HFEA Licence Committee Meeting

9 January 2014

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

Minutes – Item 3

Centre 0198 (St. Jude's Women's Hospital) - Renewal Update Report

Members of the Committee: Andy Greenfield (lay) (Chair) Bishop Lee Rayfield (lay) Debbie Barber (professional)	Legal Adviser: Sarah Ellson, Field Fisher Waterhouse
Committee Secretary: Lauren Crawford	Observing: Sam Hartley, Head of Governance and Licensing, HFEA

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

The following papers were considered by the Committee:

- Executive update
- Licence renewal inspection report
- Minutes of Licence Committee 7 November 2013
- Care Quality Commission report of St Jude's Hospital Wolverhampton September 2013.
- CQC representations decision 14 November 2013
- General Medical Council registration conditions 15 August 2013
- Further submissions from the PR and his legal representatives (tabled)
    - Letter dated 6 January 2014 from Lawford Davies Denoon
    - CQC factual accuracy comments by Mr Adeghe 3 November 2013
    - Letter dated 6 January 2014 from Mr Adeghe
    - Submissions on behalf of Mr Adeghe made to the IOP of the Medical Practitioners Tribunal Service – 5 November 2013

The Committee also had before it

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 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); and

- 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 Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. The Committee noted that a licence renewal application was considered by the Licence Committee on 7 November 2013.

2. At that meeting the Committee agreed to adjourn the licence renewal decision and requested further information be provided regarding the reviews and investigations being conducted by other regulatory agencies. In particular, the Committee wished to see the findings of the September 2013 CQC inspection report (published in November 2013 subsequent to the meeting of the Licence Committee) and details of the conditions imposed by the General Medical Council to the PR's (Person Responsible) registration. The Committee requested that an update on the status of this information be supplied for its next meeting, in January 2014.

3. The Committee in November also noted that the centre's licence expires on 31 January 2014 and indicated that, subject to the Committee receiving the update, and in the absence of any other relevant consideration, the Committee were of the view that, at the next meeting of the Licence Committee in January, it would be appropriate to issue a Special Direction for a period of three months to be in effect following the expiry of the current licence.

Discussion

4. The Committee noted they had now received the requested information from both the CQC and the GMC. The Committee also noted the tabled information from the PR and his legal representatives.

5. The Committee noted the centre's position regarding being licensed by the CQC and the PR's intentions to voluntarily revoke his CQC licence. The Committee noted that a CQC proposal to cancel his registration had been withdrawn as on review it was considered not to have been a proportionate step before using the enforcement tool of warning notices.

6. The Committee noted that since April 2012, centres carrying out only HFEA licensed activity in England are not required to also be registered with CQC. When the CQC registration status of St Jude's is finalised the HFEA Executive will consider whether any further regulatory activity should be

undertaken by HFEA to be assured of the suitability of the centre's practices and premises with particular reference to responsibilities assumed by HFEA in April 2012. The Committee will receive specific information regarding this at its meeting in March 2014.

7. The Committee noted that the PR continues to be subject to a 'fitness to practice' investigation by the GMC and his registration is subject to conditions imposed on 15 August 2013 by the Interim Orders Panel of the GMC. Further to the Interim Orders Panel hearing on 6 November 2013, the conditions imposed on 15 August 2013 remain unchanged. In summary, there is currently no restriction on the PR's clinical practice. The GMC is hopeful that it will be in a position to provide further information to the HFEA on the findings of the investigation by the end of January 2014. The Committee noted that the origins of the GMC investigation appear to be concerns raised by the Wolverhampton Clinical Commissioning Group ("CCG") and the CQC. The PR's response to the CCG concerns are summarised in the submissions prepared for the Medical Practitioners Tribunal Service Interim Orders Panel.

8. The Committee noted that some of the recommendations from the HFEA inspectorate are still outstanding and are due to be completed by the end of January and also evidence of the continued implementation of the recommendations agreed in October 2013. These will be reported on at the next meeting of the Licence Committee in March 2014.

9. The Committee noted that the centre's licence will expire on the 31 January 2014 which is before the next meeting. The Committee noted that a Special Direction will need to be issued to allow the continuation of licensed activities at this centre if the licence is not renewed before 31 January 2014. It discussed all of the tabled papers and noted in particular that the PR urged it to renew the centre's licence in full rather than imposing Special Directions

10. The Committee were reminded by their Legal Adviser of the appropriate approach in such cases in particular:

    a. That notwithstanding the power to make Special Directions, the Authority's model of licensing should wherever possible seek to have licensed activities conducted under a licence rather than under special directions and the use of such directions should therefore be carefully justified.
    b. The Committee could today determine the renewal application but it might reach a point where it remained unsatisfied as to the PR's ability to discharge his duties under section 17 of the Act. The legal phrase in the act was that that Authority had to be "satisfied that the character of [the PR] is such as is required for the supervision of the activities and that the individual will discharge the duty under sections 17 of this Act".
    c. If the Committee could not be satisfied about the PR's ability (given the available evidence) it would not be able to grant the licence.
    d. If the Committee considered that it needed further information to decide this issue it might decide that the fair and reasonable thing to do would be to adjourn and to reach no "decision" as to the grant/renewal of the licence at today's meeting.

e. However if the Committee decided it was necessary to adjourn it should consider the imminent expiry of the licence and whether it was appropriate to issue special directions on this occasion. It would need to consider the terms and length of any such directions.

Decision

11. The Committee agreed to adjourn the decision of this renewal application until the Licence Committee meeting in March to await the full completed report from the Executive incorporating both the CQC and the GMC's additional information (if available) and, most importantly, the centre's compliance with implementing the recommendations outlined within the HFEA's inspection report.

12. The Committee urged the PR to ensure that the recommendations within the HFEA report are completed within the specified timeframes and that evidence of this is provided to the executive. The Committee noted that the initial report was issued in October 2013 and that the centre has been given considerable time to implement the recommendations. It was aware that at the time of inspection there were a number of areas of practice that were non-compliant including two critical, seven major and five other areas of non-compliance. By the time the report was prepared the PR had provided satisfactory responses to a number of these issues but it was suggested further time, including some deadlines of 31 January 2014, to provide evidence of satisfactory compliance in the outstanding areas.

13. The Committee noted the progress the PR has indicated he has made in his additional documents and considered that if the inspectorate could verify these matters and provide an updated report (and recommendation) it would be in a much better position to make the decision as to renewal.

14. The Committee agreed to issue a Special Direction for the continuation of the centre's current licensed activities when the current licence expires (for a period of 3 months) from 1 February 2014 until 30 April 2014. The Committee considered that this period was appropriate, noting that the matter was expected to return to Licence Committee at its meeting on 13 March 2014.

Signed: Date: 30/01/2014

Andy Greenfield (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) or Licence Committee (LC) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 19 & 20 June 2013
Purpose of inspection: Renewal of a licence to carry out 'Treatment with Storage'

Inspection details:

The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Date of Licence Committee: 7 November 2013

Centre name	St Jude's Women's Hospital
Centre number	0198
Licence number	L/0198/7/b
Centre address	263 Penn Road, Wolverhampton, West Midlands, WV4 5SF
Person Responsible	Mr Jude Harris Adeghe
Licence Holder	Dr Chaman Lal
Date licence issued	1 February 2010
Licence expiry date	31 January 2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
The St Jude's Women's Hospital has held a licence with the HFEA since 2002 and provides a full range of fertility services.

The centre provided 244 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2013. In relation to activity levels this is a small centre.

The centre has a satellite agreement with its sister clinic, St Jude's Hospital Newcastle-under-Lyme.

