Interim Licensing Report

Centre name: St Mary's Hospital
Centre number: 0067
Date licence issued: 1 August 2012
Licence expiry date: 31 July 2015
Additional conditions applied to this licence: None
Date of inspection: 31 January 2013
Inspectors: Debra Bloor; Janet Kirkland MacHattie; Sarah Peacey
Date of Executive Licensing Panel: 26 April 2013

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 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 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

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 with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

The inspection team recommends the continuation of the centre's licence. It is acknowledged that the implementation of a success rate improvement plan in 2012 has yet to have a demonstrable impact on the centre's success rates and this will continue to be a focus of on-going monitoring. The Executive Licensing Panel will be provided with an update in relation to the centre's success rates in April 2014 or sooner if there is a significant downward trend in success rates before that time.

The team made recommendations for improvement in relation to two 'critical' areas of non-compliance, one 'major' area of non-compliance and two 'other' areas of non-compliance. The Person Responsible (PR) has provided assurance that the following recommendations have been implemented:

'Other' areas of practice that require improvement:

- The PR should review the feedback provided to the HFEA by patients undergoing treatment and consider gathering additional feedback and/or implementing corrective actions in respect of the issues of concern identified.
- The PR should review the bring-forward system to ensure that it is effective in providing sufficient advance notice of the end of the statutory storage period to prevent the storage of gametes beyond their consented storage period. A summary report documenting the findings of the review; any corrective actions and the timescale for the implementation of any corrective actions should be submitted to the HFEA.

The PR has initiated the implementation of the following recommendations and provided a commitment to the full implementation within the prescribed timescales:

Critical areas of non-compliance:

- **The PR should review the effectiveness of the bring- forward systems for cryopreserved embryos. Corrective actions should be implemented to ensure that patients are given sufficient notice of the expiry of the consent to storage of embryos to allow for relevant actions to be taken in advance of the expiry.**
- **The PR should ensure that the backlog of historic errors relating to donor registrations and/or treatments is cleared within the time that this report is considered by the Executive Licensing Panel. The PR should undertake a review to identify the factors leading to poor compliance with register submission requirements.**

Major areas of non compliance:

- The PR should review procedures for submitting patients' consent to disclosure to researchers to the HFEA.

Information about the centre

St Mary's Hospital has held a licence with the HFEA since 24 April 1992

The centre provides a full range of fertility services.

The centre provided 1280 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2012. 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 very important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Outcomes[1]

At the time of the renewal inspection in 2012, clinical pregnancy rates following IVF and ICSI in patients aged less than 38 years were lower than average at a statistically significant level. The renewal report noted that success rates have been a concern at the centre since 2007. The report also documented that the centre was implementing a, 'live birth improvement strategy' with the aim of improving IVF and ICSI success rates.

It is noted however, that HFEA held register data for the year ending 30 September 2012 indicate no improvement in the centre's success rates in terms of clinical pregnancy when compared to the previous year. Success rates are in line with national averages but with the following exceptions:

- clinical pregnancy rates following IVF in patients aged less than 38 years are lower than average at a statistically significant level;
- clinical pregnancy rates following ICSI in patients aged less than 38 years are lower than average at a statistically significant level;
- clinical pregnancy rates following ICSI in patients aged 38 years and above are lower than average at a statistically significant level.

For the year 2011 the centre reported 51 cycles of partner insemination with two pregnancies. This equates to a four per cent pregnancy rate which is consistent with national average success rate.

The centre's IVF and ICSI success rates were discussed at length in the course of the inspection and a suite of information documenting changes implemented since the last inspection and the analysis of recent success rates was provided.

[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.

This documentation provided evidence that the centre has been proactive in implementing the following:

- a revised ovarian stimulation protocol (implemented in April 2012);
- fresh embryo transfers conducted in afternoons to maximise opportunities for embryo selection (the longer embryos are left to develop in vitro, the greater the opportunity to distinguish those developing normally);
- consultant led embryo transfers (implemented in August 2012);
- introduction of changes to the process for embryo transfer (implemented in September 2012);
- a review of the single embryo transfer programme and introduction of a revised multiple births minimisation policy (implemented in December 2012).

