

Executive Licensing Panel - minutes

Centre 0348 (CREATE Fertility, Birmingham)

Interim Inspection Report

Tuesday, 28 January 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dina Halai Laura Riley	Director of Strategy and Corporate Affairs Scientific Policy Manager Head of Regulatory Policy
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Bernadette O'Leary	Licensing Manager Clinical Inspector (Induction)

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.
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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 CREATE Fertility, Birmingham is located in Solihull and has held a licence with the HFEA since 29 April 2016. The centre provides a full range of fertility services and is part of the CREATE group of fertility clinics.
- 1.2.** The panel noted that, in the 12 months to 31 August 2019, the centre had provided 323 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a small sized centre.
- 1.3.** The panel noted that, for IVF and ICSI, HFEA register data, for the period 1 June 2018 to 31 May 2019, show the centre's success rates are in line with the national averages, with the following exception;
- The clinical pregnancy rate following FET in women aged 38 years and over are lower than average at a statistically lower level.
- 1.4.** The panel noted that, in 2018, the centre reported 6 cycles of partner insemination, with one pregnancy. This represents a clinical pregnancy rate which is comparable to the national average.
- 1.5.** The panel noted that, HFEA register data, for the period between 1 June 2018 and 31 May 2019, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 2%. This represents performance that is likely to be significantly lower than the 10% multiple live birth rate target for this period.
- 1.6.** The panel noted that an unannounced inspection took place on 5 November 2019.
- 1.7.** The panel noted that at the time of inspection there was one major area of non-compliance concerning medicines management. There was also one 'other' non-compliance regarding infection control. Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement the recommendation regarding infection control and has committed to audit the effectiveness of those actions within the required timescale.
- 1.8.** The panel noted that the PR had challenged the recommendation on the non-compliance concerning medicines management. When responding to the interim report, the PR has advised that advice from their own medicine management advisor, differs from the HFEA's position. The centre's inspector will continue to work with the PR to ensure full compliance is achieved in this area.
- 1.9.** The panel noted that the inspectorate recommended the continuation of the centre's treatment (including embryo testing) and storage licence, particularly noting the centre's low multiple pregnancy rate of 2%. The centre is well led and provides a good level of patient support.

2. Decision

- 2.1.** The panel congratulated the centre on its low multiple birth rate.
- 2.2.** The panel noted that, in the twelve months to 7 November 2019, 51 patients had provided feedback through means of the centre's own patient survey, with 84% of respondents rating their experiences as 'excellent' or 'very good'. However, only six patients had provided feedback on their experience of the centre, in the last 12 months, through the 'Choose a Fertility Clinic' facility available on the HFEA website; the panel suggested that the centre actively encourages patients to use this mechanism to provide feedback.
- 2.3.** The panel was satisfied the centre was fit to have its treatment (including embryo testing) and storage licence continued.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

4 February 2020

Interim Licensing Report



Centre name: CREATE Fertility, Birmingham
Centre number: 0348
Date licence issued: 29 April 2018
Licence expiry date: 28 April 2022
Additional conditions applied to this licence: None
Date of inspection: 5 November 2019
Inspectors: Lesley Brown (Lead), Grace Lyndon
Date of Executive Licensing Panel: 28 January 2020

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 – pre review of draft by PR

The inspection team recommends the continuation of the centre's licence. In particular we note the centre's low multiple pregnancy rate of 2%.

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

The ELP is asked to note that this report makes recommendations for improvement in relation to one major and one 'other' area of non compliance or poor practice as follows:

Major areas of non compliance:

- The PR should ensure that medicines management regulations and best practice guidance are followed.

'Other' areas of practice that require improvement:

- The PR should ensure infection control practices are compliant with relevant guidance.

Information about the centre

CREATE Fertility, Birmingham is located in Solihull and has held a licence with the HFEA since 29 April 2016. The centre provides a full range of fertility services.

The centre provided 323 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2019. In relation to activity levels this is a small centre.

The centre is part of the CREATE group of fertility clinics.

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 outcomes¹

For IVF and ICSI, HFEA held register data for the period 1 June 2018 to 31 May 2019 show the centre's success rates are in line with national averages with the following exceptions:

- The clinical pregnancy rate following FET in women aged 38 years and over are lower than average at a statistically significant level;

In 2018, the centre reported six cycles of partner insemination with one pregnancy. This represents a clinical pregnancy rate which is comparable to the national average.

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 $p \leq 0.002$.

Multiple births²

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

Between 1 June 2018 to 31 May 2019 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 2%. This represents performance that is likely to be significantly lower than 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 inspection team was not able to observe any laboratory activities during the inspection but was able to discuss witnessing with staff and review the centre's own witnessing audit. These activities indicated 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 embryos and of the accuracy of 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 able to carry out their activities without distraction.

Quality Management System (QMS)

It is important that centres audit all of 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; patient feedback.

²The 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%.

The centre's procedures for auditing and acting on the findings of audits are compliant with requirements.

