

Executive Licensing Panel - minutes

Centre 0078 (Wolfson Fertility Centre - Hammersmith Hospital)

Interim Inspection Report

Tuesday, 23 April 2019

HFEA, 10 Spring Gardens, London SW1A 2BN

Panel members	Richard Sydee (Chair) Joanne Anton Kathleen Sarsfield-Watson	Director of Finance and Resources Policy Manager Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

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

The panel had before it:

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

1. Consideration of application

- 1.1. The panel noted that Wolfson Fertility Centre - Hammersmith Hospital is located in London and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services, including embryo testing, to NHS and privately funded patients.
- 1.2. The panel noted that the centre has undergone a change of ownership since the last inspection, from IVF Hammersmith Ltd to Imperial College Healthcare NHS Trust; the official sign over took place on 12 December 2016.
- 1.3. The panel noted that, in the 12 months to 30 November 2018, the centre had provided 1349 cycles of treatment (with the exception of partner intrauterine insemination treatments). In relation to activity levels this is a large sized centre.
- 1.4. The panel noted that HFEA register data, between 1 September 2017 to 31 August 2018, show the centre's pregnancy outcomes for IVF and ICSI success rates are in line with the national averages, with the following exception:
 - The clinical pregnancy rate following FET in women aged under 38 years is higher than average at a statistically significant level.
- 1.5. The panel noted that, in 2018, the centre reported 46 cycles of partner insemination with 8 pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.
- 1.6. The panel noted that HFEA register data, between September 2017 to August 2018, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17.5%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.
- 1.7. The panel noted that the inspection took place on 29 January 2019.
- 1.8. The panel noted that at the time of inspection there were two major areas of non-compliance concerning the consent to storage of gametes and embryos and the centre's website, alongside one 'other' non-compliance regarding infection control. Since the inspection, the Person Responsible (PR) has fully implemented the recommendation regarding the website and has given a commitment to fully implement the recommendations regarding the consent to storage of gametes and embryos and infection control, providing evidence that actions have been taken within the required timescales.
- 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 improved control of the multiple birth rate and good treatment success rates, achieved whilst the centre has been undergoing significant management changes.

2. Decision

- 2.1. The panel noted the overall positive interim inspection and the actions taken by the centre, thus far, to mitigate the non-compliances identified in the report. The panel was particularly pleased to see that the PR had taken steps to address the currently low level of patient feedback, through the ordering of electronic devices for the waiting area, and noted that patients would be encouraged to provide comments to the HFEA using these. The panel hoped this initiative would assist the centre on attaining patient feedback, which could be used to improve and monitor performance.
- 2.2. 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

A handwritten signature in black ink, appearing to read 'Richard Sydee', is written over a light grey rectangular background.

Name

Richard Sydee

Date

30 April 2019

Interim Licensing Report



Centre name: Wolfson Fertility Centre - Hammersmith Hospital

Centre number: 0078

Date licence issued: 1 January 2017

Licence expiry date: 31 December 2020

Additional conditions applied to this licence: None

Date of inspection: 29 January 2019

Inspectors: Mhairi West & Julie Katsaros

Date of Executive Licensing Panel: 23 April 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

The inspection team recommends the continuation of the centre's licence. In particular we note the improved control of the multiple birth rate and good treatment success rates, achieved whilst the centre has been undergoing significant management changes.

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

The PR has fully implemented the following recommendation;

Major area of non compliance:

- The PR should ensure that the centre's websites meet all CoP requirements.

The PR has given a commitment to fully implement the following recommendations and provide evidence that actions have been taken within the required timescales.

Major areas of non compliance:

- The PR should ensure that any gametes and/or embryos in storage are stored with effective storage consent.

'Other' area of practice that require improvement:

- The PR should ensure that risk mitigating actions documented in the centre's infection control risk assessments are acted upon.

Information about the centre

Wolfson Fertility Centre, Hammersmith Hospital is located in London and has held a licence with the HFEA since 1992. The centre provides a full range of fertility services including embryo testing to NHS and privately funded patients.