The centre was previously inspected by the HFEA in October 2011. This was an interim inspection, and was announced and conducted over two days, one week apart. The inspection continued to a second day because information brought to light during an audit of the centre's records prompted further exploration relating to 'traceability' and systems and processes in place protecting patient and donor confidentiality. These additional issues were addressed to the satisfaction of the inspection team on the second visit. Further to the inspection, recommendations for improvement were made in relation to three areas of 'critical' non-compliance, four areas of 'major' non-compliance and six 'other' areas of non-compliance.

At the time the report was considered by the Executive Licencing Panel (ELP) the Person Responsible (PR) had provided evidence that all 'critical,' one 'major' and two 'other' areas of non-compliance or areas of poor practice had been addressed. The PR had given a commitment to implement the remaining areas of non-compliance within the time scales required. The ELP noted that the inspectorate was awaiting two audit reports, most significantly an audit to assess the traceability of donors to recipients. In the light of this and the implementation of other recommendations awaited, the ELP adjourned a decision on the continuation of the centre's licence until such time as the audits were presented and the inspectorate could assess the centre's response to the recommendations and subsequent level of compliance.

The PR requested additional time be granted to allow sufficient time to address the issues. The centre's small team was cited as a reason, in particular its ability to undertake work additional to patient treatment and consultations coupled with a recent reduction in staffing, notably one of the two qualified embryologists. This request was agreed by the Executive. A subsequent request to extend the time to complete the audits was made by the PR. This was also agreed. The Executive reported to the ELP on 14 December 2012 at which point one audit remained outstanding. The report recommended the continuation of the centre's licence without additional conditions on the understanding that:

- the outstanding audit be submitted to the centre's inspector by 1 January 2013 and;
- the centre's anticipated licence renewal inspection (incorporating an audit of information) planned for 2013 (licence expires 31 January 2014) should be scheduled for early summer (May / June 2013) in order to ensure the centre is inspected once again within the next six months (approximately) and;

- to allow a significant amount of time for the implementation of any recommendations resulting from that full inspection in good time ahead of the centre's licence expiry date.

The ELP endorsed the inspectorate's recommendations.

The outstanding audit was provided to the centre's inspector in January 2013.

Activities of the centre:

Type of treatment	Number of treatment cycles for the period 1 June 2012 – 31 May 2013
In vitro fertilisation (IVF)	29
Intracytoplasmic sperm injection (ICSI)	171
Gamete intrafallopian transfer (GIFT)	0
Frozen embryo transfer (FET)	44
Donor insemination (DI)	0
Partner insemination (1 Jan 2013 – 31 Dec 2013)	7

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓

Outcomes*

For IVF and ICSI, HFEA held register data for the period March 2012 to February 2013 show the centre's success rates are in line with national averages with the exception that clinical pregnancy rates following IVF in patients aged less than 37 years were lower than average at a statistically significant level. However, current outcome data for this patient group shows that the centre's success rates are now in line with national averages.

In 2012 the centre reported 7 cycles of partner insemination with 1 pregnancy. This clinical pregnancy rate is consistent with the national average.

The centre's multiple clinical pregnancy rate for the time period between 1 April 2010 and 31 March 2011 for all IVF, ICSI and FET cycles for all age groups was 21%: this represented performance that was not considered likely to be statistically different from the no greater than 20% multiple live birth rate target for this period. However, the actual multiple live birth rate for this centre during this period was 35%. This represented performance that was significantly higher than the 20% target set for this period.

Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 19%: this represents performance that is not likely to be statistically different to the no greater than 15% multiple live birth rate target for this period.

*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. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

Summary for licensing decision

The Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that were non-compliant including two critical, seven major, and five 'other' areas of non-compliance or poor practice as follows:

Critical areas of non-compliance:

- The PR has failed to ensure that no gametes or embryos are retained in store beyond their statutory or consented storage period.
- The PR has failed to ensure that all critical processes are validated or that validation is documented.

Major areas of non-compliance:

- The PR has failed to ensure that witness checks are consistently recorded at the time of the procedure.
- The PR has failed to ensure that:
  - a review of the quality management system has taken place in the last year;
  - effective mechanisms for document control can be demonstrated;
  - standard operating procedures and quality indicators are established and critical procedures and processes have been audited within the last two years as specified in the body of the report.

- The PR has failed to ensure that patients and donors are screened for anti Hepatitis B core antigen (anti-HBc).
- The PR has failed to ensure that sufficient staff and resources are available as required to ensure demonstration of compliance with HFEA requirements or that there are documented procedures for staff management that ensure all staff have initial induction, basic training, updated training as required and on-going competence assessment.
- The PR has failed to ensure that all critical equipment and technical devices are validated and/or that the validation is documented.
- The PR has failed to ensure that a multiple birth minimisation strategy (MBMS) is in place which is compliant with the requirements of Directions 0003 and that the strategy is subject to regular audits and evaluations of the progress and effectiveness of the strategy. A summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer as set out in the strategy is not maintained.
- The PR has failed to comply with the data submission requirements set out in Direction 0005.

'Other' areas of non-compliance or poor practice that require improvement:

- The PR has failed to ensure that patient information, including that provided in cards displayed or other communications with centre staff is kept confidential and disclosed only in the circumstances permitted by law.
- The PR has failed to ensure that donor information forms supplied to the HFEA in accordance with donor registration form guidance include pen portrait and goodwill message sections.
- The PR has failed to ensure that the facilities provided for counselling are suitable or to ensure the clinic environment is consistently clean to an acceptable standard.
- The PR has failed to ensure that the consent period recorded in the 'bring forward' system database consistently accurately reflects that recorded in the patient's primary medical record.
- The PR has failed to ensure that the procedures for submitting consent to disclosure consent information to the HFEA identify where there may be obstacles to providing the correct information consistently and where identified, making corrections to data already submitted.

Following the renewal inspection the Executive considered that inadequacies identified in the formal, documented validation and audit of critical processes could pose a risk to the safety and quality of gametes or embryos and to the outcomes of treatment. The Executive concluded that the degree to which the centre's practices are suitable could not be fully assessed and therefore could only conclude that the centre's practices are unsuitable. On the basis of this and the evidence of non-compliance with the Act, standard licence conditions and Directions described in the body of this report, the Executive concluded that the PR had failed to adequately discharged his duties under section 17(1)(c), (d) and (e) of the HF&E Act 1990 (as amended) and therefore could not confidently recommend the renewal of this centre's licence.

In consideration of this, the PR was given an opportunity to provide to the HFEA by 19 October 2013, an action plan to robustly demonstrate how key recommendations for improvement would be implemented. The Licence Committee is asked to note that the PR

has provided documentation as evidence that these recommendations have largely been acted upon as detailed in the section of this report 'Areas of practice requiring attention by 19 October 2013'. Overall the Executive is satisfied with the PR's response and initial actions taken by the centre regarding the key recommendations made. However, the Executive considers that a period of monitoring is now required in order for the PR to demonstrate that these recommendations are implemented in practice and are effective before a conclusion on the suitability of practices can be reached.

Additionally, the Executive is of the opinion that relevant factors regarding actions in progress by other regulators are to be considered, namely:

- Concerns have also been raised by the Care Quality Commission (CQC) regarding the centre's ability to demonstrate compliance with essential standards as described in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. In particular the report of their May 2013 inspection, published in July 2013 refers to action needed as regards supporting workers (induction and training); assessing and monitoring the quality of service; and record keeping. A further inspection was conducted on 30 September 2013; to date the report of this inspection has not been published. Whilst the Licence Committee must take into account performance in relation to HFEA requirements, attention is drawn to this report as the findings are material and there are parallels with HFEA findings. .
- The PR is currently subject to a fitness to practice investigation by the General Medical Council (GMC) and his registration is subject to conditions imposed on 15 August 2013 by the Interim Orders Panel of the GMC.