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:

- Leadership
- patient support
- information provision
- extension of storage consent
- imports of gametes and embryos from outside the EU/EEA
- the use of the Single European Code
- the use of CE marked medical devices
- HFEA Clinic Focus articles regarding screening requirements

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

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;

- There are alterations and over writing of letters and numbers, in the controlled drugs register;
- The carry-over of drug stock from one page to another is not signed or witnessed in all instances.
- The amount of controlled drugs supplied to the clinician was not signed or witnessed for a number of entries;
- The time of supply and discard of controlled drugs was not recorded in a number of cases;

These practices do not assure the inspection team that the centre has robust governance for the management and use of controlled drugs.

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 because;

- The arm rest of the wipe clean phlebotomy chair was broken with the stuffing visible and posed an infection risk;
- Non wipe clean chairs were observed in the consultation rooms where clinical activities are undertaken;
- There were a number of sharps bins within the centre where the temporary closure was not in use;
- Blankets and sheets in the storeroom in the recovery area were draping on the floor.

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 in the course of the inspection: media, vitrification kits and plasticware. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support

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

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

Patient feedback

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 six patients have provided feedback in the last 12 months, giving an average 4.5 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 response audit was therefore reviewed. 51 Patients have provided feedback to the centre, in the 12 months to 7 November 2018. 84% of respondents rated their overall experience as 'excellent' or 'very good'. The website also gives the ability for patients to comment on the cost of treatment. All of the patients confirmed that they had paid what they expected to.

The centre's own audit identified several negative comments regarding problems with finance and invoicing and poor follow up care. To address these matters the centre introduced new financing procedures for easier visibility of outstanding balances; the centre have introduced a new SOP for aftercare of patients and staff have been provided with 'breaking bad news' training. The inspection team urge the centre to continue to monitor patient feedback to ensure the actions taken are effective.

No patients were available to speak to inspectors during this visit.

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.

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 fully compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in November 2017, recommendations for improvement were made in relation to one major and four 'other' area(s) of non compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented.

On-going monitoring of centre success rates

Since the last renewal inspection in November 2017 the centre has received two risk tool alerts related to performance following FET in women aged over 38 years. During discussions at the time of the inspection, the PR described that this is due to the centre's practice of providing treatment to patients within that cohort, who have very low AMH, with unstimulated cycles using the patient's own eggs. The PR confirmed that the success rates

are in line with the centre's own expectations and patients are informed of the low chance of success. This is a group wide practice and has previously been fully investigated by the HFEA and found to be compliant, as results from stimulated cycles are within the national average.

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. There are currently no significant data submission issues at this clinic. This conclusion is based on a review of the clinic's register submissions conducted on 16 January 2019.

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.

This centre was established after 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood.

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

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

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

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
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 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
<p>1. Medicines management The following was noted;</p> <ul style="list-style-type: none"> • There are alterations and over writing of letters and numbers, in the controlled drugs register; • The carry-over of drug stock from one page to another is not signed or witnessed in all instances. • The amount of controlled drugs supplied to the clinician was not signed or witnessed for a number of entries; • The time of supply and discard or controlled drugs 	<p>The PR should ensure that staff prescribing and administering controlled drugs and non-controlled drugs are aware of the record keeping requirements for prescribing controlled drugs, dispensing non-controlled drugs and maintain full compliance with controlled drugs and non-controlled drugs regulations and practice guidance.</p> <p>The PR should review practices and procedures relating to medicines management, including, but</p>	<p>1. The overwriting of letters and numbers shown were clear and legible. There was no confusion.</p> <p>2. The carry over of drug stock: We do not recall this been said at our feedback meeting on the day of inspection. The nurse who showed the inspector the CD book recalls the inspector saying she was impressed that all carry overs were signed and witnessed, and the inspector checked all signatures were recorded against staff names on the last</p>	<p>The Executive acknowledges the PR’s response.</p> <p>The Executive can confirm that the observation regarding the carry over of drug stock was observed and recorded at this inspection visit.</p> <p>The PR should be aware that the ‘Dangerous Drugs; The Misuse of Drugs Regulations 2001 (regulation 20 (c) states that “no cancellation or obliteration of any such entry shall be made”, therefore any</p>

