HFEA Licence Committee Meeting

8 May 2014

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

Minutes – Item 2

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

Members of the Committee: Andy Greenfield (lay) Chair Bishop Lee Rayfield (lay) Debbie Barber (professional) Jane Dibblin (lay) Committee Secretary: Lauren Crawford	Legal Adviser: Stephen Hocking, DAC Beachcroft LLP

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:

- PR response to the Executive summary provided to the PR 25 April 2014
- Executive summary provided to the PR 25 April 2014
- MHRA document re midazolam
- Midazolam product information document
- Letter provided by the PR to the HFEA 14 April 2014
- PR response to the Executive summary provided to the PR 4 April 2014
- Executive summary provided to the PR 4 April 2014
- Minutes of the Licence Committee 13 March 2014

Papers previously provided to Licence Committee for consideration on 13 March 2014:

- Licence renewal update report March 2014
- Executive summary
- Papers presented by the PR for submission to LC
    - Submission to the HFEA on behalf of the PR
    - Patient letter 1
    - Patient letter 2
    - CQC response to PR's complaint
- Email correspondence from PR requesting information
- HFEA response to PR request for information
- Minutes of Licence Committee 9 January 2014

Papers previously provided to licence committee for consideration on 9 January 2014:

- Executive update to LC considered 9 January 2014
- Papers tabled by the PR for presentation to LC
    - Letter from the PR's lawyer
    - Letter from the PR
    - GMC submission
    - CQC report - factual accuracy comments
- Care Quality Commission report of St Jude's Hospital Wolverhampton September 2013.
- CQC representations decision (2 part)
- General Medical Council registration conditions
- Licence renewal report considered by Licence Committee November 2013
- Minutes of Licence Committee 7 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);
- 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 this application for renewal of a treatment licence was first 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. The Committee requested that an update on the status of this information be supplied for its next meeting, in January 2014.

3. The Committee also noted that the centre's licence was due to expire on the 31 January 2014.The Committee agreed that 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, to permit continuity of treatment while the consideration of the centre's licence was concluded.

4. Further to this the item returned to the January meeting and was adjourned again for the receipt of the information and also to allow the PR (Person Responsible) at the centre to complete the recommendations outlined in the HFEA report regarding non-compliances.

5. The Committee at this time issued another Special Direction to cover the period 1 February 2014 to the 30 April 2014 for the same purpose.

6. The item then returned to the Licence Committee on the 8 March 2014. Within this item there was an updated inspection report detailing an inspection that took place on 5 February 2014.

7. In the new inspection report progress on some previously identified areas of non-compliance was reported. However there were several new non-compliances identified, two of which were critical. The executive had supplied a revised recommendation which advised that the centre's licence should not be renewed. The Centre also supplied further submissions in regards to the new recommendation which were received just days before the meeting.

8. The Committee again adjourned the item to give the Executive and the centre time to respond to the new submissions to ensure that the Committee had all the information necessary to make a decision.

Discussion

9. The Committee noted they have now received all of the requested information. The Committee considered all of this information carefully, including in particular the submissions made on behalf of the centre.

10. The Committee noted that GMC has not taken any further action or imposed any further conditions on the PR since the last meeting of the Interim Orders Panel, but that the conditions previously imposed still remain in place until 14 August 2014. The Committee understood that it is required to reach its own judgement independently on the basis of the material before it, and that it is in no way bound by any decision of the GMC. The Committee further noted that the GMC's decision is interim only. While the Committee considered that a finding of impaired fitness to practice would be in principle relevant material for a licence committee to consider, on the facts of this application the Committee placed no weight either adverse or favourable to the PR on the existence of the GMC investigation, its interim order, or its reasons for that order.

11. The Committee noted that this is an application for renewal of a licence. The Committee considered Regulation 11 of the Human Fertilisation and Embryology (procedure for revocation, variation or refusal of licences) Regulations 2009. The Committee observed that whereas the Authority bears the burden of establishing that a licence should be revoked, the person concerned bears the burden of establishing that a licence should not be

refused. The Committee therefore considered that under the Regulations it would have been entitled to require the applicant to establish that a licence should be granted, rather than the Authority to establish that it should not. However, without intending to bind either itself in the future or the Authority in any subsequent step relating to this application, and noting that the practical effect of a refusal in this case will be more similar to a revocation than to the refusal of a de novo application, the Committee decided to take a more favourable approach to the applicant and to proceed as if the burden of proof was on the Authority.

