Licence Committee - minutes

Centre 0144 (Nuffield Health Woking Hospital)

Interim Inspection Report and Incident (Grade A) Report

Thursday, 13 July 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members	Lee Rayfield (Chair) Ruth Wilde Kate Brian	
Members of the Executive	Dee Knoyle Paula Robinson	Secretary Head of Planning & Governance
Legal Adviser	Philip Grey	Mills & Reeve LLP
Specialist Adviser		
Observers		

Declarations of interest:

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

The committee had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- Interim inspection report including PR response
- Papers relating to the incident:
  - April 2017- HFEA Incident Report
  - January 2016 – Centre's Incident Report
- Previous licensing minutes for the last three years:
  - 10 July 2015 – Renewal Inspection report.

1. Background

1.1. The Nuffield Health Woking Hospital, centre 0144, is located in Woking and has held a licence with the HFEA since 1994. This is a large treatment and storage centre which provides a full range of fertility services.

2. Consideration of application – Interim Inspection Report

2.1. The committee noted that in the 12 months to 28 February 2017 the centre provided 1481 cycles of treatment (excluding partner intrauterine insemination).

2.2. The committee noted that for IVF and ICSI, HFEA-held register data for the period December 2015 to November 2016 showed the centre's success rates were in line with national averages.

2.3. The committee noted that in 2016, the centre reported 22 cycles of partner insemination with no pregnancies. This represented a clinical pregnancy rate which is in line with the national average.

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

2.5. The committee noted that at the time of the interim inspection on 23 May 2017, one major and two other areas of non-compliance were identified. The committee noted that the Person Responsible (PR) has committed to implementing these recommendations.

2.6. The committee noted the positive comments made by patients in relation to their experience at the centre.

2.7. The committee noted that the inspectorate recommends the continuation of the centre's treatment and storage licence.

3. Consideration Incident (Grade A) Report

3.1. The committee noted that the Nuffield Health Woking Hospital had reported a grade A incident (a serious adverse reaction or event).

3.2. The committee noted that a child was born with Cystic Fibrosis. This was due to the husband's screening results for Cystic Fibrosis being mis-reported as normal in an unsigned letter from the Frimley Health NHS Foundation Trust to the clinic.

3.3. The committee noted that the HFEA Executive carried out an incident inspection visit on 11 April 2017 to find out why the incident occurred and what action was needed to minimise the risk of a similar incident reoccurring in the future.

3.4. The committee noted that in 2013 the couple attended an appointment with a Gynaecology Consultant at Frimley Health NHS Foundation Trust for possible IVF treatment. This Consultant was also the Consultant at Nuffield Health Woking Hospital. The Consultant requested screening for Cystic Fibrosis, a routine investigation for male patients with a low sperm count. Later that year the couple had a successful IVF cycle at the clinic and their first child was born in 2014.

3.5. In 2015 the couple underwent a frozen embryo transfer. This did not result in a pregnancy.

3.6. In 2016 the couple commenced a new IVF cycle resulting in the birth of their second child.

3.7. As part of routine post-natal screening, the baby was diagnosed with Cystic Fibrosis. Due to this diagnosis, the female patient contacted the clinic requesting her husband's Cystic Fibrosis status. She was informed that her husband's results reported him as a carrier for a gene mutation for Cystic Fibrosis. It has been identified that the results of the blood test carried out in response to an abnormal semen analysis at Frimley Health NHS Foundation Trust were incorrectly transcribed as negative for Cystic Fibrosis, DNA Cystic Fibrosis mutation screening and karyotype, rather than positive as it should have been. This was in a letter to the clinic, which was not signed by the Consultant who requested the screening, at the time of the screening process for fertility treatment. The positive results were stapled to the back of the letter and there was no evidence that the Consultant had reviewed the letter before it was sent.

3.8. The clinic's practice at the time, in 2013, was for the screening results to be attached to the 'front' of the patient's medical records for the Consultant to review. Further to this the letter should have been detached from the screening results and filed in the "correspondence section" of the patient's medical records. Once reviewed the screening results should have been filed in the "results section" of the patient's notes. However, on this occasion the results were not filed in the "results section" of the notes and remained attached to the letter filed in the "correspondence section" of the medical records.