The centre's own monitoring of success rates from August to October 2012 reflected that of the HFEA with outcomes showing a downward trend. The HFEA's monitoring of success rates has a three month time lag (centres are given up to eight weeks after the treatment cycle completion date to report early pregnancy outcomes) and so monitoring at the time of the inspection did not extend beyond September 2012. However, information provided by the PR indicated that there has been an upward trend in success rates in the time period from October to December 2012 and the PR was hopeful that this demonstrates an impact of the improvement strategy implemented by the centre and documented above.

The centre's documentation also lists plans for further changes to complete the proposed improvement plan and this is evidence that the PR recognises that further improvements are required.

In the course of discussions, the PR also noted that this centre only provides NHS funded treatment and that funding criteria mean that more than 95% of women treated are childless. Further, once a successful treatment has been provided, the centre is not able to provide further treatment for sibling pregnancies. The HFEA is not able to analyse the possible impact of this but it is acknowledged that as this is the only HFEA licensed facility that provides NHS treatment only (and therefore has no opportunity to provide self funded treatment to patients of proven fertility who have had a child as a result of previous NHS funded treatment) this centre's patients may be a unique cohort.

In consideration of the information provided by the centre documenting the on-going review of procedures and implementation of changes anticipated to improve success rates; proposed long term changes to the service to influence patient demographics by offering privately funded treatment, and; recent indicators of an upward trend in success rates, it is concluded that the PR has taken steps to ensure the use of suitable practices in compliance with HF&E Act 1990 (as amended), Section 17 (1d) and that no further regulatory action in relation to success rates would be proportionate at this time. The centre's success rates will continue to be the subject of on-going monitoring.

Multiple births[2]

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

In 2010/11 the centre's multiple clinical pregnancy rate for all treatment cycles for all age groups was 18%: this represented performance that was not likely to be statistically different from the 20% live birth rate target.

For the time period April 2011 to September 2012 the centre's multiple clinical pregnancy rate for all treatment cycles for all age groups was 16%: this also represents performance that is not likely to be statistically different from the 15% live birth rate target.

The progress in reducing the clinical multiple pregnancy rates from 2010/11 to 2011/12 suggests that the centre is being proactive and effective in adapting their strategy to meet the HFEA's multiple birth rate target.

Witnessing

Good witnessing processes are vital in ensuring 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: identity checks at egg collection; processing of eggs; sperm preparation; embryo thawing. All of the procedures observed were witnessed in accordance with HFEA requirements using manual or electronic witnessing systems as appropriate.

The inspection team reviewed the records of six patient treatments and concluded that records of manual witnessing are maintained in the patient records. The centre does not keep a paper copy of electronic witnessing records in the patients' records but the laboratory manager provided assurance that the relevant electronic records are maintained and can be accessed if required. While this is non-compliant with the requirements of Standard Licence Condition (SLC) T71 this omission is not considered a risk and no recommendations have been made in respect of this non-compliance.

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interchange (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 12 patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in six of the records reviewed. The consents in the remaining six records did not match the consents as reported electronically to the HFEA. In all of the cases, the patients

[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2010/11 MLBR target of 20% is calculated as equivalent to a MCPR of 25%: the 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

were reported to the HFEA as not having given consent to disclosure: the records of four of the six patients contained documented consent to disclosure and there was no record of consent in the records of two patients. See recommendation 3.

Consent: To the storage of cryopreserved material

A review of the centre's database indicated that on the day of the inspection the centre did not have written effective consent for the storage of cryopreserved embryos for three sets of patients. Subsequent to the inspection the PR provided written confirmation that only one of the three sets of embryos remained in storage without effective consent and that a decision would be made about the fate of these remaining embryos by 1 March 2013. See recommendation 1.

The laboratory manager explained that the centre keeps hard copy records of stored gametes and that these are reviewed annually to identify the samples which have consents due to expire. It was not possible to confirm that the centre had written effective consent for the storage of all cryopreserved gametes because the documentation of consent is not readily accessible for review. This observation suggests that the centre's bring-forward system in respect of cryopreserved gametes may not be suitably robust. See recommendation 4.

Staffing

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

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out.

Patient experience

During the inspection visit we spoke to nine patients who provided feedback on their experiences. A further 22 patients also provided feedback directly to the HFEA in the time since the last inspection. The written feedback provided to the HFEA was mixed with 15 respondents having compliments about the service provided and 11 having complaints.

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;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information including information on the purpose and side effects of drug treatment, availability of counselling and how to contact the centre in an emergency.