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), and other material information, the Executive considers that there is currently sufficient information to conclude that:

- the PR is suitably qualified for the role
- the premises are suitable;
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

Recommendation to the Licence Committee

The Executive considers that there is currently insufficient information to conclude that:

- the PR is suitable and has discharged his duties under section 17(1)(c), (d) and (e) of the HF&E Act 1990 (as amended);
- the practices are suitable.

Section 16 (1) of the Act gives the Authority the power to grant a licence where the requirements of section 16(2) are met. Amongst other requirements, Section 16(2)(b)(ii) requires the Authority to be satisfied that the applicant, in this case the Person Responsible, is a suitable person to hold a licence. As set out above and as detailed in

the body of this report, the Executive considers there is currently insufficient information available to make a recommendation as to the suitability of the Person Responsible.

In addition, as detailed above, the outcomes of the CQC and the GMC proceedings, which may be relevant to any consideration of the suitability of the Person Responsible, are not yet known.

In light of the lack of information upon which to assess the suitability of the Person Responsible, the requirement of section 16(2)(b)(ii) of the Act cannot be met and thus at present, it is the Executive's view that the Authority does not have the power to grant a licence.

The Executive recommends that the fair, reasonable and proportionate step to take in the circumstances is to permit the centre to continue operating under the supervision of the Person Responsible thus affording the Person Responsible further time to:

- demonstrate that the corrective actions implemented following the inspection have been effective in ensuring that practices are suitable. The centre needs to be active in order to assess this and it is expected that the demonstration of the effectiveness of measures overall, will not be possible until March 2014;
- demonstrate implementation of further recommendations regarding non-compliances identified in this report within specified time frames and;
- allow the Executive the opportunity to monitor the centre's overall performance and consider the outcome of actions taken by other regulators.

The Executive recommends that Licence Committee issue Special Directions to allow the centre to continue to operate from the date the centre's licence expires on 31 January 2014 to 30 April 2014. The Executive will present an executive update to this report to Licence Committee in March 2014 with any further recommendations that it is able to make at that time.

The Authority's power to issue Special Directions for the purpose of dealing with a situation arising in consequence of a licence ceasing to have effect, as this licence will on 31 January 2014, are set out in section 24 (5A), (5B) and (5C) of the Act.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient, and children born following treatment

Witnessing and assuring patient and donor identification (Guidance note 18)

What the centre does well.

The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are partially compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

Witnessing steps observed during the inspection included those for sperm preparation and preparation of eggs and sperm for ICSI. Witnessing was performed in accordance with CoP requirements except as noted below. Records of all required witnessing steps were present in 10 sets of notes audited on inspection, with three exceptions, also noted below. (SLC T71 & CoP Guidance 18.4).

What the centre could do better.

During observations of witnessing procedures the scientific inspector observed three occasions on which the witness did not sign the witnessing record sheet contemporaneously. During the preparation for ICSI the witness (a different witness to the previous procedure) failed to sign the witnessing record for one step witnessed and had to be reminded to sign the record following a further witnessing step. (SLC T71)

The trainee embryologist and other members of the team responsible for witnessing could not provide evidence of training or documented assessment of competence to conduct witnessing procedures. (SLC T15(a))

In two of the 10 sets of patients' notes audited, the patient providing a sperm sample had not signed to confirm his identity and that the sample was his. In one other record the witness had not signed to confirm the identity of the sperm provider and his sample. (SLC T71)

Laboratory staff could not provide evidence of having established quality indicators or objectives relative to witnessing procedures. (SLC T35)

The senior embryologist provided a document dated 2012 which stated 'witnessing audit 100%' but the document did not provide any further detail. The inspection team

considers that this does not constitute sufficient evidence of a documented audit of witnessing practices for compliance with witnessing protocols, regulatory requirements and quality indicators. (SLC T36)

Patient and donor selection criteria and laboratory tests

- Screening of patient and / or donors prior to procuring, processing and / or transporting gametes and embryos (Guidance notes 11 and 15)
- Payments for donors (Guidance note 13)
- Donor assisted conception (Guidance note 20)

What the centre does well.

Screening of patients and / or donors (Guidance notes 11 and 15)

The centre's procedures for screening patients are broadly compliant with HFEA requirements with two exceptions noted below. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13)

The centre does not recruit donors directly, known egg or sperm donors are not provided with monetary compensation. The centre provides a limited egg share scheme. Egg sharers are not compensated beyond the provision of treatment services.

Donor assisted conception (Guidance note 20)

People born as a result of donation are entitled to request and receive their donor's name and last known address, once they reach the age of 18. Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre is broadly compliant with the requirements of the HFEA to ensure the donor conceived will be able to receive this information with the exception noted below.

What the centre could do better.

Screening of patients and / or donors (Guidance notes 11 and 15)

In records reviewed on inspection it was noted that one known donor had not been screened for Neisseria gonorrhoea.

Gamete providers are not screened for anti-HBc before their material is stored and/or processed. (SLC T50)

Donor assisted conception (Guidance note 20)

Pages 3 and 4 of the donor report contain the donor's pen portrait and goodwill messages. This ensures that, when a valid 'opening the register' request is made to the HFEA by the parents of a donor conceived child or in time, a donor conceived child, that information is readily available to the applicant. A copy of these pages should be sent to the HFEA at the time of donor registration, regardless of whether the donor had chosen to provide a message. A check made by the register team identified that these pages are missing for 19 donors registered between 2008 and 2012. The relevant details have been provided to the PR for correction.

Good clinical practice

What the centre does well.

Multiple births (Guidance note 7)
The single biggest risk of fertility treatment is a multiple pregnancy. The centre's current clinical multiple pregnancy rates suggest that the centre is likely to meet the HFEA's multiple birth rate target.

Traceability (Guidance note 19)
The centre's procedures are partially compliant with HFEA requirements to ensure it has the ability -
(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
(b) identify the donor and recipient of particular gametes or embryos,
(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and
(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety with the exception noted below.

The centre demonstrated that all containers used in the procurement, processing, use and storage of gametes, (including tubes used to collect follicular fluid during egg collection) are labelled and identifiable. The centre also practices a 'clean down' of areas after egg collection.

Quality management system (Guidance note 23)
The centre has a quality management system in place which is partially compliant with requirements with the exceptions noted in the body of this report and in the section below. The PR is also the centre's quality manager. The PR reported that a new quality management computer software package was installed three months ago and that he was now beginning to migrate the centre's quality management information into this system. It was not possible to see the software in use on inspection. The PR also stated that the centre was due an International Organisation for Standardisation (ISO) inspection in August 2013 following their last ISO inspection two years ago. Standard Operating Procedures (SOPs) were seen for the majority of the centre's key activities. The PR was able to provide evidence of quality indicators and audit for a number of procedures and processes undertaken at the centre. A patient satisfaction survey has been conducted within the last year. Evidence of periodic staff meetings where quality and outcome issues were discussed was also seen. There is a documented laboratory manual in use and the majority of key laboratory SOPs were seen to be version controlled.

Third party agreements (Guidance note 24)
The centre has agreements in place which cover the :
(a) procurement, testing or processing of gametes or embryos on behalf of the licensed centre, or
(b) supply of any goods or services (including distribution services) to the licensed centre which may affect the quality or safety of gametes or embryos.

Transport and satellite agreements (Guidance note 24)
The centre has systems in place to manage satellite activities that are compliant with HFEA requirements. This ensures that activities performed at the satellite clinic on behalf of the licensed centre are suitable. All activities conducted at the satellite clinic are conducted by centre 0198 staff and are subject to the centre's quality management measures.