12. The Committee further noted that it was to be satisfied on any matter to the civil standard, and reminded itself that it must have regard to the need to be transparent, accountable, proportionate, consistent and take action only in cases that require action.

13. The Committee discussed all of the current issues surrounding the centre and the PR. The Committee noted that the PR has managed to make good progress with the recommendations stemming from the original inspection report.

14. The Committee noted that the Executive considers, however, that taking consent for gamete donation after egg collection under or in recovery from conscious sedation represents a serious error of judgement on the part of the PR and that this represents unsuitable practice and is a critical non-compliance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) and standard licence conditions T2 and T58. The Committee noted that the PR had admitted that consent had been taken from a patient under or recovering from sedation on one occasion. The Committee agreed with the Executive's judgement as to the severity of this matter. A decision to become a gamete donor is one of profound significance to the patient, to any family they may have, to the recipient, to the donor conceived person and to society at large. Parliament has accordingly found it necessary to legislate in some detail to regulate the process, particularly in the area of consent. It is wholly inappropriate for any part of that process to take place at a time when a patient is or even may be under the influence of a sedative. There can be no justification for having done so. It is no answer to say, if it is said, that the patient appeared unaffected by the medication, nor, which is said, that the medication had been administered some time previously, and that the patient had indicated a willingness to become a donor before sedation. The Committee considered that these matters should have been obvious to any PR, and that even one lapse of this nature would be capable of being sufficiently serious to justify a decision that a licence should not be renewed.

15. The Committee was aware that the patient has not made a complaint to the Authority concerning this matter. It agreed with the Executive that this is not significant. Information relevant to the character of the PR and the suitability of the practices at a centre will be taken into account whether or not it derives from a formal complaint.

16. The Committee noted that the centre allowed NHS patients to share eggs. The update report states that these patients did not receive any benefit in

kind, that egg sharing is likely to have had an impact on their treatment outcome, and that the only patient information on egg sharing which the centre has provided to the Authority references egg sharing in terms of treatments that will provide the sharer with a benefit in kind. The Committee noted that the response received from the centre's solicitors dated 17 April 2014 does not address this concern. The Committee therefore concluded on a balance of probability and on the evidence before it that NHS patients have not being given appropriate information on egg sharing. The Committee noted that this issue again goes to the question of obtaining proper and informed consent.

17. The Committee also noted that the Executive had found practices that resulted in eggs being allocated for donation without completion of appropriate donor screening.

18. These practices are not suitable and represent a critical noncompliance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) and standard licence conditions T2, T52 and T57.

19. The Committee noted that there were significant discrepancies between the patients and treatments recorded in GMC supplied data and that recorded in the HFEA register. It noted that work was ongoing and that the Executive could not conclude that information supplied to the HFEA by the centre on licensed activity between 1 April 2011 and 31 March 2012 was inaccurate or incomplete. The Committee felt that the provision of accurate information to the HFEA is an important obligation imposed on a centre. Failure to maintain accurate records would be a serious concern. However, as this matter is still under investigation and it has not been established that the centre's records are inaccurate, the Committee did not take this issue into account at this time.

20. The Committee noted that, although the PR has supplied a detailed response to the Executive's report, the Executive still recommends that the centre's licence should not be renewed at this time because they conclude that:

    - the PR is not suitable and has not discharged his duties under section 17(1)(c), (d) and (e) of the HF&E Act 1990 (as amended);and
    - the centre's practices are not suitable.

21. The Committee noted that the report now offers several options that are open to the Committee including the power to issue a licence to the centre if they see it is fit to do so, and also to issue a further Special Direction with restrictions imposed.

22. The Committee noted that if they were to grant the centre's licence the Executive recommends that the following condition be added to the licence: '*The PR should not undertake any 'egg sharing' or 'altruistic egg donation' until the centre's practices have been reviewed by an independent clinician; any actions recommended as a result of the review have been fully and demonstrably implemented to the satisfaction of the reviewer and a*

summary report has been provided to the HFEA outlining that the condition has been complied with'.

Decision

23. The Committee understood that it was not bound by any recommendation of the Executive, and applied its own mind to the matter.

24. The Committee had regard to its decision tree for the renewal of licences for treatment. The Committee found, based on all of the evidence before them, that the character of the PR is not suitable and he had not discharged his duties under section 17(1)(c), (d) and (e) of the HFE Act 1990 (as amended). Nor were the centre's practices suitable.