3.9. The patient's treatment checklist (completed by the nursing staff) states "cystic fibrosis mutation screening -ve, plus normal karyotype."

3.10. There is no evidence that the screening results were reviewed by the Consultant or clinic staff.

3.11. The clinic has implemented several changes since the incident, detailed in the report.

3.12. The committee noted that Frimley Park Hospital is part of Frimley Health Foundation Trust. Although Frimley Health NHS Foundation Trust does not fall within the Authority's regulatory remit for the completeness of this investigation report their recommendations have been noted and a review of the current job plans of those consultants undertaking fertility clinics will be conducted. The Lead Gynaecologist will discuss with the Laboratory Manager a way to identify if a positive result can be made more obvious within the report to enable easier identification and the Trust will review the mechanism for the way results are reviewed by clinicians which should be an IT based solution with a robust audit pathway.

3.13. The committee noted the inspectorate's recommendation to note the outcome of this report.

4. Decision

4.1. The committee had regard to its decision tree.

4.2. The committee considered the interim inspection report and incident (grade A) report, together with the centre's response.

4.3. The committee noted that it is poor practice to accept results summarised in letters and that chromosomal and genetic screening must always be verified and evidenced by the Consultant. However, at the time of the incident there was no robust system in place to provide evidence that the results and letters were reviewed by a Consultant or Fertility Nurse.

4.4. The committee was satisfied that the centre had successfully conducted a comprehensive root

cause analysis, with staff cooperation, to draw a conclusion and learn from this incident.

4.5. The committee agreed that the centre had handled a very difficult situation well and demonstrated good patient engagement and sharing of findings so that others can learn. The committee was satisfied with the outcome of the report and the sensitive manner in which the centre has dealt with the patients concerned and agreed that no further regulatory action was needed.

4.6. The committee had no objection to the HFEA Incident Inspection Report being published alongside the minutes of this meeting on the HFEA website, in the interests of transparency and sharing leaning with the sector.

4.7. The committee agreed that the centre was fit to have its treatment and storage licence continued.

5. Chair's signature

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

Signature

Name

Bishop Lee Rayfield

Date

22 August 2017

Interim Licensing Report

Centre name: **Nuffield Health Woking Hospital**
Centre number: **0144**
Date licence issued: **1 October 2015**
Licence expiry date: **30 September 2019**
Additional conditions applied to this licence: **None**
Date of inspection: **23 May 2017**
Inspectors: **Shanaz Pasha (lead), Lesley Brown**
Date of Licence Committee: **13 July 2017**

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. For 2015-2017 the focus of an interim inspection is:

- **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 Licence Committee (LC) with information on which to make a decision about the continuation of the licence.

Summary for the Licence Committee

The inspection team recommends the continuation of the centre's licence. In particular we note the positive comments made by patients in relation to their experiences.

The Licence Committee is asked to note that there are recommendations for improvement in relation to one major and two 'other' areas of non compliance or poor practice as follows:

'Major' areas of non compliance:

- The PR should ensure that only CE marked medical devices are used wherever possible.

'Other' areas of practice that require improvement:

- The PR should ensure that the outcomes of audits are documented and that audits have appropriate quality indicators.
- The PR should commission an Infection Prevention and Control (IPC) risk assessment of the flooring.

The PR has committed to implementing these recommendations.

Information about the centre

The Nuffield Health Woking Hospital is located in Woking and has held a licence with the HFEA since 1994. The centre provides a full range of fertility services. The centre provided 1481 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28 February 2017. 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 outcomes[1]

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

In 2016, the centre reported 22 cycles of partner insemination with no pregnancies. This represents a clinical pregnancy rate which is in line with the national average.

Multiple births[2]

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

Between December 2015 and November 2016, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 10%: this represents performance that is not likely to be statistically different from the 10% multiple live birth rate target

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur.

Inspectors were not able to observe any laboratory activities during the inspection but were able to discuss witnessing with staff and review witnessing in patient records. These activities indicated that witnessing procedures are compliant with HFEA requirements.

[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%.

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, audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed. 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 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 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: witnessing, consent to storage and legal parenthood.