The centre's current licence has been varied to reflect:

- a change of premises in December 2016, following a refurbishment of the laboratory suite. There was no structural change but all critical laboratory equipment was replaced with new equipment purchased by the Trust;
- a change of Licence Holder and centre name in September 2017;
- a change of Person Responsible (PR) in April 2017; and
- a change of centre name and variation to licensed premises in January 2017.

The centre has undergone a change of ownership since the last inspection, from IVF Hammersmith Ltd to Imperial College Healthcare NHS Trust, the official sign over of which took place on 12 December 2016.

The centre provided 1349 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 November 2018. In relation to activity levels this is a large 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 outcomes¹

For IVF and ICSI, HFEA held register data for the period 1 September 2017 to 31 August 2018 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 under 38 years is higher than average at a statistically significant level.

In 2018, the centre reported 46 cycles of partner insemination with 8 pregnancies, a success rate which is in line with the national average.

Multiple births²

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

Between September 2017 to August 2018 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17.5%. 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 $p \leq 0.002$.

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 had received a Risk Tool alert about its multiple pregnancy rate before the inspection. It responded by reviewing its Multiple Birth Minimisation Strategy (MBMS) to better control the number of double embryo transfers while not reducing the overall pregnancy rate. At the time of writing this report, the multiple pregnancy rate had fallen to 14.8% for treatments in the year to 31 October 2018, suggesting that the review and changes to the MBMS have been effective.

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 in the course of the inspection: fertilisation checks; thawing of embryos. All of the procedures observed were witnessed using an electronic witnessing system in accordance 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, the 'bring-forward' system was discussed with staff and storage records were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are partially effective.

Review of the storage logs for patient-derived gametes and embryos showed that all samples were stored within their consented storage periods. However an audit provided by the centre of the records of patients who had extended storage beyond the statutory 10 year maximum, showed that six such patients had completed appropriate consent forms to do this, but that medical practitioner's statements confirming their premature infertility or risk thereof, had been completed between one and nine months *after* the end of the ten year statutory storage period. Thus the requirements for extending the storage period beyond the statutory 10 year maximum were not adhered to.

A review of the donor sperm storage database revealed that stored donor sperm is managed separately from patient-derived gametes and embryos. One donor sperm sample was observed to have a storage date based on the date it arrived in the clinic, not the date it was originally frozen, meaning that the storage consent expiry date was calculated incorrectly. Another donor sperm sample was consented to be stored for 55 years and was recorded as such. As a result the bring-forward system would not alert staff to when the sample had been stored for ten years, and an assessment had to be made of the patient to whom the gametes were allocated, to determine whether the requirements for an extension of the statutory storage period were met.

See recommendation 1.

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 and were available to carry out witnessing activities when required.

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; consent to storage.

The centre's procedures for auditing and acting on the findings of audits are generally compliant with requirements, with one exception discussed below in the section: 'Infection control'.

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:

- information provision
- implications of treatment and consent
- counselling
- 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

The centre has been broadly effective in ensuring compliance with guidance issued by the HFEA. See recommendation 2.

The centre has two websites, one for NHS patients and one for self-funded patients. Both websites display the same success rates but neither: cites or provides a link to comparative national success rates; defines what the measure of success is, e.g. clinical pregnancy rate or live birth rate; or breaks down the data related to frozen embryo transfer success rates into age groups. The NHS website also does not provide a date range for the success rates provided. The inspection team also considers that the presence of two websites could be misleading for patients who may think that there are two entirely separate clinics. The website was a non compliance at the renewal inspection in 2016. The clinic responded after that inspection to confirm that changes to the website had been made. These changes were not apparent in either website when reviewed at this inspection.

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 compliant with HFEA requirements.

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 broadly compliant with guidance. Multiple radiators in the centre, including those in the corridor outside the theatre and laboratories, were covered in a large amount of peeling paint. This had been recorded twice by the centre's own infection control risk assessment along with risk mitigating actions. No actions have however been taken. See recommendation 3.

The inspection team acknowledge that approval of funding is taken at a higher level in the hospital trust and the centre has limited control over this, but also note that a component of the PR's leadership role is to have influence over this decision making process so ensuring that funding is available to maintain the centre's on-going compliance with HFEA requirements and guidance.