25. The Committee agreed that the main reasons for that conclusion were taking donor consent from a patient under sedation or recently sedated, allowing egg sharing for patients who would receive no benefit from the process without providing clear information to that effect and the donor screening practices being undertaken at the centre. The first two matters are both unsuitable practices and contrary to licence conditions (s.17(d) and (e)), and whether taken individually or collectively they also led the Committee to conclude that the PR's character is not such as is required by the Act s.16(2)(cb). Informed patient consent is of the utmost importance and any PR should realise this. The last matter is an unsuitable practice and contrary to licence conditions.

26. At this point the Committee agreed that the licence could not be granted and therefore decided to refuse this renewal application both on the basis that the PR is unsuitable and the practices at the centre are unsuitable. The Committee wishes to make clear that even were future practices at the centre to be updated, its conclusion concerning the PR's character would stand. The failings are so serious no PR should ever have countenanced them.

27. The Committee is aware that the PR will have the right to make representations. The Committee was advised that a decision to refuse a licence, and to make no provision for continuity of treatment services pending any representations, might be open to legal challenge. The Committee also had regard to the situation of patients currently undergoing treatment at the centre. But for these considerations the Committee would have required treatment services to cease immediately. Without prejudice to its view of the seriousness of the matters found, in order to allow for the statutory representations (and, if necessary, reconsideration) process to be completed (should the PR decide to invoke his right to make representations), the Committee agreed to issue a special direction for the continuation of the centre's current licensed activities, under Section 24 (5A) of the Act. However, in light of the Committee's concerns expressed above, it agreed that the special direction would specify that the PR must not:

    a. Take on any new patients;
    b. Initiate any new treatment cycles;

c. Undertake any new egg sharing;
d. Undertake any new altruistic egg donation.

28. The special direction will be effective immediately, and will expire on the earliest of either:
    a. six months from the date of the special direction, or;
    b. on completion of the statutory representations and reconsideration process, if notice is given;
    c. 31 July 2014 if the full statutory periods for making representations (under section 19(4) of the Act) and reconsideration (under section 20 of the Act) have passed without the PR giving notice to the Authority under these sections.

    The existing special direction in place until 31 July 2014 (S.D.2014/01/0198/b) will be revoked by the new special direction.

Signed Date: 22/05/2014

Andy Greenfield (Chair)

Licence renewal update report

Purpose of the Inspection Report

This is a report to update the Licence Committee on progress made in relation to a licence renewal application.

Date of Licence Committee: 13 March 2014

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[1]
Additional conditions applied to this licence	None

[1] To note since 31 January 2014, this centre has been operating under the terms of Special Directions

Section 1: Background

Background

1. A report of a licence renewal inspection of St Jude's Women's Hospital (centre 0198) was considered by the Licence Committee on 7 November 2013. The Licence Committee adjourned the licence renewal decision and requested that further information be provided to it at a subsequent meeting on 9 January 2014 regarding reviews and investigations being conducted by other regulatory agencies together with progress in achieving compliance with HFEA requirements through the implementation of recommendations made in the renewal report.

2. In particular, the Committee requested they be provided with the findings of the September 2013 Care Quality Commission (CQC) inspection report (unpublished at the time of Committee) for St Jude's Women's Hospital and details of conditions imposed by the General Medical Council (GMC) on the registration of the Person Responsible (PR).

3. An update (including primary reports and additional information provided by the PR) was provided to the Committee on 9 January 2014: the Committee noted the expiry of the centre's extant licence on 31 January 2014 and issued Special Directions to permit the centre to continue providing treatment and storage activities for three months from 31 January 2014.

4. The Executive was asked to provide the Committee with a further report in March 2014 in relation the centre's progress in complying with requirements further to recommendations made in the November 2013 renewal report and other matters considered material to the Committee's decision on licence renewal. This report provides this information.

5. Subsequent to the consideration of the renewal inspection report on 7 November 2013 and the update provided to Licence Committee on 9 January 2014, the HFEA was provided with a copy of an anonymous complaint made initially to an NHS funding body and shared with the GMC. The HFEA considered the complaint and decided to conduct a further site visit to the centre on 5 February 2014 in order to inspect the records of patients who appeared to have chosen to donate some of their eggs for the treatment of others whilst in the course of their own NHS funded treatment cycles. The complaint was made because the patient's partner felt that it was inappropriate that consent to donation of her eggs was taken after his partner had undergone egg collection carried out under conscious sedation. Because the complaint related to compliance with the consent requirements of Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) it was appropriate for the HFEA to investigate and an anonymised account of the complaint was provided to the HFEA on 23 January 2014.