ICSI (Guidance note 21)
The centre has an SOP to direct the practice of intra-cytoplasmic sperm injection (ICSI) and monitors ICSI fertilisation rates monthly as a quality indicator. Only the senior embryologist conducts ICSI and was able to demonstrate training and continued competence.

Equipment and materials (Guidance note 26)
All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff. Validation of critical equipment is in place with one exception noted below.

Premises (Guidance note 25)
The centre conducts all of the licensed activities in an environment considered to be appropriate, in line with good clinical practice. All diagnostic testing of blood is performed at Clinical Pathology Accreditation (UK) (Ltd) (CPA) accredited laboratory.

The centre performs diagnostic semen analysis but the laboratory is not CPA accredited. However, the centre has a quality management system (QMS), validated equipment for semen analysis and Health and Care Professions Council (HCPC) registered staff suitably qualified to perform semen analysis and interpret results. The centre also participates in the national external quality assessment scheme (NEQAS) for semen analysis. The results of the most recent assessments conducted in June 2013 were provided to the centre's inspector and are considered to satisfactory. The centre is therefore considered to be broadly working to a standard equivalent to CPA for diagnostic semen analysis with the exception noted below regarding process validation. (SLC T21)

Adverse incidents (Guidance note 27)
The centre has reported no adverse incidents (including serious adverse, near miss events or serious reactions) to the HFEA since 2006. The centre's incident log did not reflect any incident that should have been reported to the HFEA. The centre's SOP for incident management and reporting was reviewed on inspection and was considered to be compliant with HFEA requirements. Incident reporting was discussed and the PR agreed that if he or his team had any debate regarding what constitutes an incident reportable to the HFEA he would consult the centre's inspector or the HFEA Lead for Clinical Governance for advice.

What the centre could do better.
Multiple births (Guidance note 7)
The strategy provided for review on inspection was that produced in 2008 by a Primary Care Trust commissioning treatment for patients at the centre. There was no evidence that this strategy had been reviewed since then. This was not considered to be a current multiple birth minimisation strategy which accurately reflects the requirements of Directions 0003.

A summary log is kept of all multiple embryo transfers but this log does not record which of those patients was eligible for elective single embryo transfer. (Directions 0003).

Traceability (Guidance note 19)

The centre does not have an SOP which directs procedures for the traceability of consumables and equipment which come into contact with gametes or embryos. (SLC T33(b))

The centre has not established quality indicators related to traceability. (SLC T35)

The centre has not audited their traceability procedures (equipment and materials) for compliance with approved protocols, regulatory requirements and quality indicators in the last two years. (SLC T36)

Evidence of training and the documented assessment of competence in traceability procedures for relevant staff could not be provided on inspection. (SLC T15(a))

Process Validation(Guidance note 15)

The centre has not documented the validation of all critical processing procedures to ensure that these procedures are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient. A document 'Process for clinical and embryology validation' was provided at inspection which appeared to be a template document but was not populated. (SLC T72)

ICSI (Guidance note 21)

It was noted that the centre practices a high ratio of intra-cytoplasmic sperm injection (ICSI) to in-vitro fertilisation (IVF) procedures. Of 200 cycles of fresh IVF / ICSI treatment cycles conducted in the year to 31 May 2013, 83% were ISCI. The rationale for using ICSI was noted in patient records seen on inspection in all cases where ICSI was used. The high incidence of ICSI was discussed with the senior embryologist who stated that the decision to provide ICSI was made according to the prescribed criteria and the clinical decision of the PR. The senior embryologist was able to provide a copy of the centre's criteria for using ICSI.

The centre's validation of their ICSI processes has not been documented. (SLC T72)

The centre has not audited their procedures for ICSI for compliance with approved protocols, regulatory requirements and quality indicators in the last two years. (SLC T36)

Quality management system (Guidance note 23)

It was noted during the course of the inspection that there were significant 'gaps' in the overall quality management system as detailed in the related parts of this report and in the section 'Areas of practice requiring attention' regarding:

- the provision of SOPs for certain activities (SLC T33(b)) namely:
    - information to be provided prior to consent;
    - traceability of consumables and equipment
- evidence of training and reference manuals (nursing) for all relevant staff (SLC T33(b) SLC T15 CoP guidance 2.1, 2.2, 2.11), namely:
    - evidence of documented procedures for staff management that ensure all

staff have:
    - (a) initial basic training and updated training as required namely;
        - satisfactory evidence of induction and basic training for trainee staff
    - (b) on-going competence assessment, with audits of this assessment namely:
        - witnessing
        - welfare of the child assessment
        - consent
        - information to be provided prior to consent
        - traceability
- an effective document control system which ensures all key documents are version controlled to ensure that only the current document is in use (SLC T34);
- establishment of quality indicators for all key activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence (SLC T35) namely:
    - witnessing
    - information to be provided prior to consent
    - consent
    - traceability
    - procurement and processing procedures (including IVF)
    - submission of data to HFEA
- documented audit, corrective actions and implementation of actions for activities and processes authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence against compliance with the regulatory requirements and their own approved protocols and quality indicators at least every two years namely:
    - witnessing
    - information to be provided prior to consent
    - consent
    - traceability (consumables and equipment)
    - procurement and processing procedures (including IVF)
    - ICSI
    - submission of data to HFEA

Equipment and materials (Guidance note 26)

The gamete and embryo storage dewars have not been validated. (SLC T24)

Premises (Guidance note 25)

The centre is housed within a large converted residential dwelling; the premises were, overall considered suitable. It was however noted that the room allocated to the counsellor is situated under the stairwell in an annex to the main building. The area is dark, sparsely furnished and has little access to natural light. Though somewhat 'jaded' in parts, the premises appeared to be clean at the time of inspection but a collection of dust was noted on several pieces of equipment in the consultation room. Negative comments were noted regarding the fabric and cleanliness of the premises by two of 11 people providing written feedback to the HFEA about their experiences. (See section 2).

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance note 1)

The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

The PR has academic qualifications in the field of medicine and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

The PR has successfully completed the HFEA PR Entry Programme certificate number T/1095/7.

Staff (Guidance note 2)

The centre is broadly compliant with the requirement to have suitably qualified and competent staff in sufficient number to carry out all of the licensed activities and associated services except for concerns expressed below.

What the centre could do better.

Person Responsible (Guidance note 1)

The PR has not fully discharged his duties under section 17(1) (d) and (e) of the HF&E Act 1990 (as amended) as:

- the PR is unable to demonstrate that the conditions of the licence are complied with as described in the body of this report;
- the suitability of practices could not be fully assessed in the absence of formal process validation and audit findings for key licensed activities

Staff (Guidance Note 2)

While it is acknowledged that the centre's activity levels are small and, on inspection there appeared to be sufficient numbers of staff to accommodate the current level of licensed activity, it appears that there may not be sufficient resource available to ensure demonstrable compliance with HFEA requirements.

This concern is based on the following observations:

- the team is small;
    - the PR is the only clinician practicing at the centre and is also the quality manager. Time available to him and other key members of the team to develop and maintain the quality management system adequately in order to demonstrate regulatory compliance appears to be very limited;
    - there are currently two Nursing and Midwifery Council (NMC) qualified nurses, one of whom is the lead nurse who is responsible for day to day nurse consultations, provision of information and treatment pathway organisation. The lead nurse is responsible for the submission of data to the HFEA. Both she and the PR also provide consultations and monitoring of

patients at the centre's satellite clinic. The second nurse is a relatively recent appointment and has no previous experience of fertility nursing, on inspection the PR told the inspection team that it was likely this nurse was leaving to take up another post;
    - there is one full time Health and Care Professions Council (HCPC) registered embryologist and one part time trainee who is in the early stages of training and is not yet eligible for registration with HCPC; the senior embryologist described that her role is currently limited to supervised andrology and witnessing;
- historically the centre has required repeated extensions to the time allowed for the implementation of compliance recommendations; the reasons cited being the availability of staff time to address these matters.