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 medical devices was reviewed in the course of the inspection, including culture medium, vitrification and thawing media, culture dishes and other plasticware used to manipulate gametes and embryos. 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 nine patients have provided feedback in the last 12 months, giving an average four 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 inspection team discussed this with the PR who

confirmed that electronic devices had been ordered for the waiting area, and patients would be encouraged to provide feedback to the HFEA using them.

The HFEA website also allows patients to comment on the cost of their treatment. The majority of patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting staff at the clinic, and the ease of the process during their treatment at the clinic.

There were also several negative comments regarding difficulties in getting in contact with staff at the clinic and these were discussed with the PR. He advised the inspectors that actions have already been taken to address this matter. 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 except where noted above.

Compliance with recommendations made at the time of the last inspection

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

The PR subsequently provided information and evidence that five of the recommendations were fully implemented within the required timescales. However the actions taken to address one 'other' non-compliance related to the centre's website, appear to have been rescinded as this non compliance has recurred (see recommendation 2). This matter has therefore been escalated to a major non compliance in this interim inspection report.

On-going monitoring of centre success rates

Since the last renewal inspection in September 2016 the centre has received one risk tool alert related to its multiple pregnancy rate. The PR responded appropriately, as discussed in the section 'Multiple births'.

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.

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 that inspection in September 2016, legal parenthood consenting processes were found to be robust.

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

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. Consent to storage of gametes and embryos</p> <p>Six patients have extended their embryo storage consent beyond the statutory storage period, but medical practitioners’ statements regarding their infertility, or their risk thereof, were not documented within 10 years of the gametes being stored.</p> <p>Two donor sperm samples had incorrectly documented consent expiry dates such that the bring-forward system would not have detected the</p>	<p>The PR should ensure that embryos are stored only with the effective consent of the gamete provider(s). The PR should also ensure storage is only extended beyond the statutory storage period when there is compliance with the relevant storage regulations, both in relation to patient consent and a medical practitioner’s opinion regarding premature infertility, or a risk thereof.</p> <p>In any cases where there has been a failure to comply with the relevant storage</p>	<p>We are in the process of contacting these six patients. As all of them are now over 50 (youngest is 54 and oldest is 58) we would initially need to confirm if they wish to continue storage of their embryos. Given the ages of the patients, we believe it is likely that the majority will not. For any patient who does wish to continue storage we would seek legal opinion from the hospital legal team regarding the gap in the medical practitioners statement and its impact on consent. We note that all statutory consent forms</p>	<p>The Executive acknowledge the PR’s response to addressing this non-compliance and the actions taken.</p> <p>Further action is required.</p> <p>If, after contacting them, any of the patients in question wish to continue the storage of their embryos, further actions will be required to demonstrate that, in relation to all cases, the relevant statutory provisions have been satisfied such as to enable lawful storage for longer than the statutory storage</p>

