these areas and therefore a risk of infection.	The PR should ensure that clinical waste is stored in line with regulatory requirements. The PR should update the centre's inspector on the return if this report, to confirm that the issues highlighted in this report have been dealt with. The PR should ensure that all flooring is sealed in line with infection control regulatory requirements in all clinical areas and areas where there is a risk of bodily fluid contamination.	Feedback acknowledged. We have a new padlock with key-code for the clinical waste to secure access. Clinical waste collections have increased to fortnightly. All sharps bins now labelled appropriately. We consider the risk of bodily fluid spillage to be minimal as all treatments involving bodily fluids occur in one of the two treatment rooms which do have a sealed floor, consequently the risk of infection was assessed as extremely low. We	The Executive acknowledges the PR's response and commitment to implementing this recommendation. The Executive acknowledges the centre's opinion that the risk of infection outside of the treatment rooms is low. However, patients can become ill once they have been transferred to recovery areas after undergoing procedures, which may result in spillage of bodily fluid. No further action other than providing confirmation to the

DH Health and Social Care Act 2008: Code of practice on the prevention and control of infections and related guidance. DH Health Building Note 00-09: 'Infection control in the built environment' 2013.	The PR should inform the centre's inspector of the actions taken to address this area of non-compliance by 12 July 2019.	acknowledge the feedback and will commission this work.	centre's inspector when work to seal the floor has taken place.
3. Safety and Suitability of Premises Four small oxygen cylinders were leaning against the wall, unsecured, in the patient recovery areas. Storage of gas cylinders was cited as a non-compliance in the last renewal inspection report. The defibrillator has not been serviced or validated since 2017. SLC T17, T26. British Compressed Gases Association (BCGA) 2016 Code of Practice 44, The	The PR should ensure that compressed gases are stored in line with regulatory requirements. The PR should seek to make immediate arrangements for the safe storage of compressed gases and inform the centre's inspector of the actions taken to address this area of non-compliance when responding to this report. The PR should ensure that all emergency resuscitation equipment is regularly serviced as per manufacturer instructions.	A 12 cylinder storage trolley has been purchased and cylinders are now stored in this within a non-patient area. A new defibrillator has been ordered and should be in situ by 12 July 2019. This will be the same model as those used in our acute NHS Trust, allowing familiarity for staff who work at both sites. Following the CARE acquisition, all emergency resuscitation equipment is being serviced in line with CARE's service agreements.	The Executive acknowledges the PR's response and implementation of this recommendation. No further action.

Storage of gas cylinders 6 (6.2). DH (2006) Medical gases Health Technical Memorandum 02-01: Medical Gas Pipeline Systems, Part B. Resuscitation council 2016; Quality standards for cardiopulmonary resuscitation practice and training.	He should provide confirmation that the defibrillator has been serviced in line with manufacturer's requirements or replaced to the centre's inspector by 12 July 2019.		
4. QMS The centre's procedures for auditing and acting on the findings of audits are not robust. The centre's gamete and embryo cryostorage audit findings were disseminated to staff, but the audit did not summarise the findings, contain documented evidence of root cause analysis, corrective or preventative actions, despite several areas of inaccuracy found by the audit.	The PR must ensure that there is an effective and robust audit process in place, to improve the quality and effectiveness of the service provided in accordance with standard licence conditions and HFEA practice guidance. The PR should conduct a review of the centre's audit process to ensure that audits are performed against regulatory requirements and corrective actions are implemented, documented and reviewed for effectiveness.	Feedback acknowledged. We have conducted a review of our audit processes and accept that our audit reports should be improved to better describe the scope, process, root cause analysis and any corrective actions required. Past audits have been carried out according to schedules/ processes used in previous years. Going forward, we will ensure that any planned audit is checked against current regulatory requirements before each occasion it is carried out, to ensure the scope of the audit is sufficient	The Executive acknowledges the PR's response and commitment to implementing this recommendation. Further action is required. The PR should inform the centre's inspector how he is assured that all staff involved in conducting audits have had appropriate training and competence to undertake effective audits of practice and procedure. The outcome of the review of the changes detailed by the centre's response to this report