The centre's procedures for auditing and acting on the findings of audits are broadly compliant with requirements. The centre does not systematically document proposed corrective actions and the dates that corrective and preventative actions were implemented. The centre staff described a process by which they audit storage consent forms against the expiry of storage consent recorded in the IDEAS computer system, six months after material is first stored. The audit findings have not been formally documented, nor are there any associated quality indicators. See recommendation 2.

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:

- the use of CE marked medical devices;
- the content of the centre's website;
- the use of the most recently issued HFEA consent form versions;
- the centre's audit of legal parenthood;

- HFEA Clinic Focus articles regarding Posthumous Birth Registration forms, Zika and Ebola updates.

The centre has been broadly effective in ensuring compliance with guidance issued by the HFEA; please see section 'Equipment and Materials' for details.

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 guidance.

Prescription of intralipid 'off label'

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

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. The clinical rooms in the centre are carpeted. Phlebotomy is carried out in these areas. This could pose an infection risk if there were any spillages. The centre has not undertaken risk assessment of the flooring. See recommendation 3.

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, media supplements, flush solution, vitrification kits; sperm prep kits; PVP solution. We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices wherever possible because the following medical devices are not CE marked: sperm pots and 5 well dishes used for the culture of embryos. See recommendation 1.

Patient experience

During the inspection, we spoke to two patient couples and one lady about their experiences at the centre. Five patients provided feedback directly to the HFEA in the time since the last inspection. Feedback was positive, with one of the individuals providing written feedback giving complements about the care received.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions;
- maintains an effective system for responding to patient phone calls.

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 for those recommendations stated elsewhere in this report.

Compliance with recommendations made at the time of the last inspection

Following a renewal inspection in 2015, a recommendation for improvement was made in relation to one major area of non compliance. The PR subsequently provided evidence that the recommendation was fully implemented within the required timescale.

On-going monitoring of centre success rates

Since the last renewal inspection in 2015 the centre has not received any performance related risk tool alerts.

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 one couple was affected by legal parenthood consent anomalies. The PR was only able to contact one partner who did not wish to take further action.

On this inspection we reviewed the centre's audit and found that it had been performed according to the method specified by the HFEA. No non-conformances had been identified from the audit.

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

In summary, the inspection team considers the processes used to collect legal parenthood consent at this center to be compliant with HFEA requirements.

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 carried out.

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 area of non compliance requires immediate action to be taken by the Person Responsible.

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

‘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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Equipment and Materials The following medical devices used by the centre are not CE marked: • sperm pots • 5 well dishes SLC T30	The PR should ensure that only CE marked medical devices are used wherever possible. We would not recommend the implementation of precipitous changes that might impact on the quality of treatment that is provided to patients. In consideration of this the PR should identify suitable CE marked alternative products by 23 August 2017 and confirmation, along with a timeline for introduction, provided to the centre’s inspector.	We have sourced alternatives for sperm pots and 5 well dishes that are CE marked for MEDICAL USE, noting that the originals were only CE marked. Our Embryology manager will submit a separate report confirming this, but a present we are awaiting confirmation from Nuffield Health Corporate that we can add this to our standard ordering system. We expect to submit confirmation of ordering new CE marked for MEDICAL USE devices by 12th July 2017. We are also checking the CE marking of other disposable laboratory equipment	The Executive acknowledges the PR’s commitment to implementing this recommendation. No further action is required.

‘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.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
2. QMS The centre does not systematically document proposed corrective actions and the dates that corrective and preventative actions were implemented. The storage consent audit findings have not been formally documented, nor are there any associated quality indicators. SLC T36 and T35	The PR should ensure that the centre’s quality management system is effective. The PR should review the centre’s audit process to ensure that where anomalies are found, that corrective and preventative actions are documented and the dates of implementation are also systematically documented. Quality indicators should be established for all activities. A summary report should be sent to the centre’s inspector by 23 August 2017.	We note that we technically don’t document our monthly audit but that over a period of one year, our sytem audits all embryos and sperm held in cryostorage. We will submit a copy of the proposed audit tool and submit an audit going back to April 2017. The audit tool well be submitted by 27th June 2017.This audit will be performed and submitted by the Quality Manager by 23rd August 2017	The Executive acknowledges the PR’s commitment to implementing part of this recommendation and we look forward to receiving the consent audit report. However, the PR is reminded of the additional requirement to review the centre’s audit practice in general to ensure corrective and preventative actions are documented and that quality indicators are established for all activities. A summary report is expected to be submitted by 23 August 2017 and will be followed up by the Executive.
3. Premises and facilities The clinical rooms in the centre are carpeted. Phlebotomy is carried out in these areas. This could pose an infection risk if there were any spillages. The	The PR should commission an IPC risk assessment of the flooring. A summary of the report, and any proposed actions should	The Hospital Infection Control Officer has already prepared a report for Nuffield Corporate on other areas of the Hospital with similar issues. The Hospital Director and Matron have been	The Executive acknowledges the PR’s commitment to implementing this recommendation.