These concerns are reinforced by the current findings of this report whereby a significant number of non-compliances have been identified, many relating to evidence of training and quality management issues. The information team of the HFEA also report major delays in the reporting of required data to the HFEA. The implementation of corrective actions as recommended in this report will require significant resource in order to demonstrate compliance within the required timeframes and to a standard satisfactory to the HFEA. (SLC T12)

Although there was no apparent cause for concerns about the competence of experienced staff, not all staff were able to provide evidence of training or the documentation of their competence to participate in licensed activities. The induction and training file for the nurse in training requested on inspection could not be provided as the nurse was not on duty and the file was said to be in her possession. At the time of writing, documented evidence of her has not been provided by the centre subsequently. Evidence of induction and training for the trainee embryologist available on inspection was considered by the inspection team to be incomplete and did not provide meaningful detail. (SLC T15)

Welfare of the child (Guidance note 8)

What the centre does well.

The centre's procedures for taking into account the welfare of the child are broadly compliant with HFEA requirements. The centre takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth.

What the centre could do better.

No evidence of training or documented assessment of competence to conduct welfare of the child assessments could be provided on inspection. (SLC T15(a))

2. The experience of patients

Patient feedback

What the centre does well.

During the inspection visit a member of the inspection team spoke to three patients who provided feedback and commented positively on their experiences. A further 11 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was mixed, five of the individuals providing feedback commented that they have compliments about the care that they 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 of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better.

Three of the individuals providing written feedback to the HFEA commented that they have complaints about the service they received. All of those who commented that they had complaints about the centre made reference to the degree of cleanliness and fabric of the premises and about their care appearing to be disorganised.

Treating patients fairly

What the centre does well.

Counselling (Guidance note 3)

The centre's counselling procedures are compliant with HFEA requirements, ensuring that counselling support is offered to patients and donors providing relevant consent.

Gamete sharing arrangements (Guidance note 12)

The centre facilitates egg sharing. Procedures for egg sharing arrangements are compliant with HFEA requirements to ensure that:
(a) care is taken when selecting egg providers donating for benefits in kind
(b) egg and sperm providers are fully assessed and medically suitable, and
(c) the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)

The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements to ensure that the arrangement is legal and protects the rights of the surrogate and the commissioning couple. Patients providing gametes in surrogacy arrangements are screened as donors in order to safeguard the health of the surrogate.

Complaints (Guidance note 28)

The centre's complaints log was reviewed on inspection. The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. The centre uses any complaints as an opportunity to learn and

improve their services.

Treating patients fairly (Guidance note 29)
The centre appears to treat prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are broadly compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors

What the centre could do better.
Confidentiality and privacy (Guidance note 30)
It was noted on inspection that a large number of 'thank you' cards and pictures sent to the PR and staff are on display in the waiting room and consulting rooms at the centre. A great many of these cards displayed contained identifying information about those being treated, included the home address or email address of those treated. (SLC T43 CoP Guidance 30.1)

Information

What the centre does well.
Provision of information
The centre's procedures for providing information to patients and / or donors are compliant with HFEA requirements with the exception noted below. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

Provision of a costed treatment plans (Guidance note 4)
The centre provides a costed treatment plan to all of its self-funding patients. This ensures that patients know the full cost of their proposed treatment before deciding on whether to proceed or not.

Responsible use of websites (Chair's letter CH(11)02)
The centre's website is complaint with Chair's letter CH(11)02. Reference to their satellite centre declares that part of the treatment will take place at the primary centre.

What the centre could do better.
An SOP for the procedure to be followed when providing information to patients consenting to treatment, donation or donation for use in training could not be provided on inspection. (SLC T33(b))

Quality indicators relative to the provision of information have not been established or monitored against. (SLC T35)

The centre's procedures and processes for the provision of information have not been audited for compliance with approved protocols, regulatory requirement and quality indicators in the last two years. (SCL T36)

Consent

What the centre does well.

Consent (Guidance note 5)
The centre's procedures for obtaining consent are broadly compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research
The Register started operating in August 1991 and is a rich source of information about assisted reproductive technologies (ART), its outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA is permitted to disclose non-identifying information to researchers it can only provide identifying information with the consent of patients and donors. Therefore, it is important that patients and donors are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA.

The centre's procedures for doing this are broadly compliant with HFEA requirements with the exception noted below: this ensures that the HFEA holds an accurate record of the patient or donor's consent, so that it only releases identifying information, to researchers, with their consent with the exceptions noted below.

What the centre could do better.

Consent (Guidance note 5)
The centre has not established quality indicators relevant to consent procedures. (SLC T35)

The centre has not audited procedures for taking consent for compliance with approved protocols, regulatory requirements and quality indicators in the last two years. (SLC T36)

Disclosure of information, held on the HFEA Register, for use in research
An audit comparing patient and partner disclosure consents found on the patient files and related data submitted by the centre for inclusion in the register was conducted by the register team as part of the register audit conducted on a licence renewal inspection. One issue was identified.

One patient who had been registered and treated before the introduction of consents to the use of register information for research purposes had subsequently returned for further treatments and completed the consents. This patient withheld consent to non-contact or contact research but consent variation (CV) form has not been submitted to the HFEA register to reflect this.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well.

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- Licensed activities only take place on licensed premises.
- Only permitted embryos are used in the provision of treatment services.
- Embryos are not selected for use in treatment for social reasons.
- Embryos are not created by embryo splitting.
- Embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman.
- Embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better.

Nothing noted on inspection.

Storage of gametes and embryos

What the centre does well.

The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical therapies such as oncology or surgery. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without additional invasive procedures being performed for egg collection.

To assess the efficacy of the centre's bring forward system, which affords patients sufficient warning of the expiry of their consented storage period to decide if they wish to continue storage, a sample audit was conducted on inspection. The consent recorded in the patient record was compared with the consent decision recorded on the centre's 'bring forward' data base for three sets of embryos and three sperm samples nearing the end of their consented storage period. All samples were being stored within their consented storage period but the centre's database recorded an incorrect consent expiry date for one set of embryos as described below.

The centre's procedures for storing gametes and embryos are partially compliant with HFEA requirements. These measures are to ensure that the gametes and embryos are stored appropriately to maintain their quality and safety and in accordance with the consent of the gamete providers.

What the centre could do better.

Storage of gametes beyond the statutory storage period.

On the day of the inspection the centre was storing the gametes of one patient beyond the statutory storage period and one beyond the consented storage period. (Schedule 3, 8(1)

HF&E Act). The circumstances surrounding this were explained. One patient's gametes were stored for the preservation of fertility in 1999 at another licensed centre prior to the patient having oncology treatment. Samples for continued storage were transferred to centre 0198 when that centre ceased to operate as a licensed centre.

The centre provided evidence that they have tried on numerous occasions over a number of years since 2009 to trace the patient but had failed. The PR explained that the gamete provider was a young man at the time his sperm was stored and in the light of this the PR stated that he is very reluctant to allow the samples to perish as it cannot be determined whether the patient is living but has not yet considered having a family. There is no evidence of a medical endorsement that the patient is still infertile. The PR stated that he is unfamiliar with the patient's specific circumstance so cannot provide an opinion himself as to whether the patient's fertility is still impaired.