The centre's audit of medicines management was not robust in scope, with no detailed methodology, quality indicators, anomalies found, or corrective, preventive actions implemented. The documented scope of audit of consent to legal parenthood was not complete. It did not include the audit of offer of counselling, or that of whether consent had been withdrawn. These areas had in fact been audited, evidenced by the raw data, and no non compliance found, but had not been documented in the audit scope and methodology, or discussed in the results. There was no documented evidence that the recent HFEA alert regarding connection of medical gases to incubators had been considered. SLC T32 & T36.	The PR must ensure that staff have the appropriate training and competence to undertake effective audits of practice and procedure. The PR should provide detail of this review, including staff training requirements and timescales for implementation of the actions to be taken to rectify the shortcomings of the audit process, to the centre's inspector when responding to this report. The outcome of the review and any changes made should be submitted to the centre's inspector by 12 July 2019. The PR should summarise the findings of the cryostorage audit, determine and carry out any required root cause analysis, and corrective or preventative actions, and supply a copy of these findings and the actions taken as a result, to the centre's inspector by 12 July 2019.	and it is fit for purpose. We will also have access to CARE's audit tools. It has become evident that the Laboratory Director does not have sufficient time to perform the role of Quality Manager in addition to her other duties. We have therefore appointed a person to act as Quality Manager, working alongside the Laboratory Director and the Clinic Director. Currently our Project Manager, she is familiar with our clinic's activities and will take over this role from 3 June 2019. The Laboratory Director will provide training in this role. We will review outcome of these changes and submit the findings to our inspector by 12 July 2019. The vast majority of non-compliances in our storage audit were data entry errors on the IDEAS database system (original paper records of location, freeze date and	should be submitted to the centre's inspector by 12 July 2019.

	The PR should review of the most recent medicines management audit, taking into account the findings in this report, and submit a plan, including a revised scope and methodology, for the next scheduled audit to the centre's inspector by 12 July 2019. The PR should review or implement the process for considering information and advice issued by the HFEA, and documentation of any actions required. This process should be submitted to the centre's inspector by 12 July 2019.	expiry date were accurate). Actions were taken at the time to minimise the risk of recurrence although we accept that the actions were not well-documented. Our inspector has been provided with a summary of the storage audit and root cause analysis. We will carry out another storage audit within 12 months to assess the impact of our actions. Bath Fertility is now part of the CARE Group and by June 2019 will have access to the CARE Datix system used for alert notifications and incident reporting. Datix will be used to record consideration of, compliance with and any actions taken as a result of HFEA alerts in addition to any other relevant alerts e.g. from MHRA.	
5. Legal Parenthood The process for documenting a patient's marital status is not	The PR should ensure that the marital status of all patients is established and clearly and	The PR has reviewed the process for assessing and	The Executive acknowledges the PR's response and

robust. When patients declare themselves to be not married to the person with whom they are attending for treatment, the centre does not ascertain if either patient is married to anyone else. In one record marital status was recorded as 'same sex', which is irrelevant to marital status. Failure to identify a patient couple's marital status accurately and act on it appropriately while assisting couples providing consent to legal parenthood, may undermine the quality and effectiveness of the consents provided. Legal parenthood was a critical non-compliance at the renewal inspection in 2017. Section 44(1) of Part 2 of the HF&E Act 2008. SLC T61.	accurately documented in the records. The PR should review the process for assessing and documenting marital status of patients and make any changes required. This process should be submitted to the centre's inspector by 12 July 2019. The PR should ensure that relevant staff have received training in this process and confirm to the centre's inspector that this has taken place, by 12 July 2019. Three months after implementation, the PR should conduct an audit of assessment and documentation of marital status, to ensure the effectiveness of the new process and the staff training. This audit should be submitted to the centre's inspector by 12 October 2019.	documenting marital status and the findings are below. Marital status is recorded by the couple themselves on their registration form which is kept in the patient's record. We have introduced an additional question asking whether either partner is married to anyone else. Although the instance where "same sex" was recorded was on a checklist and would not have been taken as the definitive indication of marital status, we will ensure that relevant staff understand the importance of recording marital status accurately on such checklists. All staff have been emailed reminding them to re-check and accurately record marital status at the start of each treatment cycle. Our Counsellors have scheduled an educational meeting for staff on 13 June 2019 and Legal Parenthood training will be provided.	implementation of this recommendation. No further action required other than submission of an audit of documentation of marital status to the centre's inspector by 12 October 2019.

		Once our IT system is fully integrated with that of CARE, our staff will have access to the online "Learning Lab" and relevant staff will be able to study a module covering Legal Parenthood. We will conduct another Legal Parenthood audit in 3 months and submit the findings to our inspector.	

‘Other’ areas of practice that requires improvement

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

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

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None found			

Additional information from the Person Responsible