<p>was not recorded in a number of cases;</p> <ul style="list-style-type: none"> Guidelines Controlled Drugs in Peri-Operative Care 2019 (Good practice for controlled drugs administered directly by registered healthcare professionals in the theatre environment, page 7). The Association of Anesthetists of Great-Britain and Ireland (AAGBI) 'Controlled Drugs in Perioperative Care' 2006. Section 4, section 7. Misuse of Drugs (safe Custody) Regulations 2001 (regulation 20 (a) 20 (c), regulation 27 DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'. (Sections 4.7.1.4, 4.11.1.2, 4.11.3, 4.11.14, 4.7.1.2,). 	<p>not exclusively, the issues identified in this report.</p> <p>A summary report of this review, including any corrective actions, staff training, with timescales, should be provided to the centre's inspector by 5 February 2020.</p> <p>Three months after the implementation of corrective actions, the PR should audit medicines management practice and procedures to ensure that corrective actions implemented, have been effective in achieving compliance.</p> <p>A summary report of this audit should be provided to the centre's inspector by 5 May 2020.</p>	<p>page. We are surprised that there are discrepancies in what was said on the day of inspection and what is mentioned in the report</p> <p>3.The inspector stated that we are required to obtain six signatures per prescribed CD drug, one from both anesthetist and ODP next to the amount supplied, on drug administration and finally on discarding . The times at which they took place should also be indicated (X3 entries per drug). At present the anesthetist and ODP complete the amount supplied, dose and time of administration with signatures and amount discarded .This is in accordance with previous recommendations from the HFEA ,on discussion with the inspector she was not able to provide an explanation for the inconsistency in advice . Following the inspection, our Head of Nursing has discussed this with our external pharmacy adviser</p>	<p>overwriting, regardless of legibility, is not compliant.</p> <p>The Executive is unable to reconcile the PR's assertion that the failure to fully complete the section of the controlled drug concerned with the supply, administer and discard of controlled drugs is compliant with controlled drugs management guidelines and regulations.</p> <p>The Executive refers the PR to The Department of Health Document (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)', which states: 'All entries should be signed by a registered nurse, midwife or ODP and should be witnessed preferably by second registered nurse, midwife or ODP'.</p> <p>Further action required.</p>
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<p>Nice Guidance [NG46] April 2016 'Controlled drugs: Safe use and management(1.7.8)</p>		<p>who has confirmed that we are following the guidelines for management of Controlled drugs. We are disappointed at the inconsistent advice given by the clinical inspector and have brought it to the attention of the Chief Inspector.</p> <p>We have communicated the feedback from the inspection to all staff involved.</p> <p>We have regular audits of Medicines Management and will provide these to the inspector by the 5 May 2020.</p>	
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► **‘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
<p>• Infection Control The following were noted;</p> <ul style="list-style-type: none"> • The arm rest of the wipe clean phlebotomy chair was broken with the stuffing visible and posed an infection risk; • Non wipe clean chairs were observed in the consultation rooms where clinical activities are undertaken; • There were a number of sharps bins within the centre where the temporary closure was not in use; • Blankets and sheets in the storeroom in the recovery area were draping on the floor. 	<p>The PR should ensure compliance with infection prevention and control and safe sharps disposal guidance.</p> <p>The PR should ensure that all stored equipment and materials are stored off the floor.</p> <p>The PR should provide a summary of actions taken to address this recommendation when responding to this report.</p> <p>Three months after the implementation of any corrective actions, the PR must audit infection control practices including, but not exclusively, those areas of non-compliance identified in this report, to ensure that corrective actions</p>	<p>The phlebotomy chair arm rest had 2 small scuff/wear marks of approximately 1cm, the secondary layer exposed, not the stuffing. The arm rest was removed post inspection and re-covered.</p> <p>There was 1 non wipe clean chair in one of the consultation rooms. It was taken in during a meeting (staff). No clinical procedures had been undertaken. The chair was placed back into the corridor post inspection.</p> <p>The containers themselves were safely constructed with date and signature of the person who had put it together and indicating specific clinical area.</p> <p>The boxes were stored on a secure surface way from the</p>	<p>The Executive acknowledges the PR’s response and confirmation that the issues with the phlebotomy chair and chairs observed in consultation rooms have been resolved.</p> <p>The Executive is assured that the PR has committed to ensuring that staff employ the temporary closure when sharps bins are not in use.</p> <p>The Executive acknowledges that the PR has reviewed the centre’s process for storing blankets and sheets and has taken corrective action.</p> <p>As corrective actions have been implemented, the PR should provide a copy of the required infection control audit to the</p>

<p>DH Health Building Note 00-09: 'Infection control in the built environment' 2013. (Sections 3.109, 3.110, 3.111, 3.133 and 3.79),</p> <p>Healthcare-associated infections: prevention and control in primary and community care Clinical guideline [CG139] 2017 (section 1.1.4.4)</p>	<p>taken have been effective in achieving and maintaining compliance with regulatory requirements.</p> <p>A summary report of this audit should be provided to the centre's inspector by 5 May 2020.</p>	<p>main traffic of patients. Staff have been informed to ensure the close is in place on all sharps.</p> <p>With regards to the blankets and sheets - the nurse manager viewed the area to find the blanket was off the floor in a sealed bag (hanging over the bottom shelf) following delivery and did not compromise cleaning of the area or pose a risk to infection control / health and safety . However moving forward we have ordered plastic boxes for additional storage.</p> <p>We have regular infection control audits as part of our rolling internal audit schedule and will forward these which will include the corrective actions described above by 5 May 2020.</p>	<p>centre's inspector by 20 March 2020.</p> <p>Further action required.</p>
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Additional information from the Person Responsible

The PR and staff of Create Fertility Birmingham are grateful to the inspection team for their time and thorough inspection. We were disappointed at the attitude of the clinical inspector and have brought it to the attention of the Chief Inspector. We always appreciate the guidance from the inspection team and the HFEA in general for their support. We are committed to delivering the most cost-effective and the best care to our patients. Create Fertility takes pride in reducing complications, preventing OHSS and providing less invasive and successful treatment options to women and couples