Although it is acknowledged that 31 patients is only a small and potentially non representative sample of the centre's patients it is noted that feedback from a small number of patients highlighted the following concerns:

- 40% of respondents noted that they had not been informed of the need to maintain contact with the centre: this is potentially important when patients are expected to report outcomes or make decisions about cryopreserved gametes or embryos;
- 20% of respondents commented on general disorganisation and disjointed service;
- 10% of respondents reported that it is difficult to contact the centre by telephone.

See recommendation 5.

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

No non-compliances were identified on the basis of information submitted by the centre in their self assessment questionnaire or from observations during the visit to the centre.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in February 2012 recommendations for improvement were made in relation to one critical area of non-compliance, six major areas of non-compliance and four 'other' areas of non-compliance or areas of poor practice.

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

The following recommendation related to a critical non-compliance that remains an issue of concern:

- In relation to outcomes following IVF and ICSI, the PR should ensure that laboratory and clinical practices are suitable to provide a good quality service to patients.

See section above: "outcomes".

The following recommendations related to major non-compliances have not been fully implemented:

- The PR should ensure that all critical equipment is validated. Evidence of validation of any outstanding critical equipment to be forwarded to the inspector by 3 May 2012
- The PR should ensure that all critical processes are validated. Evidence of validation of any outstanding critical processes to be forwarded to the inspector by 3 May 2012
- The PR should ensure that issues concerning the accurate and timely submission of data to the Authority are resolved as a matter of urgency. This was an issue at the previous inspection and has still not been successfully resolved. The PR should provide details about how this issue is to be resolved by 3 May 2012.

In responding to the report immediately after the inspection, the PR agreed to implement the recommendations relating to the completion of validation of equipment and critical processes and submitted an action plan to the HFEA executive that outlined that all validation would be complete by July 2013. In advising the HFEA of the likely timescales for the completion of validation the PR noted that the centre intended to use a system recommended by the British Andrology Society and that this system is robust but labour

intensive. The PR has kept the HFEA informed of progress and the completion of the process will continue to be monitored.

In relation to the timely submission of data to the HFEA, the HFEA's register information team reported some improvement post inspection. This improvement has not been maintained however: See section below: "Provision of information to the HFEA".

On-going monitoring of centre success rates

In the six months to January 2013 the centre was issued with three performance alerts in relation to IVF and ICSI success rates. The PR has kept the HFEA informed of actions taken in relation to the review of these procedures and during discussions at the time of the inspection the PR provided evidence of measures taken to implement a "success rate improvement plan". See section above: "outcomes".

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.

The HFEA's register information team report that there has been copious and regular communications with the centre in relation to register submission errors and historic unregistered/unmatched donors. Some modest progress was being made in reducing the number of the latter but this has not been maintained.

The centre has on a number of occasions attributed submission issues to its third party IT system.

Current submissions include a number of errors (though improvements have been made in the second and third quarters) but there is a backlog of historic errors to be addressed. There are also a number of duplicate submissions.

See recommendation 2.

Annex 1

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 area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or 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
1. On the day of the inspection the centre did not have written effective consent for the storage of cryopreserved embryos for three patients. HF&E Act (as amended)	The PR should provide the HFEA with an update on the number of embryos remaining in store without effective consent by 2 March 2013. The PR should review the effectiveness of the bring-forward systems for cryopreserved embryos. Corrective actions should be implemented to ensure that patients are given sufficient notice of the expiry of the consent to storage of their embryos to allow for relevant actions to be taken in advance of	There are now no embryos remaining in storage without effective consent. The issues around the three sets of embryos detailed in the inspection report have been resolved as follows: - Patient 1 – the embryos have now been allowed to perish. - Patient 2 – the embryos have been allowed to continue in storage as consent for this has	No further action is required in relation to the critical non-compliance arising as a result of the storage of embryos without consent. The PR's assurances about the robustness of the bring forward system are acknowledged. No further action is

Schedule 3 paragraph 8 (1).	the expiry. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA. The PR should also review the effectiveness of procedures for auditing storage of cryopreserved material as this regulatory non-compliance had not been highlighted by the audit process. The PR is reminded of guidance issued by the HFEA in CH(03)02 (http://www.hfea.gov.uk/2721.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material. This recommendation should be implemented by 30 April 2013	been extended. - Patient 3 – the embryos have been allowed to perish. The PR can confirm to the HFEA that an effective electronic bring-forward system exists for cryopreserved embryos and oocytes. The 3 lots of embryos that were identified as not having valid consent for storage at the time of the inspection were known to the PR and their status was being resolved at the time of the inspection. The PR can now confirm that all embryos and oocytes currently in storage in the centre have valid consent. The PR is aware of HFEA guidance relating to timely disposal of cryopreserved gametes where there is consent to do so and assures the HFEA that Centre 0067 is fully compliant with this guidance.	recommended but it is expected that if the system is effective, no further instances of storage without consent should be observed. Further action is required in relation to the submission of a summary report of the review of the centre's procedures for auditing storage of cryopreserved material.