<p>date of consent expiry.</p> <p>The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996.</p> <p>The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009.</p> <p>SLC T79.</p>	<p>regulations, the PR should seek independent legal advice on how to proceed. Proposed actions in response to this advice should be forwarded to the HFEA for review prior to any action being taken.</p> <p>The outcome of this investigation, including the centre's intended actions and the timescales for their implementation should be submitted to the centre's inspector by 29 April 2019.</p> <p>The PR should ensure that the process used to monitor donor sperm storage consent is robust. The PR should conduct an audit of this system and submit a report of the audit, including any correct actions, to the centre's inspector by 29 April 2019.</p>	<p>are in place and that the patients medical condition did not alter during the period in question; it would therefore appear reasonable to make a case to the legal team that usage should be permitted in the interest of the patient.</p> <p>We have done a further audit of the donor samples in the unit and can confirm that we have put measures in place to reduce the risk of incorrect documentation and a reaudit has shown that there are no further issues. A copy of this audit will be provided to the HFEA by 29/04/2019.</p>	<p>period, taking into account which particular regulations were in place at the time of the extension to consent to storage.</p> <p>The PR should ensure that any legal advisors are fully conversant with the requirements of the HF&E Act 1990, and also the differing requirements for extending storage of gametes or embryos, depending on the applicable regulations in place at the time of the extension.</p> <p>If the patients indicate that they wish to continue the storage of their embryos, the PR should seek legal advice, which considers the advice given above, and that detailed in an email to the PR from the centre's inspector on 18 March 2019, and provide evidence of compliance with the appropriate regulations for each individual case to the centre's inspector. The PR should update the centre's inspector on a monthly basis.</p>
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			<p>The executive note that the PR is of the opinion that statutory consent forms are in place to allow legal extension of consent to storage for these sets of embryos. The executive considers that this may not be the case. The PR will be required to demonstrate that he and relevant 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 PR should provide evidence of training or competence of those staff to the centre's inspector within 3 months, or by 29 July 2019.</p> <p>The PR should also review the centre's processes for extending consent to store embryos and gametes and ensure that there are procedures in place to ensure full compliance with extended storage regulations. The PR will be required to provide a copy of these procedures to the centre's inspector.</p>
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			<p>Further and detailed discussions will be held outside of this report, and the executive will provide the ELP committee with an update when further information is available.</p> <p>As he has acknowledged, the PR should also submit a copy of the centre's audit of the system used to monitor donor sperm consent by 29 April 2019.</p>
<p>2. Website The centre has two websites; both display the same success rates but neither:</p> <ul style="list-style-type: none"> • cites or provides a link to national success rates; • defines what the unit or measure of success is; • breaks down the data related to frozen embryo transfer success rates into age groups. <p>One of the websites also does not state a date range for the success rates provided, thus it is unclear if the data is less</p>	<p>The PR should review the centre's websites and ensure they are compliant with CoP guidance 4.8. The PR should also make sure that the websites' content is such that patients cannot be confused by the presence of two websites.</p> <p>The PR should inform the HFEA by 29 April 2019 of the results of the review and of the actions taken to ensure that the centre's websites are compliant.</p>	<p>Imperial College Healthcare NHS Trust policy is to keep the NHS and private services distinct - as a result of this we have two separate websites. I have raised the issue of the IVF service being integrated for both groups of patients and that we do not differentiate in the service provided for the two groups clinically. We recognise that the current situation can cause confusion so we are in the process of reviewing content of the two sites and ensuring that both are consistent in content.</p>	<p>The Executive acknowledge the PR's commitment to addressing this non-compliance and the actions taken.</p> <p>No further action required.</p>

<p>than three years old.</p> <p>The presence of two websites for the centre is potentially confusing for patients.</p> <p>CoP guidance 4.8.</p> <p>The centre's website was cited as a non-compliance at the last renewal inspection in 2016. Action was taken but on-going compliance has not been maintained, hence this non compliance being upgraded to a major.</p>		<p>Additionally, we have opened a discussion with the NHS Trust and have asked to amalgamate the two websites into a single one for both NHS funded and private patients. In the interim, we have made changes to the data presented to ensure that there is a link to national success rates, clearly define the unit of success and have broken the data down by age groups for both fresh and frozen transfers.</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>3. Infection control Multiple radiators in the centre, including those in the corridor outside the theatre and laboratories, were covered with peeling paint. This has been documented twice by the centre’s own infection control risk assessment, but no action has been taken.</p> <p>DH Health Building Note 00-09: ‘Infection control in the built environment’ 2013.</p>	<p>The PR should ensure that risk mitigating actions in the centre’s infection control risk assessments are implemented, so that risks identified are effectively controlled.</p> <p>The PR should provide an update to the centre’s inspector by 29 April 2019.</p>	<p>This has now been added to the Trust risk register and has been escalated. We have been advised that this issue is now a priority action for the estates team and we should hopefully have this completed soon.</p>	<p>The Executive acknowledge the PR’s commitment to addressing this non-compliance and the actions taken.</p> <p>The PR should provide an update to the centre’s inspector when the actions have been implemented.</p> <p>Further action required.</p>

Additional information from the Person Responsible

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