A second sample for which consent for storage expired in 2012 remains in store.

'Bring forward' system
It was noted during the sample embryo storage audit that in one instance the consent expiry date recorded in the centre's bring forward system differed from that recorded in the patient's record.

Distribution and / or receipt of gametes and embryos

What the centre does well.
The centre's self assessment questionnaire (SAQ) states that the centre does not distribute gametes or embryos or contact a third party to distribute gametes or embryos. This was confirmed on inspection.

The centre does very occasionally receive donor gametes from other licensed centre suppliers in transport equipment provided by the supplier. The centre's procedures for distributing and / or receiving gametes were not reviewed in detail during the course of this inspection on the basis of the SAQ. On this limited basis however, it is concluded that the centre is compliant with HFEA requirements for the receipt of gametes and embryos.

What the centre could do better.
Nothing noted on inspection.

Use of embryos for training staff (Guidance note 22)

What the centre does well.
The centre does not use embryos for training staff.

What the centre could do better.

4. Information management

Record keeping and submitting information to the HFEA

What the centre does well.

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are partially compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a result of their donation. In order to maintain this Register, Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

To confirm that data submitted by the centre for inclusion on the register accurately reflects that found in primary records held at the centre, a sample of assorted data submissions were reviewed against that held on the HFEA register.

No critical errors or omissions were found in the data submitted (i.e. errors that would prevent the authority fulfilling its statutory obligations) with the exception noted below.

The centre's procedures for submitting information, about licensed activities, to the Authority are partially compliant with HFEA requirements and ensure the HFEA can supply accurate information to a donor-conceived person and their parents, the exceptions are noted below.

What the centre could do better.

Record keeping and document control (Guidance note 31)
Documents reviewed during the course of the inspection provided no evidence of a consistent method in place to ensure that only the current version of authorised documents is in use. A number of key documents viewed had no indication of authorisation or date control. (SLC T34)

Obligations and reporting requirements (Guidance note 32)
Only 5% of treatments in the audit sample of treatment data submitted to the HFEA register were reported within the five days of treatment taking place as required by Direction 0005. Treatment reporting was very late with 56% of treatments more than 60 days late and 33% of treatments 90 days late. The failure to report promptly will impact on the HFEA's risk based assessment tool (RBAT) information and outcome and activity reporting of the centre's performance.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2011, recommendations for improvement were made in relation to three areas of critical non-compliance, four areas of major non-compliance and six 'other' areas of non-compliance.

Prior to the report being presented to the ELP, the PR provided information and evidence that recommendations relating to three critical, one major and two 'other' areas of non-compliance had been fully implemented.

The PR requested an extension to the time permitted to complete the remaining recommendations on two occasions. The outstanding recommendations have now been implemented.

A sample critical process validation was provided following that inspection, however this remains a recommendation in this report as, on inspection, evidence of validation of all critical processes could not be provided.

Areas of practice requiring action by 19 October 2013

This report sets out matters which the Executive considers require action, the actions required and the timeframes for satisfactory submission of evidence of implementation, if consideration is to be given to submitting the inspection report before a licence committee with an alternative recommendation to that which currently stands.

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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. 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	Executive Review
1. Storage of gametes and embryos On the day of the inspection the centre was storing the gametes of one patient beyond the statutory storage period. A second sample for which consent for storage expired in 2012 remains in store. (SLC T79) (Schedule 3, 8(1) HF&E Act).	The PR should ensure that no gametes or embryos are retained in store beyond the statutory or consented storage period. By 19 October 2013 where gametes remain in store beyond the statutory or consented storage period, a plan should be submitted to the HFEA documenting the centre's intended		The centre has given assurance that samples identified on inspection were allowed to perish on 26 August 2013. The update provided by the centre states that a full storage audit will be available in December 2013. The PR is to provide a copy of this audit to the centre's inspector by 31 January 2014. A further document submitted

	actions to resolve this and the anticipated timescale for their implementation. The PR should provide monthly updates to the centre's inspector on progress in implementing the proposed actions. 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.		is an audit of all samples transferred in 2006 from the closed centre. All samples are being stored within the gamete provider's consent. The Executive is satisfied with the PR's response.
2. Validation of critical processes Validation of critical procurement and processing procedures has not been documented. A process validation template and guide was seen on inspection but had not been completed. (SLC T72)	The PR should ensure that all critical processes are validated and that validation is documented. The PR should provide a list of all procurement and processing procedures		A list of processes which the PR considers critical has been provided to the HFEA, namely: Consent to treatment Pt's ability to self inject U/S follicle tracking * Egg collection *

	that are considered critical by 2 September 2013. The PR should then provide fortnightly written updates on progress in completing validation. It is expected that validation will be prioritised on the basis of risk associated with the procedure and that process validation will be complete for all critical processes by 19 October 2013 and a copy of each validation is to be provided to the centre's inspector by that date. This non-compliance is categorised as a 'major' in the Executive's 'Compliance Framework'. However, as this was a recommendation from the last inspection and would appear not to have been met and remains outstanding, it has therefore been escalated		Diagnostic sperm analysis * Sperm prep for IVF * ICSI * Embryo transfer * Embryo culture* / culture media Embryo storage / consent / bring forward system Submission of data to HFEA Screening of egg donors Communicating with patients For processes marked with * a validation document has been provided. The Executive is satisfied with the overarching documentation provided however, in order for suitable practices to be demonstrated, further detail of information supporting the validation of a sample of processes will be requested by the Executive for submission to the HFEA by 31 January 2013.

	to a critical non-compliance.		

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 to a 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 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	Executive Review
3. Witnessing During observations of witnessing procedures the scientific inspector noted three occasions in which the witness did not sign the witnessing record sheet contemporaneously. During the preparation for ICSI the witness (a different witness to the previous procedure) failed to sign the witnessing record for one step witnessed and had to be reminded to sign the record following a further witnessing step. (SLC T71) In two of the 10 sets of patients' notes audited, the patient providing a sperm sample had not signed to confirm his identity and that the sample was his. In one other record the witness had not signed to confirm the identity of the sperm provider and his	The PR should revise the process and training for recording witnessing to ensure that all witness checks are recorded at the time of the procedure with immediate effect. The PR should review the process confirming the identity of the sperm provider and his sample before a sample is accepted. The PR should provide detail of the outcome of this practice review including how any changes to practice have been implemented by 19 October 2013.		The document 'Embryology update' provided by the PR states that actions from the witnessing audit have been implemented and practice changed regarding hand over and positive ID of sperm samples. Competence assessments for contemporaneous witnessing have been revised to ensure all who witness are aware and are competent. Copies of the competence assessment to perform witnessing for current staff have been provided to the centre's inspector. A witnessing audit (raw data) and audit summary has been provided

sample. (SLC T71)			which demonstrates 96% compliance for the contemporaneous recording of witnessing steps and records corrective action - a monthly sample audit to be conducted and compliance discussed at QMS meetings to 'tighten the system' Audit appears fit for purpose. In order for suitable practices to be demonstrated, the PR is to provide a copy of the witnessing audit conducted each month to the centre's inspector commencing October 2013.
4. Quality management system The centre could not demonstrate that adequate processes are in place for reviewing the performance of the quality management system to ensure continuous and systematic improvement. (Interpretation of mandatory requirements 23A CoP guidance 23.12, 13, 14 & 15)	The PR should ensure the quality management system and all its services are reviewed at least annually. The review should identify the need for changes and opportunities for improvement. The results of the review of the quality management system should be documented and should include the decisions and actions for improving the quality management system. The PR is to provide a copy of the		The PR's response is recorded in the section 'response for the PR to this inspection report' below. The document 'Embryology update' provided states that 'QMS is in place and will be ready Dec 2013 with the introduction of software. Traceability SOP for consumables and equipment is already existing and provided. Document control will be ready in Dec 2013'.