6. It was noted by the Executive that the complainant's partner was donating eggs whilst undergoing her own cycle of NHS funded treatment; defined by the HFEA as 'egg sharing'. Egg sharing is usually undertaken by women choosing to share their eggs in

order to receive a benefit in kind (commonly a reduction in treatment cost). The risk of egg sharing being potentially detrimental to the outcome of treatment is usually offset by the benefit in kind to the egg sharer. Where patients are receiving full NHS funding for their treatment cycle, there is no financial or treatment benefit in kind to the egg sharer.

7. As part of their ongoing investigations, on 24 January 2014 the GMC also asked that data provided to the GMC by the NHS funding body relating to treatments provided to 135 patients and reported to the funding body by the PR be cross referenced against treatment cycle data reported to the HFEA.

8. This update report also sets out the findings of that records inspection and the findings of the cross referencing of treatment cycles and documents further recommendations in relation to these findings.

Section 2: Summary for Licence Committee

The Licence Committee is asked to note that at the time of the licence renewal inspection on 19 and 20 June 2013, two critical, seven major, and two 'other' areas of non-compliance or poor practice were identified.

By the time the Licence Committee considered the report of this inspection on 7 November 2013 the PR had provided evidence of full compliance in relation to one critical area of non-compliance (relating to the storage of gametes and embryos) and three major area of non-compliance relating to witnessing, equipment validation and the centre's multiple birth minimisation strategy and two 'other' areas of non-compliance.

At January 2014 further action was still required in relation to one critical and four major non-compliances as documented below.

Following the renewal inspection the Executive considered that inadequacies identified in 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 PR has provided evidence that the centre is now broadly compliant with requirements regarding the validation of critical processes. The Executive considers that while further action is required, this no longer poses a risk to the safety and quality of gametes and embryos and to the outcomes of patient treatment.

The PR has provided evidence that the centre is now broadly compliant with requirements related to one one major non-compliance regarding patient screening but the required patient / donor screening audit is outstanding.

The PR has provided evidence that the centre is broadly compliant with requirements related to one major non-compliance regarding implementation of the quality management system which is ongoing. An audit of information provided prior to consent is outstanding.

The PR has provided evidence that the centre is partially compliant with requirements related to one major non-compliance regarding staffing. Evidence of the assessment of competence to witness for relevant staff has been provided and additional staff have been recruited although one quality manager/embryologist post remains vacant. Sufficient evidence of a documented induction and training plan or competence assessment framework is outstanding.

At the time the licence renewal report was considered by Licence Committee, the PR reported that the backlog of data submissions to the HFEA identified at the renewal inspection had been cleared and where identified as required, corrections made. However, subsequent to the renewal inspection new information came to the attention of the HFEA regarding the accuracy and completeness of treatment information submitted to the HFEA. This remains a major non-compliance.

In relation to activities of other regulatory bodies, the GMC's investigation is ongoing but the GMC has not imposed any restrictions on the PRs registration relating to clinical activity. The CQC's Notice of Proposal to cancel registration was not upheld.

Since the consideration of the report of the licence renewal inspection by Licence Committee on 9 January 2014 a further two critical and three major areas of non-compliance were identified in the course of the on-site visit to inspect patient records on 5 February 2014 and as a result of an exercise carried out to cross reference information on the HFEA register with information provided by the PR to an NHS funding body. These non-compliances are as follows:

Critical areas of non-compliance:

1. In a set of patient's records reviewed in the course of the on-site inspection on 5 February 2104, evidence was seen that a patient's eggs were stored and allocated for donation in the absence of effective consent to donation and the absence of appropriate donor screening;
2. In discussion during the on site visit the PR said that on occasion patients are asked to give consent to donation after undergoing egg collection performed under conscious sedation: the PR later clarified that this practice had been employed on one occasion only. The Executive is concerned that consent taken in this manner may not be effective as required by Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) and considers this unsuitable practice.

Major areas of non-compliance:

3. Some treatments undertaken by the centre appear not to have been reported to the HFEA and there are anomalies between the records of treatments reported by the PR to an NHS funding body and those reported to the HFEA;
4. The Executive is concerned about the suitability of practices in relation to patients consenting to egg sharing when receiving NHS funded treatment and where there is no financial or treatment benefit in kind to the egg sharer;
5. Patient information relating to egg sharing provided to the HFEA by the centre only references egg sharing undertaken where there is a benefit in kind for the egg sharer. The information does not inform the egg sharer of any potential negative impact her donation may have on the effectiveness of her own treatment. During the course of the on site visit the inspectors were made aware that patients may not be being provided with important information on which to base effective consent as English is not the first language of some patients consenting to share their eggs.