centre has not undertaken a risk assessment of the flooring. SLC T17 and Health Building Note 00-10: Part A, 2.4	be sent to the centre's inspector by 23 August 2017.	informed and I have asked that this is registered on the Nuffield Health Risk Register. We will perform the risk assessment using the existing protocol and submit to the authority by 23rd August 2017, but would hope to submit a report by 12th July 2017	We look forward to receiving a summary report of the risk assessment.

Additional information from the Person Responsible

Incident Investigation Report

Centre name: Nuffield Health Woking Hospital
Centre number: 0144
Date licence issued: 1 October 2015
Licence expiry date: 30 September 2019
Additional conditions applied to this licence: None
Date of site visit: 11 April 2017
Inspectors: Paula Nolan (Clinical Governance Lead), Sharon Fensome-Rimmer (Chief Inspector)
Date of Licence Committee: 13 July 2017

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.

Licence 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).

When an A grade incident (a serious adverse reaction or event) is reported, we immediately contact the centre to obtain further information and agree what further action needs to be taken. We will also carry out an incident inspection visit to find out why the incident occurred and the action needed to minimise the risk of a similar incident reoccurring in the future.

The report together with the centre's response is presented to the HFEA's Licence Committee which decides if any further regulatory action needs to be taken. The report and the minutes of the Committee decision are published on this website on the relevant clinic's page in the Choose a Fertility Clinic section. The exception to this practice is where the information is considered potentially patient identify.

This is a report of an investigation into a serious adverse reaction involving an infant born with Cystic Fibrosis (CF). The CF screening results had been misreported as normal in an (unsigned) letter from the Consultant.

The Executive wishes to place this report before the Licence Committee in the interests of transparency and sharing leaning with the sector.

Section 1

Brief description of the centre and its licensing history

1. Nuffield Health Woking Hospital (the clinic) has held a Treatment and Storage licence with the HFEA since 1994 and provides a full range of fertility services. The clinic provides approximately 1100 cycles of treatment a year. In relation to actively levels this is a large clinic.

Background information on incident

2. In 2013 the couple attended an appointment with a Gynaecology Consultant at Frimley Health NHS Foundation Trust for possible IVF treatment. This Consultant is also the Consultant at Nuffield Health Working Hospital. The Consultant requested a Cystic Fibrosis screen. This is a routine investigation for male patients with a low sperm count.

3. Later that year the couple had a successful IVF cycle at the clinic and their first child was born in 2014. In 2015 the couple underwent a frozen embryo transfer. This did not result in a pregnancy. In 2016 the couple commenced a new IVF cycle resulting in the birth of their second child.

4. As part of routine post-natal screening the baby was diagnosed with Cystic Fibrosis. Because of this diagnosis, the female patient contacted the clinic requesting her husband's Cystic Fibrosis status. She was informed her husband's results reported him as a carrier for a gene mutation for Cystic Fibrosis.

5. It has been identified that the results of the blood test carried out in response to an abnormal semen analysis at Frimley health NHS Foundation Trust were incorrectly transcribed as negative, rather than positive as it should have been, in a letter to the clinic at the time of the screening process for fertility treatment.

Findings of the centre's internal investigation

6. The letter received from Frimley Park NHS Foundation Trust to the clinic incorrectly stated the male patient was negative for Cystic Fibrosis, DNA Cystic Fibrosis mutation screening and karyotype[1]. The letter was not signed by the Consultant who had requested the screening. The positive results were stapled to the back of the letter (no evidence that the Consultant reviewed the letter prior to it being sent).