2. There continue to be errors in the data submissions provided to the HFEA, and historic errors in HFEA register information relating to gamete donors. There are also a number of duplicate submissions. This is non-compliant with the requirements of Directions 0005: this non-compliance is cited as critical because it remains an issue of concern after being cited as a major non-compliance at the time of the renewal inspection in February 2012.	The PR should ensure that the backlog of historic errors relating to donor registrations and/or treatments is cleared within the time that this report is considered by the Executive Licensing Panel The PR should undertake a review to identify the factors leading to poor compliance with register submission requirements. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 30 April 2013.	The PR wishes to reassure the HFEA that the centre is working hard to resolve the errors in data submissions to the HFEA and historic errors in HFEA register information relating to gamete donors. The PR has also instigated an urgent review of this issue and this has highlighted a combination of human and database (ACUBase) factors. The centre has appointed a Data Management Officer to coordinate all data management issues for the centre and we believe this will improve the data submission problems we have had. He monitors missing outcomes/errors with data, filters errors and reports them directly to the manager on a monthly basis. This should ensure that all identified errors are cleared in a timely manner. **Registration Errors** Registration errors appear to be occurring because of human factors to do with the process currently in place for resolution of problems that occur with completion of the history summary forms at the time of the consultation. The PR has now developed the	The PRs commitment to review this issue is acknowledged and the appointment of a data management officer is welcomed. HFEA staff have been in contact with the newly appointed data management officer to discuss register submissions and there has been some recent improvement in the accuracy of *current* register submissions. At the time of the inspection, there were 47 *historic* donor issues to be resolved. On 11 April 2013 the PR advised the HFEA that the number of historic donor registration errors had been reduced to 5 but this was not supported by information from the HFEA register which suggests that the number of historic errors remains largely unchanged. The HFEA register information team will liaise with the PR to clarify the number of

		completion of this section of the history as a specific competency that all clinicians have to attain and has provided the necessary training session to achieve this. The PR has mandated that **Errors in electronic data submission (including duplicate submissions)** This centre has experienced perennial problems with its electronic database (ACUBase) that the HFEA is aware of. These problems include the following examples: 1) Outcomes submitted and report sent to HFEA. (Form number can be seen on our data base). HFEA do not receive report. 2) When data is inputted, the electronic form sent to HFEA doesn't always have the full data transcribed onto it. To address these issues, the centre has instituted the following corrective actions: • A new Data Management Officer has been appointed to manage the Center's data management issues. • A new Nurse Manager was appointed in May 2012 and she is currently looking at all nursing	outstanding historic donor registration errors and an update on progress in resolving these errors will be provided to the Executive Licensing Panel. The PR is advised that the HFEA does not prescribe the method of submission of data and that the HFEA will continue to monitor the impact of measures implemented by the PR in relation to the accuracy of register submissions through the usual monitoring systems.

		processes to identify problematic processes in order to make changes that will be effective in resolving the problems. • There is a new process in place on how nurses chase and record outstanding outcomes. This includes reorganizing where/how patient records (ICPs) are stored and designating a nominated person to chase outcomes on a daily basis. • Training sessions on the data management process have been arranged for all staff (including nursing staff). The PR will continue to assess the effectiveness of these measures in addressing the Center's data management issues and will feedback to the HFEA.	