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 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 recognises that progress has been made in achieving compliance with requirements set out in the licence renewal inspection report. Overall the progress made is largely acceptable to the Executive although some further action is still required for full compliance to be demonstrated.

The Executive does consider however that taking consent after egg collection under conscious sedation represents a serious error of judgement on the part of the PR and that this represents unsuitable practice and is a critical non-compliance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) and standard licence conditions T2 and T58.

Similarly, practices that resulted in eggs being allocated for donation in the absence of consent or completion of appropriate donor screening and practices that do not ensure the provision of suitable information to patients are not suitable and represent a critical non-compliance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) and standard licence conditions T2, T52 and T57.

The Executive therefore concludes that:

- the PR is not suitable and has not discharged his duties under section 17(1)(c), (d) and (e) of the HF&E Act 1990 (as amended);
- the centre's practices are not 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. In light of the evidence presented which demonstrates that the PR is not compliant with his duties under section 17(1)(c), (d) and (e), it is submitted that the PR is not a suitable person to hold a licence and thus, a licence cannot be granted under section 16(1).

On the basis of the evidence presented in this report and supporting documentation, the Executive cannot recommend renewal of the centre's licence.

The Executive cannot recommend the grant of a licence in light of the evidence presented in this report, however, should the committee nevertheless consider granting a licence, the table 'Areas of practice requiring further action' sets out the actions that would be required to ensure suitability of practices.

Section 3: Update

This section provides an update to the Committee on the following:

- **Progress in achieving compliance with HFEA requirements**
- **Care Quality Commission (CQC)**
- **General Medical Council (GMC)**

Progress in achieving compliance with HFEA requirements

Further to the Executive's report of a renewal inspection carried out on 19 and 20 June 2013 several areas of non-compliance were identified that were considered to pose a risk to the safety and quality of gametes or embryos and/or to patients' treatment outcomes. The non-compliances; their associated recommendations and information on progress in implementing the recommendations are documented in the tables below.

The 'Executive Review' column provides a commentary on the action taken since the report was presented to a Licence Committee on 7 November 2013 and an update was provided to the Committee on 9 January 2014.

The Executive recognises that progress has been made in achieving compliance with requirements set out in the licence renewal inspection report. Overall the progress made is largely acceptable to the Executive although some further action is still required for full compliance to be demonstrated.

Areas of practice requiring action by 31 January 2014

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 renewal 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 remained 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 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		The PR gave assurance that samples identified on inspection were allowed to perish on 26 August 2013. The update provided by the centre stated that a full storage audit will be available in December 2013. The PR was required to provide a copy of the storage audit to the HFEA by 31 January 2014. A copy of the audit of stored material was provided and appears fit for purpose. The audits provided state that all

	should there be a possibility of legal challenge to the disposal of cryopreserved material.		gametes and embryos are stored in accordance with the gamete providers consent and remain within their statutory storage period. No further action required
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 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 to a critical non-compliance.		A list of processes which the PR considers critical was provided to the HFEA and the Executive was largely satisfied although it was requested that further detail of process validation be provided to the HFEA by 31 January 2013. The Executive visited the centre on 5 February and reviewed a small sample of process validation documents. It remains the opinion of the Executive that the documentation does not include enough detail in relation to the rationale for carrying out procedures according to the chosen protocol. This was discussed with the centre's embryologist and it was agreed that further action was required to improve the process validation documentation.

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	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. Assessments of the competence of staff to carry out contemporaneous witnessing have been revised to ensure that all staff who witness are aware of requirements and are competent. Copies of the assessments of competence to perform witnessing for current staff have been provided to the centre's inspector. A witnessing audit (raw data) and

provider and his sample. (SLC T71)			audit summary has been provided which demonstrates 96% compliance with the requirement to perform contemporaneous recording of witnessing steps. The audit also records corrective actions with a monthly sample audit to be conducted and compliance discussed at QMS meetings to 'tighten the system'. The audit appears fit for purpose. The PR was required to provide a copy of the witnessing audit conducted each month to the centre's inspector commencing October 2013. The centre was providing only a small number of treatment cycles in the last quarter of 2013 and as a result, the witnessing audit was not completed monthly as originally planned. The raw data and summary of the audit of 10 patient records of procedures conducted between September and December 2013 was provided to the HFEA on 10 February 2014. The audit showed there were no non compliances noted against the audit tool used.