7. The clinic's practice at the time (2013) was for the screening results to be attached to the front of the patient's medical records for the Consultant to review. Further to this the letter should have been detached from the screening results and filed in the "correspondence section" of the patient's medical records. Once

[1] Letter and screening results can be found at the back of this report.

reviewed the screening results should have been filed in the "results section" of the patient's notes.

8. On this occasion the results were not filed in the "results section" of the notes and remained attached to the letter filed in the "correspondence section" of the medical records.

9. The patient's treatment checklist (completed by the nursing staff) states "cystic fibrosis mutation screening -ve, plus normal karyotype.

10. There is no evidence the actual screening results were reviewed by the Consultant or clinic staff.

Findings and observations of the HFEA's investigation

11. The Executive has undertaken a site visit, interviewed senior staff at the clinic, reviewed the couple's medical records. As well and reviewing and discussing the clinic's root cause analysis and a copy of Frimley Health NHS Foundation Trust's (draft) serious incident final report.

12. The senior staff at the clinic and the wider Nuffield Hospital have been open and honest in accounting for the events leading up to the incident. A senior member of the hospital staff acted as a "critical friend" to review the report and its findings. The staff have dealt sensitively with the family including offering coordinated meetings with the Trust. The clinic also made it a priority to share their investigation finding with the family.

13. The Executive endorses the clinic's investigation findings. It is poor practice to accept results summarised in letters. Chromosomal and genetic screening must always be verified and evidenced by the Consultant. At the time of the incident there was no robust system in place to provide evidence the results and letters were reviewed by a consultant or fertility nurse prior to being filed.

14. The clinic has implemented several changes since the incident. All letters to be signed by the Consultant. All pathology results must be reviewed and evidenced by each receiving provider. All results are reviewed irrespective of cycle number. The standardised form for checking patient screening status has been reviewed and amended to reflect this requirement. This process has been incorporated into the audit cycle to monitor levels of compliance.

15. The clinic's manager has agreed to draft an article for Clinic Focus regarding her thoughts on the investigation process and lessons learnt.

16. Although Frimley Health NHS Foundation Trust does not fall within our regulatory remit for the completeness of this investigation report their recommendations should be noted. A review of the current job plans of those consultants undertaking fertility clinics will be conducted. The Lead Gynaecologist will discuss with the Laboratory Manager a way to identify if a positive result can be made more obvious within the report to enable easier identification. The Trust will

review the mechanism for the way results are reviewed by clinicians, this should be an IT based solution with a robust audit pathway.

Recommendation to the Licence Committee

17. The Licence Committee is asked to note the outcome of the investigation report.

Additional information from the Person Responsible

I wish to thank the HFEA investigation team for their independent analysis and comments. All actions identified in the IVF unit at Nuffield Health Woking Hospital have been implemented but unfortunately at Frimley Park Hospital (part of Frimley Health Foundation Trust) to date there does not appear to have been conclusion of all of their own recommendations, although I do confirm that job planning has identified more time for results to be reviewed.

Secretary: 01276 604013
Results Line: 01276 526694
Fax: 01276 604240

Frimley Park Hospital NHS
NHS Foundation Trust

Clinic: 21.08.13
Date Typed: 31.10.13

Portsmouth Road
Frimley
Camberley
Surrey
GU16 7UJ

Tel: 01276 604604

Woking Nuffield Hospital
Assisted Conception Unit
Shores Road
Woking
Surrey
GU21 4BY

Date Received
04 NOV 2013
Victoria Wing
Nursing

Dear

I enclose copies of results which are negative for CF DNA cystic fibrosis mutation screening and karyotype.