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
- 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
3. The consents to disclosure to researchers documented in six of the 12 records reviewed in the course of the inspection did not match the consents as reported electronically to the HFEA. In all of the cases, the patients were reported to the HFEA as not having given consent to disclosure: the records of four of the six patients contained documented consent to disclosure and there was no record of consent in the records of	The PR should review procedures for submitting patients' consent to disclosure to researchers to the HFEA. A summary report of the findings of the review including corrective actions and the timescale for implementation of the corrective actions should be submitted to the HFEA. Three months after the implementation of corrective actions the centre should audit a random sample of ten sets of patient records to ensure that consent to disclosure to researchers taken from patients	The PR undertook an urgent review of this issue and agrees with the HFEA that there appears to be a problem with the process for submission of research consent to the HFEA to the effect that patients who want their children to be enrolled in health follow up studies may be effectively denied this. It is not very clear at the present time why this is the case but the PR is undertaking further investigations. The PR has instigated an immediate more robust audit of 50 sets of notes of patients treated	The PRs commitment to resolve this issue is acknowledged. The PR provided a summary report of the findings of the audit including proposed corrective actions and the timescale for their implementation on 28 March 2013. Further action is required to provide the results of the re-audit conducted three months

two patients. This is non-compliant with Directions 0005.	has been correctly transferred to the HFEA register. The records audited should have had this consent completed within the previous three months. This audit should be submitted to the HFEA for cross reference against the records held by the HFEA. The HFEA may require the centre to perform an audit of individual consent records against the consent decision held by the HFEA in the future if an application by researchers is made for the release of that information. This recommendation should be implemented by 30 April 2013.	within the last 3 months and will share the findings, recommendations and action plans developed from this audit with the HFEA. The PR has commissioned an audit as detailed above and can assure the HFEA that the actions and recommendations from this audit will be implemented and a further audit will be undertaken to assess the impact of any change made.	after the implementation of corrective actions.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
4. It was not possible to confirm that the centre had written effective consent for the storage of all cryopreserved gametes and this was considered likely to suggest that the centre's bring forward system for cryopreserved gametes may not be suitably robust. Code of Practice guidance 17.18.	The PR should review the bring-forward system to ensure that it is effective in providing sufficient advance notice of the end of the statutory storage period to prevent the storage of gametes beyond their consented storage period. A summary report documenting the findings of the review; any corrective actions and the timescale for the implementation of any corrective actions should be submitted to the HFEA The PR should also submit a summary report documenting the consent expiry date and status (awaiting disposal; awaiting completion of new consent etc.) of any gametes that are being stored without effective consent.	The PR can also confirm to the HFEA that there remains a historic difficulty with the bring-forward system that exists for cryopreserved sperm as that system utilises non-electronic recording of the storage on a card file system that is then stored on a manually generated database. It has therefore been difficult and time-consuming to audit this system annually. This is a historical issue which the PR has agreed a plan with the Andrologists to resolve as detailed below. The PR has instructed the Andrologists to immediately undertake the following actions: • urgently audit the card file system of stored sperm so that the status of all sperm in storage can be assessed and any necessary	On 11 April 2013 the PR confirmed that the centre "have been working through our stored sperm and are now back up to date". This is interpreted to mean that at this date, the centre is not storing any sperm without effective consent. The PR also reported that a review of the SOP for storage and recall of gametes has been completed and procedures are considered robust however, corrective action is planned to develop an electronic bring forward system which will be operational from September 2013.

	This recommendation should be implemented by 30 April 2013	corrective actions taken. • transfer the entire sperm storage database to our electronic database (ACUBase) which should make annual audits more robust and compliant. • eventually transfer the long term storage system to the new DRM electronic database that is currently being developed.	No further action is required.
5. In feedback provided to the HFEA by 22 patients, 11 patients had complaints about the service provided. Negative feedback was varied but referenced a lack of guidance on maintaining contact with the centre; inability to contact the centre by telephone; poor organisation leading to delays in appointments and in treatment.	The PR should review the feedback provided to the HFEA by patients undergoing treatment and consider gathering additional feedback and/or implementing corrective actions in respect of the issues of concern identified. A summary report documenting the centre's actions should be provided by 30 April 2013.	**Contact by Phone to the department** The PR has undertaken an urgent immediate review of the processes within the Centre and agrees with the HFEA that some processes could be made more robust including management of telephone contact with the Center. As part of corrective actions emanating from this review, the following actions have been implemented: • The administration office has introduced a telephone rota. One member of the clerical team is now responsible for answering and dealing with all telephone enquiries during core	The PR's proactive response to this feedback is commended. The proposed changes include some changes to the way feedback is sought and the HFEA inspector is reassured that the centre are acting on the feedback provided to the HFEA. No further action is required.