			No further action required.
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) 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;	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 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		The PR's response was recorded in the section 'response for the PR to this inspection report' in summary that:'QMS is in place and will be ready Dec 2013 with the introduction of software…Document control will be ready in Dec 2013'. It was recommended that the PR should provide an update to the centre's inspector regarding the status of the QMS and software installation and copies of the following audits: • Information provided prior to consent • Consent • Procurement and processing procedures by 31 January 2014. An audit of ICSI procedures was made available for review during the on site visit in February. An audit of the consent records for 20 patients treated between May and August 2013 was provided by centre. The audit showed that there were consent failures or discrepancies in

• 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 • 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)	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 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		10% of records seen. The audit also identified the need to provide a suitable interpreter when indicated. It is noted that consent to donation did not form part of this audit. The analysis of a 20 patient sample satisfaction survey of the medication and injection teaching process was provided. Although a useful exercise, the Executive does not consider this to be an audit of the information provided, verbally or in writing to patients and donors prior to consent.

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. (SLC T34)	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 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		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. It was recommended that in order for suitable practices to be demonstrated, the PR should provide a copy of the outstanding

	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.		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. A copy of the donor selection SOP which incorporates screening has been provided. A copy of the patient / donor screening audit has been requested but remains outstanding.
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 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	The PR should ensure that the resources required to ensure compliance with HFEA requirements are available. The centre's inspector should be 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		The PR stated in his response that the centre is in the process of recruiting additional staff. The PR was able to confirm during the on site visit that additional staff have been employed and have commenced induction and training and that he hoped to recruit into the embryology / quality manager role soon. Copies of the competence assessments to perform witnessing for current staff have been provided. It was recommended that in order for suitable practices to be

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),	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.		demonstrated, the PR should 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. During the on site visit on 5 February a newly recruited member of the nursing team was able to describe her induction over the previous weeks which appeared to be appropriate. The PR provided a list of six bullet points documenting high level, overarching training objectives for this nurse over next three months and a copy of an email describing arrangements for an observation visit to a large licensed centre in the region. The Executive does not consider this constitutes a documented induction and training plan or competence assessment framework. This has been requested from the PR but is

			outstanding.
9. Obligations and reporting requirements At the time of the licence renewal inspection, 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. Directions 0005	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 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		An audit of EDI submissions was provided by the centre for the period July – September 2013. Actions recorded are that documented – weekly checks and three monthly audits are to be implemented to ensure compliance. Quality indicators to this effect were also noted on the overarching quality indicator protocol submitted. Choose a fertility Clinic (CafC) data held by the HFEA for live births for the period Jan to Dec 2011 and clinical pregnancies for Jan to Dec 2012 was signed off as accurate by the PR in October 2013 At the time the licence renewal report was considered by Licence Committee, the centre reported to the register team of HFEA that the backlog of submissions identified at the time of the renewal inspection had been cleared and where identified in the audit, corrections made. However, subsequent to the renewal inspection new information to hand regarding the accuracy and completeness of treatment

			information submitted to the HFEA register suggests that data reporting is inaccurate and not provided in accordance with the requirements of Directions 0005. Further action required

Care Quality Commission (CQC)

1. At the time that the renewal inspection report was considered by the Licence Committee a "Notice of Proposal" under Section 17 of the Health and Social Care Act 2008 had been issued by CQC to cancel the registration of St Jude's Hospital as a provider of CQC regulated activity. This notice was issued on the grounds set out by CQC that Mr Adeghe had failed to comply with regulations under the Health and Social Care Act 2008.

2. Following representations regarding this notification the Notice of Proposal to cancel registration was not upheld although it was highlighted that concerns remained regarding on-going compliance issues and it was recommended that a 'management review meeting' be conducted by the CQC 'as a matter of urgency to determine next steps'. These actions were pending at the time that the renewal report was considered by a Licence Committee and remain outstanding at the time of preparing this update.

General Medical Council (GMC)

3. Mr Adeghe 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. No restrictions have been placed on the PR's clinical practice.

4. As part of their ongoing investigations, on 24 January 2014 the GMC asked that data provided to the GMC by an NHS funding body relating to treatments provided to 135 patients and reported to the funding body by the PR be cross referenced against treatment cycle data submitted to the HFEA register. This cross referencing has taken significant time to complete: the findings to date are as follows:
    a. treatments for 31 of the 135 patients reported as having treatment to the NHS funding body have not been reported to the HFEA;
    b. of 48 patient treatment cycles looked at in detail
        i. 15 treatment outcomes reported to the funding body were different to the outcomes reported to HFEA;
        ii. 6 patients appeared from the HFEA register data to have received only one cycle of treatment while two cycles were reported to the funding body.