Evidence could not be provided on inspection that SOPs are in place for: • information to be provided prior to consent; • traceability of consumables and equipment (SLC T33(b)) Evidence could not be provided on inspection to demonstrate; • establishment of quality indicators for all key activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence (SLC T35) namely: o witnessing o information to be provided prior to consent o consent o traceability o procurement and processing procedures o submission of data to HFEA	review with detail of actions required and a timescale for the implementation of those actions by 19 October 2013 The PR should ensure that SOPs are in place for the procedures identified and that a copy of each is provided to the centre's inspector by 19 October 2013. The PR should ensure that meaningful, measureable quality indicators for the areas of practice identified are established. These quality indicators and a method of monitoring the agreed quality indicators should be documented and a copy provided to the centre's inspector by 19 October 2013. The PR should ensure that a		In order for suitable practices to be demonstrated, the PR will periodically be requested to provide evidence of QI monitoring as described in the SOP 'Quality Indicators'. The PR is to provide an update to the centre's inspector regarding the status of the QMS and software installation and provide the following outstanding audits: • Information provided prior to consent • Consent • Procurement and processing procedures (including IVF) By 31 January 2014 The document provided, 'SOP Quality Indicators' is well laid out and appears comprehensive, with three overarching sections: Patient experience Laboratory Clinical outcomes Each section is comprehensively sub divided into QI's and

• documented audit, corrective actions and implementation of actions for activities and processes authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence against compliance with the regulatory requirements and their own approved protocols and quality indicators at least every two years namely: o witnessing o information to be provided prior to consent o consent o traceability (consumables and equipment) o procurement and processing procedures (including IVF) o ICSI o submission of data to HFEA The centre could not demonstrate that there is an effective document control system which ensures all key documents are version controlled to ensure that only the current document is in use.	meaningful and detailed audit of the procedures and processes specified is conducted. The order in which the audits are preformed should be prioritised on the basis of risk. The PR should submit and action plan detailing the sequence and time scale of completing the required audits to the centre's inspector by 2 September 2013. Audits of key processes, namely witnessing, ICSI, procurement and processing procedures (including IVF) are to be completed and a documented report, including corrective actions and evidence of implementation of those actions is to be submitted to the centre's inspector by 19 October 2013. As part of the quality management system, the PR should ensure all documents are effectively controlled to ensure that only the current version is in use. An action plan as to how the		assessment of activities included within that section which echoes QI requirements required by the CoP Audits provided: Witnessing Traceability – consumables Data submission

(SLC T34)	document control management system is to be revised to ensure effective control should be provided to the centre's inspector with detail of the timescales for implementation by 19 October2013.		
5. Patient and donor screening An audit of three donor records conducted on inspection demonstrated that donors are not screened for anti Hepatitis B core antigen (anti-HBc). An audit of donor records showed that one donor had not been screened for Neisseria gonorrhoea SLC T52b	The PR should ensure that all patients and donors are screened for anti Hepatitis B core antigen (anti-HBc) with immediate effect and that checks are in place to ensure that all required screening is in place before processing or storage of gametes takes place. SLC T52b. The PR should ensure that all relevant screening SOP's are updated to reflect this and that this requirement is made known to all personnel responsible for donor / patient screening. A copy of the updated SOP should be provided to the centre's inspector by 19 October 2013.		Evidence provided in a letter from the third party testing laboratory dated 02 September 2013 confirms that anti-HBc has been added to the screening profile. In order for suitable practices to be demonstrated, the PR is to provide a copy of the outstanding patient and donor screening SOP and an audit of patient and donor screening conducted between September 2013 and December 2013 to the centre's inspector by 31 January 2014.
6. Staff While it is acknowledged that the centre's activity levels are small and, on inspection there appeared to be sufficient numbers of staff to accommodate the current level of	The PR should ensure that the resources required to ensure compliance with HFEA requirements are available. The centre's inspector should be		The PR states in his response below that the centre is in the process of recruiting additional staff.

licensed activity, it appears that there may not be sufficient resource available to ensure demonstrable compliance with HFEA requirements as described in the body of this report. The centre could not provide evidence of documented procedures for staff management that ensure all staff have initial basic training and updated training as required namely; • satisfactory evidence of induction and basic training for trainee staff • on-going competence assessment, with audits of this assessment namely: o witnessing o welfare of the child assessment o consent o information to be provided prior to consent o traceability (SLC T33(b) SLC T15 CoP guidance 2.1, 2.2, 2.11),	advised of the actions to be taken in relation to this recommendation by 2 September 2013. The PR should ensure that a suitable induction plan is established and documented. A copy of the induction plan should be submitted to the HFEA before any new staff are inducted. The PR is to inform the centre's inspector of any staff changes, leavers and new starters before the event. The PR should ensure that evidence of the assessment of competence to conduct their assigned tasks for all relevant staff is documented and available on request. (SLC T15(b)) For all staff participating in witnessing procedures, documented evidence of witnessing training and competence assessments specifically should be provided to the centre's inspector by 19 October 2013.		Copies of the competence assessments to perform witnessing for current staff have been provided. In order for suitable practices to be demonstrated, the PR is to provide to the centre's inspector, a copy of the outstanding induction and training plan and competence assessments for • welfare of the child assessment • consent • information to be provided prior to consent By 31 January 2014.

7. Equipment Validation of the cryo-preservation storage dewars has not been documented. (SLC T24)	The PR should ensure that all critical equipment and technical devices are validated, regularly inspected and maintained in accordance with the manufacturer's instructions. A copy the documented validation of this piece of equipment should be provided to the centre's inspector by 19 October 2013.		Documentation regarding the validation of the dewars has been provided. The Executive is satisfied with the PR's response.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
8. Multiple births The strategy provided for review on inspection was that produced in 2008 by a Primary Care Trust commissioning treatment for patients at the centre. There was no evidence that this strategy had been reviewed since then. This was not considered to be a current multiple birth minimisation strategy which accurately reflects the requirements of Directions 0003 A log is kept of all multiple embryo transfers but this log does not record which of those patients was eligible for elective single embryo transfer. (Directions 0003).	The PR should ensure that a multiple birth minimisation strategy (MBMS) is formulated which is compliant with the requirements of Directions 0003 in that 'the strategy' identifies suitable cases for single embryo transfer (SET), including criteria in relation to embryo assessment and patient selection criteria; and identifies how the centre intends to reduce its annual multiple birth rate and to ensure that it does not exceed the maximum rate of 10% of the annual birth rate for the centre. A copy of the MBMS is to be provided to the centre's inspector by 19 October 2013. With immediate effect, where multiple embryos are transferred to a patient who meets the criteria for single embryo transfer as set out in the strategy, the centre must retain a summary log of all such instances and record this fact in the patient's		A MBMS dated 12 September 2013 has been provided which broadly encompasses the requirements of Directions 0003 in that it states the aim is compliance with the current HFEA target and sets the criteria for eSET and how this will be communicated to patients. Patient information regarding the associated risks of multiple pregnancy is incorporated into this document. The Executive is satisfied with the PR's response however in order for suitable practices to be demonstrated, the implementation of this strategy will be monitored.

	medical record together with: (a) a clear explanation of the reasons for transferring more than one embryo in that particular case; and (b) a note confirming that the risks associated with multiple pregnancy have been fully discussed with the patient. The PR is to confirm this practice is in place by 19 October 2013.		
9. Obligations and reporting requirements Only 5% of treatments in the audit sample of treatment data submitted to the HFEA register were reported within the five days of treatment taking place as required by Direction 0005. Treatment reporting was very late with 56% of treatments more than 60 days late and 33% of treatments 90 days late.	The PR should ensure the centre complies with the data submission requirements set out in Direction 0005. Working closely with the register team of the HFEA, the PR should ensure that the backlog of treatment data is submitted. Procedures for the submission of data to the HFEA should be reviewed and also the availability of suitable staff to ensure compliance with the requirements of Direction 0005. The PR is to provide an action plan as to how this back log will be addressed and actions to be taken to ensure		An audit of EDI submissions has been provided for the period July – September 2013. Actions recorded are that documented – weekly checks and three monthly audit is to be implemented to ensure compliance. QI's to this effect were also noted on the overarching QI protocol submitted. CafC sign off has been received 10 October 2013 The register team report that the backlog of submissions

Directions 0005	the timely submission of required data going forward. This non-compliance had been escalated to major due to considerable length of time taken for reporting seen in the audit sample. By 19 October 2013		has been cleared and where identified in the audit, corrections made. Samples of QI monitoring and audits conducted will be requested periodically by the Executive. The Executive is satisfied with the PR's response.