		office hours (8.30am-4.30pm) on a daily basis. There is a message book in the office for use if patients cannot get through to the treatment office these will be passed on. • Phones in the treatment office are now answered by a member of the clerical team from 8am until 11am. One member of clerical staff is responsible for this on a daily basis. Outside this time, the phone will be answered by a member of the nursing team who would deal with urgent clinical enquiries and any other enquiries relating to treatment. Catherine Price, the Center's new Nurse Manager has been requested to ensure adequate staffing of the phone call rota. **Lack of guidance on maintaining contact with the centre** The PR has similarly undertaken an immediate investigation of this issue and agrees with the HFEA that the process of communicating the need for patients to maintain contact with the Center can be	

		made more robust and corrective action has been taken as detailed below: 1) At present patients undergoing IVF, ICSI and IUI treatment are told verbally to maintain contact with the Center during their clinic consultation. This information will now be communicated to patients by letter and also included in the information booklet given to patients at the beginning of their journey through the Unit. A further letter will be given to patients reiterating the need to maintain contact with the Unit at the point when they have gametes put into storage. 2) Patients storing sperm long term are requested to sign a consent form which clearly highlights that they need to contact the unit if they have any changes in circumstances. 3) All patients receive a written letter by land and recorded delivery when the storage of any gametes is due to expire. Their address details are checked against the NHS portal to ensure that the letter is sent to the correct address.	

		Negative feedback from patients with regards to organization of the Center The PR has requested the Nurse Manager and Operation Manager for the Center to undertake an immediate review of all our processes and report back to him any actions to address this patient observation. At present the Nurse Manager carries out a monthly quality care round. This includes speaking to patients about their experiences of using our service. Feedback from this has generally tended to be good but this might reflect the face to face nature of the contact. This process will be made more comprehensive. The Centre plans to introduce a patient experience tracker in the next couple of months and this will provide monthly patient experience data in real time. This will help us to develop action plans in a more timely fashion that responds to the patients' feedback.	

		The PR acknowledges that patients have to wait longer than is ideal for new and follow up appointments because of the nature of the service. The Center is therefore trialling telephone consultation clinics to better manage its clinic capacity.	

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

26 April 2013

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 4

Centre 0067 – (St Mary's Hospital) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett – Director of Finance and Facilities (Chair) Hannah Darby – Senior Policy Manager David Moysen – Head of IT	Rebecca Loveys

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that the centre has held a licence with the HFEA since 24 April 1992.

2. The Panel noted that this is a large centre which provides a full range of NHS funded fertility services.

3. The Panel noted that the centre's current licence was issued 1 August 2012 and is due to expire 31 July 2015.

4. The Panel noted that, at the time of inspection, two critical and one major area of non-compliance were identified by the Inspectorate.

5. The Panel noted that the critical areas of non-compliance concerned, firstly, review of the bring-forward systems for cryopreserved embryos and, secondly, the centre's backlog of historical errors regarding donor registration and information. The latter was reported as a major non-compliance at the previous inspection and had been escalated because it had not been fully resolved.

6. The Panel considered and agreed to accept the information regarding the second critical non-compliance tabled 25 April 2013 via the Inspectorate as it was relevant to consideration of progress towards resolving this non-compliance.

7. The Panel noted that insufficient progress towards resolving this non-compliance was potentially an aggravating circumstance that might lead to further licensing sanctions. However, the Panel also noted the mitigating factors evident, including the PR commitment, some remedial action and the PR insights offered on the non-compliance.

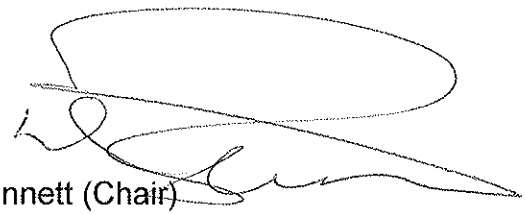
Decision

8. The Panel received information both from the Inspectorate and also the clinic relating to progress on resolving donor registration and information. The tables of information provided by each supported the two different views of progress represented.

9. The Panel observed that there were different views about whether progress to date had been satisfactory of not. The Panel was concerned that this critical non-compliance may not have been addressed properly and accurately. Therefore, the Panel agreed to defer consideration of this report pending an agreed update on this critical area of non-compliance. The Panel is also keen to understand the risk management arrangements and actions which are put in place if information on donors cannot be accurately or timeously obtained.

The Inspectorate is requested to obtain this within two weeks from 30 April 2013.

10. On completion of this update, the interim inspection should once more be considered by the Panel including the update requested above.

Signed:  Date: 2 April 2013

Mark Bennett (Chair)