5. These observations raise serious concerns about the accuracy and completeness of information provided to the HFEA register. Despite assurances given by the PR to the HFEA register information team that a backlog of submissions identified at the time of the renewal inspection had been cleared and errors in information provided had been corrected by the centre substantial doubt remains about the capacity of the centre to submit robust information (see recommendation 3 below).

6. Subsequent to the consideration of the renewal inspection report on 7 November 2013 and the update provided to Licence Committee on 9 January 2014, the HFEA was provided with a copy of an anonymous complaint made initially to an NHS funding body and shared with the GMC. The HFEA considered the complaint and decided to conduct a further site visit to the centre on 5 February 2014 in order to

inspect the records of patients who appeared to have chosen to donate some of their eggs for the treatment of others whilst in the course of their own NHS funded treatment cycles. These records were inspected in response to an anonymised complaint passed to the GMC by the NHS funding body. The complaint was made because the patient's partner felt that it was inappropriate that consent to donation of her eggs was taken after his partner had undergone egg collection carried out under conscious sedation.

7. The records of two patients treated at St Jude's Hospital were identified from the HFEA register for inspection as these patients appeared to have followed a similar treatment pathway to the complainant's partner. The records of the two patients were inspected in the course of a visit to the centre on 5 February 2014.

8. The first patient whose records were reviewed had undergone two fresh cycles of IVF: in her first treatment cycle, 25 eggs were collected and 17 were shared with two recipients. In the second cycle, eight eggs were collected and four were shared with a single recipient. The records of the egg share donor contained evidence of discussion of egg sharing at the first consultation; copies of appropriate donor screening test results, completed donor consent forms and HFEA donor registration forms. It was noted that the HFEA donor registration form, was dated December 2011. The completion of this form appeared to pre-date the first consultation and the senior nurse commented that the date was entered on the form in error. The donor registration form was not submitted to the HFEA until July 2012.

9. The second patient whose records were reviewed had undergone three NHS funded cycles of IVF. In her first treatment cycle in early 2012, 25 eggs were collected and the laboratory sheet recorded that 12 eggs were used for the patient's own treatment with the rest frozen for donation. At the time of this treatment the patient's records showed no evidence of donor screening having been undertaken or of consent to donation having been obtained, although a completed HFEA donor registration was present in the records which predated egg collection. No information about the donation and use of the donated eggs was submitted to the HFEA register at the time of treatment. The PR reported that these eggs were frozen and were subsequently used by a recipient in 2013.

10. Despite there being eggs in store from her first cycle of stimulation the patient underwent a further two fresh IVF cycles, one of which was abandoned (due to poor response according to HFEA register data) and one where 30 eggs were collected and 20 were shared with two recipients. The patient's records contained copies of appropriate donor screening test result donor consent forms and HFEA donor registration forms which were completed prior to the second egg collection. As with the records of the first patient, the HFEA donor registration, while dated January 2012, was not submitted to HFEA until September 2012, after the second donation cycle was complete.

11. The allocation of eggs for donation without consent being in place and before completion of appropriate donor screening is not suitable practice and may constitute a breach of the 1990 Human Fertilisation and Embryology Act (as amended), Schedule 3, paragraph 5 (1) and SLC T52, T57 and T58 (see recommendation 1 in the table below).

12. In the course of this visit, Mr Adeghe was advised that an allegation had been made that a patient had been asked to give consent to donate some of her eggs *after* undergoing an egg collection procedure under conscious sedation. Mr Adeghe responded that he had done this on occasion. He explained that he did this so that the patient could make a decision on sharing only when it was clear that she had sufficient eggs to share. Mr Adeghe later clarified that he had only taken consent *after* egg collection under conscious sedation on one occasion.

13. The Executive is concerned that consent taken after egg collection under conscious sedation may not be effective and that taking consent after administration of sedation is an unsuitable practice and represents a breach of SLC T2.

14. In the course of discussions about the completion of consent forms the centre's senior nurse commented that she is sometimes required to assist patients in completing consent forms, particularly where the patient's first language is not English. This is potentially non-compliant with SLC T59 and does not reflect GMC Best Practice Guidelines[2] on communicating effectively (see recommendation 2 below). It is noted that the centre's own consent audit identified the need for an appropriate interpreter to be available.