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	Executive Review
10. Confidentiality and privacy It was noted on inspection that a large number of 'thank you' cards and pictures sent to the PR and staff are on display in the waiting room and consulting rooms at the centre. A great many of these cards contained identifying	The PR must ensure that patient information, including that provided in cards or other communications with centre staff is kept confidential and disclosed only in the circumstances permitted by law. The centre should ensure that patients, their partners, and donors do not have		In his response below the RP states that this has been addressed. This will be checked at the next inspection visit.

information about those being treated, included the home address or email address of those treated. (SLC T43 CoP Guidance 30.1)	access to any other person's information without that person's consent. The PR should review this practice and, if the decision is that the centre continues to display the thank you cards and messages from those treated at the centre, identifying information as described should be redacted before display with immediate effect. The PR should inform the centre's inspector when this has been done for those messages currently displayed by 2 September 2013.		
11. Premises It was noted that the room allocated to the counsellor is situated under the stairwell in an annex to the main building was dark, was very sparsely furnished and had little access to natural light. Though somewhat 'jaded' in parts, the premises appeared to be clean at the time of inspection but a collection of dust was noted on	The PR should review the location and facilities provided for counselling and consider how, given the confines of the premises, the environment in which counselling may be improved. In the light of patient feedback and observations made on inspection, the PR should review provisions for domestic		In his response the PR states that the Counsellor considers the room suitable. The PR is to provide to the centre's inspector with an update regarding the required review of provisions for domestic services and evidence of the implementation of actions by

several pieces of equipment in the consultation room. Negative comments were noted regarding the fabric and cleanliness of the premises by two of 11 people providing written feedback to the HFEA about their experiences. (SLC T17)	services within the centre to ensure the environment is consistently clean to an acceptable standard. The outcome of these reviews should be provided to the centre's inspector and should include actions implemented for improvement. By 19 October 2013.		31 January 2014.

Reponse from the Person Responsible to this inspection report

Response provided by the PR on 19 October 2013.

PR Response to Renewal Inspection report (Centre 0198)

I wrote to you on 30th August 2013 to give my initial response to the draft report following the renewal inspection conducted on 19th and 20th June this year. In that letter I expressed the willingness and determination by all St Jude's staff to work towards correcting the non-compliances identified in the report. I outlined a four-pronged improvement plan as below:

a) Review & re-organisation of staff roles
b) Recruitment of additional staff, in particular an Embryologist / Quality manager
c) Advice / Input from external experts & practitioners on a consultancy basis
d) Re-organisation of clinic's day-to-day diary to make for more efficient working

I am pleased to say that we are making good progress towards achieving the desired goal of becoming a fully compliant centre. As you know, I have over the past 6 to 7 weeks e-mailed

to you a list of documents / information in fulfilment of the set goals. These e-mails have been sent under the caption of "PROGRESS REPORTS" and so far I have sent six such e-mails each one with several attached documents.

Below are specific examples of how we deployed our improvement plan:

1) All key members of staff have already visited other Fertility centres on "study days" (Birmingham Women's Fertility Centre – Director is Dr Sue Avery; Bath Fertility Centre – Consultant Embryologist – Dr Stephanie Gadd). These visits have been most helpful and have provided useful guidance on correcting some issues raised in your draft report

2) I commissioned an independent expert review which have been carried out by a top practitioner , Dr Sue Avery (Director of Birmingham Women's Fertility Centre). Her excellent report and guidance is providing the basis for improvement in the short, medium, and long term.

3) On the back of Dr Avery's review, St Jude's is proposing a formal co-operation arrangement between our two units whereby St Jude's staff will interact with the team in Birmingham on a regular basis for support and benchmarking.

4) I have conducted interviews to employ another embryologist /Quality manager and have identified a couple of suitable candidates. I propose to make a formal offer to the best candidate once our license is renewed. I am sure you will agree that it would be unfair and against employment laws to employ someone when there is uncertainty about our license.

5) I have also advertised for a new Fertility Nurse and have received applications from a good number of candidates. Interviews will be conducted during the week beginning 28th October. Again, suitable candidates will be identified and offers will be confirmed when our license is renewed.

6) At a junior staffing level, we already employed a Fertility Clinic Assistant and will forward details to the HFEA after the probationary 3months period.

Non-compliances that have been corrected so far

1) Submission of HFEA data is now up to date. We have defined quality indicators for submission of HFEA data and have just completed an audit of the process for the period
July to September 2013.

2) Hepatitis B Core Total antibody testing has been added to our screening tests profile

3) Gametes / Embryos in storage without valid consent have been perished

4) Significant progress have been made regarding processes and equipment validation. All equipments and processes will be fully validated by end of year 31/12/13.

5) Regarding ***Witnessing*** the clinic has now reviewed and revised it's procedures. New witnessing forms have been developed and copies will be forwarded to you.

6) The clinic has defined ***Quality indicators*** for key activities and a method for monitoring satisfactory performance. A copy has already been submitted.

7) Audit of *witnessing* has recently been done and submitted

8) Document control system – At present we have established a basic document management system which involves the following: a) An electronic folder accessible to all staff containing all current versions of documents, b) Printing directly from the folder instead of photocopying, and (c) when a document is amended the old version is moved to an archive folder, and the new version in the current version folder, (d) Ensuring that relevant staff are informed when there is a new version and that any remaining old versions are destroyed. Going forward we to hope to migrate to a software based document management system using either IPASSPORT or Q PULSE within 12months

9) Copies of validation of the storage dewars have been submitted

10) Our Multiple birth minimisation strategy has been updated and a copy already submitted. We have started a register of patients meeting the criteria for eSET against whether or not they actually have eSET and if not the reason is documented.

11) Information provided to patients prior to consent / treatment have been re-written and a copy submitted.

12) We have defined KPIs within ***our Quality Management system*** which are monitored monthly.

13) The very few cases (from several years ago) where identifying information was contained in "Thank you" cards on display have been rectified. Where possible such information have blanked out. In one or two cases the cards have been removed altogether.

14) We believe we have a decent counselling service with a notice board in the waiting room relevant counselling information. The counselling room is decent and offers privacy, confidentiality in discussion, and is clean and appropriate. Our counsellor expressed approval for the room and has never expressed any reservations about it.

In conclusion, we believe we have responded well to the HFEA inspection comments and have made good progress in a relatively short time. It is my commitment as PR, fully backed by all staff to continue our good trajectory of progress. We believe we deserve renewal of our treatment and storage license.

Yours sincerely,

JHA

Mr J. Adeghe
PR – Centre 0198