Yours sincerely

DICTATED NOT SIGNED

CONSULTANT OBSTETRICIAN & GYNAECOLOGIST

Please note that medical secretaries are not able to provide patients with results of blood tests, scans or procedures. Results will be discussed either at your next follow up appointment, or if your consultant feels it is necessary they will write to you

NHS SURREY PATHOLOGY SERVICES CPA

Frimley Park, Royal Surrey County and Ashford & St Peters Hospitals NHS Trusts

Biochemistry and Haematology Report -

Pathology Helpline 01276 604998
Non GP enquiries: FPH site - 4117, RSCH site - 4707
Ashford site - 4501, St Peters site - 3039

[redacted]

Clinical details:
Very low sperm count

Tests to Follow: None

DNA Cystic Fibrosis	CF OLA: Heterozygous for c.1521_1523delCTT (p.Phe508del) This patient is heterozygous for the c,1521_1523delCTT (p.Phe508del) CFTR gene mutation, but negative for the other 31 CFTR gene mutations listed in the report. Although this does not completely exclude the presence of a second CFTR gene mutation, this test accounts for at least 90% of mutations in populations of NW European origin and 71% of mutations in the worldwide population. Relatives of this patient can now be offered testing for the presence or absence of this mutation. Please see filed report for further details. Copy of full report sent to [redacted] on 21.10.2013 Results are from Wessex Regional Genetics Lab
Karyotype	46,XY This patient has an apparently normal male karyotype. Please see filed report for further details. Copy of full report sent to [redacted] on 18.10.2013. Results are from Wessex Regional Genetics Lab

[redacted]
24 OCT 2013
OBSTETRICS & GYN

FILE ☐
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Lab No: 13C734338
Sample Type: Blood
Sample Collected: 11/09/13
Sample Received: 11/09/13 13:24
Report Status:
Report Printed:
Authorised by: STEVAN
This report printed: 21/10/13 17:35

WESSEX REGIONAL GENETICS LABORATORY

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CPA Accredited Medical Laboratory Reference No. 1175

Director: Professor NCP Cross

MOLECULAR GENETICS REPORT

Consultant Obstetrician
Frimley Park Hospital NHS Trust
Portsmouth Road
Frimley
Surrey
GU16 7UJ

WRGL Sample No:		Referred By:	
Date Requested:	**14/10/2013**	Date Reported:	**17/10/2013**
Clinical Genetics No:	**N/A**	External ID:	

Test Requested: ***CFTR* gene analysis**

Referral Details: **Very low sperm count.**

RESULTS:

Analysis	Result
CF OLA	**Heterozygous for c.1521_1523delCTT (p.Phe508del)**

CF OLA = Analysis of the following 32 *CFTR* gene mutations, using reference sequence NM_000492.3 (traditional nomenclature given in brackets): p.Phe508del (DF508), p.Gly551Asp (G551D), p.Gly542X, c.489+1G>T (621+1G>T), c.1585-1G>A (1717-1G>A), p.Arg553X, p.Trp1282X, p.Asn1303Lys, c.3717+10kbC>T (3849+10kbC>T), p.Arg117His (R117H), p.Arg1162X, p.Arg334Trp, p.Ala455Glu, p.Lys1177fs (3659delC), p.Ile507del, p.Arg347Pro, c.2988+1G>A (3120+1G>A), c.2657+5G>A (2789+5G>A), c.1766+1G>A (1898+1G>A), c.579+1G>T (711+1G>T), p.Gly85Glu, p.Lys684fs (2183AA>G), p.Lys684fs (2184delA), p.Arg560Thr, p.Ser549Asn, p.Ser549Arg, p.Val520Phe, p.Leu88fs (394delTT), p.Arg347His, p.Phe316fs (1078delT), p.Leu1258fs (3905insT), p.Ser1248fs (3876delA).

is heterozygous for the c.1521_1523delCTT (p.Phe508del) *CFTR* gene mutation, but negative for the other 31 *CFTR* gene mutations listed above. Although this does not completely exclude the presence of a second *CFTR* gene mutation, this test accounts for at least 90% of mutations in populations of NW European origin and 71% of mutations in the worldwide population. Relatives of can now be offered testing for the presence or absence of this mutation.

N.B.: Of males with infertility due to congenital absence of the vas deferens (CAVD), 17% have one *CFTR* gene mutation, 26% have one *CFTR* mutation and a 5T polypyrimidine tract allele and 26% have two *CFTR* mutations (www.genetests.org).

If this patient has CAVD and you would like the polypyrimidine tract analysed, please contact the laboratory or discuss the case with Consultant Clinical Geneticist at St George's Hospital (telephone 0208 7255305).

Reported by:

Principal Clinical Scientist

Senior Genetic Technologist