15. It was noted by the Executive that in the anonymised complaint provided to the HFEA by the GMC, the complainant's partner was donating eggs whilst undergoing her own cycle of NHS funded treatment; defined by the HFEA as "egg sharing". Egg sharing is usually undertaken by women choosing to share their eggs in order to receive a benefit in kind (commonly a reduction in treatment cost). The potentially negative impact of egg sharing on the sharers likelihood of achieving a pregnancy is usually off set by the benefit in kind provided to the egg sharer. Where patients are receiving full NHS funding for their treatment cycle, there is no financial or treatment benefit in kind.

16. There is concern that patients consenting to share their eggs in the course of NHS funded treatment at St Jude's hospital have not been fully informed regarding the potential impact of sharing on the outcome of their own treatment. Patient information on egg sharing used by the centre only references egg sharing in terms of treatments that will provide the sharer with a benefit in kind. This is a breach of SLC T58 (see recommendation 4 in the table below)

[2] http://www.gmc-uk.org/guidance/good_medical_practice/communicate_effectively.asp

Areas of practice requiring further action

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. In one set of patient records evidence was seen that eggs were allocated for donation and placed into storage without effective consent to donation being in place or appropriate donor screening having been completed. This practice is not considered suitable (SLC T2) and is a potential breach of The 1990 Human Fertilisation and Embryology Act (as amended), Schedule 3, paragraph 5 (1) and SLC T52, T57 and T58.	The PR should undertake a review of procedures for obtaining consent to donation and donor screening. A summary report of that review documenting corrective actions (if required) and timescales for their implementation should be provided to the HFEA by 3 March 2014. An audit of the records of consent and donor screening for all patients who donate eggs between 4 February and 4 August 2013 should be completed and a summary report provided to the HFEA by September 2014.		
2. The Executive is concerned that consent	Following the inspection, the PR was asked to		The PR

taken after egg collection under conscious sedation may not be effective. This practice is not considered suitable (SLC T2) and is a breach of The 1990 Human Fertilisation and Embryology Act (as amended), Schedule 3, paragraph 5 (1).	provide immediate written confirmation that this practice would not be undertaken in future. The PR should seek his own legal advice on the implications for the patient of their consent to donation being ineffective. A summary report of the advice, recommended actions and a timescale for their implementation should be provided to the HFEA as soon as it is available.		provided the requested written assurance.

Major areas 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. HFEA has identified that some treatments undertaken by the centre may not have been reported to the HFEA and that there may have been errors in other treatments that were reported. This is non-compliant with the requirements of Directions 0005.	The HFEA will liaise with the PR to investigate the reasons for the anomalies between treatment information reported to the NHS funding body and the HFEA register.		
4. There is concern that patients consenting to share their eggs in the course of NHS funded treatment at St Jude's hospital have not been fully informed regarding the potential impact of sharing on the outcome of their own treatment. Patient information on egg sharing used by the centre only references egg sharing in terms of treatments that will provide the sharer with a benefit in kind. In the course of discussions about the completion of consent forms the centre's senior nurse commented that she is sometimes required to assist patients in completing consent	The PR should seek the opinion of an independent, appropriately qualified and experienced clinician to review the centre's practice of allowing women undergoing NHS funded treatment to share eggs. The timescales for completion of the review and submission of a summary report, including any changes of practice and the timescale for their implementation, to be agreed with the HFEA Executive. The PR should also undertake a review of the centre's information for egg sharers to ensure that those undergoing NHS treatment and agreeing to		

forms, particularly where the patient's first language is not English. Further comment made that 'the patient had signed using her family name, her English is really not very good' specifically related to the consent records for one egg share patient reviewed during the on site visit. The HFEA has received no complaints or information to suggest that this practice has caused a problem but it appears not to demonstrate GMC Best Practice Guidelines[3] on communicating effectively to ensure that patients are providing fully informed consent. This is a breach of SLC T58 and T59 and there is concern that this may constitute unsuitable practice (SLC T2).	share their eggs are fully informed that they will not receive any financial benefit and that the sharing of eggs may have a negative impact on their chances of achieving a pregnancy. A summary report of that review and a copy of information revised as a result of the review should be provided to the HFEA by 3 March 2014.		
Reponses from the Person Responsible to this update report			

[3] http://www.gmc-uk.org/guidance/good_medical_practice/communicate_effectively.asp