Licence Committee - minutes

Centre 0157 (Assisted Reproduction and Gynaecology Centre) – Renewal Inspection report

Monday, 20 June 2016
HFEA, Level 2, 10 Spring Gardens, London, SW1A 2BU

Committee members	Andy Greenfield (Chair) Lee Rayfield (Deputy chair) Margaret Gilmore Kate Brian Ruth Wilde Anita Bharucha	
Members of the Executive	Trent Fisher Ian Brown	Secretary Head of Corporate Governance
Legal Adviser	Ros Foster	Browne Jacobson LLP
Observers	None	

Declarations of interest:

- Dr Andy Greenfield declared that in 2012 he had previously been chair of a Representations Hearing involving the PR of centre 0157
- Rt Reverend Dr Lee Rayfield declared that he was the chair of a previous Representations Hearing involving the PR of centre 0157
- Ruth Wilde declared that she is currently employed by a licensed clinic
- Kate Brian declared that she is London Representative of Infertility Network UK and Lead of the Women's Voices Panel at the RCOG

The committee had before it:

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

The following papers were considered by the committee:

- executive summary
- Executive Licensing Panel minutes of 20 May 2016
- papers considered at the Executive Licensing Panel of 20 May 2016
  - Renewal inspection report
  - Renewal application form
  - Executive Licensing Panel minutes of 11 July 2014

The following papers were tabled at the committee meeting:

- correspondence between Hempsons (solicitors for the PR) and Fieldfisher (solicitors for the Authority)
- renewal inspection report considered at the Executive Licensing Panel on 18 May 2012
- minutes of the Executive Licensing Panel held on 18 May 2012

1. Background

1.1. The committee noted that the Assisted Reproduction and Gynaecology Centre (centre 0157) has held a treatment licence with the HFEA since 1995 and provides a full range of fertility services. The executive is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

1.2. The committee noted that the centre provided 700 cycles of treatment (excluding partner intrauterine insemination) in the 12 months leading to 31 December 2015. In relation to activity levels, it is considered to be a medium sized centre.

1.3. The committee noted that since the last inspection in March 2014, the Person Responsible (PR) has been sent 17 alerts triggered by the HFEA risk tool relating to success rates. As a result of these alerts, the PR was requested to review:

- procedures for the provision of ICSI treatment in patients aged under 38. A review was requested on each occasion relating to alerts issued in October 2014, January, February, June, July, August and September 2015
- procedures for the provision of ICSI treatment in patients aged 38 and over in response to an alert issued in July 2015
- multiple pregnancy rates. A review was requested on each occasion relating to alerts issued in April, June, July, August 2014, February, March, April, May 2015 and January 2016

1.4. The committee noted that the executive had not received a response from the PR concerning the above alerts.

1.5. The committee noted that the average success rates for ICSI in both age groups for the period of October 2014 to September 2015 were above average at a statistically significant level and the apparent low success rates in the months March 2014 – September 2014 were due to late reporting of treatment outcomes by the centre.

1.6. The committee was concerned with the late reporting of treatment figures because that constituted a failure to comply with General Direction 0005.

1.7. The committee noted that for the 12 months ending in September 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 25 percent, and that this represents performance that is statistically different from the 10 percent multiple live birth rate target set by the Authority.

1.8. Having regard to the outcome of inspections of the centre that took place in 2012 and 2014 the committee was concerned that the centre's multiple birth rate remains high; however, it noted that this is reducing steadily year by year.

1.9. The committee noted that the centre's current licence is due to expire on 30 June 2016.

2. Consideration of application

2.1. The committee noted that the licence renewal application was considered at the Executive Licensing Panel meeting of 20 May 2016. The panel adjourned its decision due to the non-routine nature of the findings of the inspection report.

2.2. The committee determined that the 'non-routine' nature of the findings was in relation to the general non-engagement and lack of communication by the PR and the consequent absence of evidence that non-compliance matters, namely the long standing critical area of non-compliance and the number of major and other non-compliances, have been adequately addressed.

2.3. The committee noted that at the time of the centre's renewal inspection, 28 January 2016, the executive had found 12 areas of non-compliance including one critical, five major and six other. These were as follows:

- critical area of non-compliance:
  - The PR should arrange to have the effectiveness of the centre's multiple births minimisation strategy reviewed by an independent expert, and establish, and ensure the accurate use of, summary logs for treatment cycles in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer.
- major areas of non-compliance:
  - The PR should take immediate action to ensure that witnessing is completed and recorded at all critical points of the clinical and laboratory process.
  - The PR should provide written confirmation that the export of embryos outside the European Economic Area that was reviewed during the inspection met the requirements of General Directions 0006, schedule 4 (b), (c) and (i).
  - The PR should review the efficacy and appropriateness of the centre's procedures for obtaining patient consent to storage of gametes and embryos, including where consent may be considered to be fettered to payment of storage fees.
  - The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.
  - The procedures used to submit licensed treatment data, including the number of cycles of partner insemination, should be reviewed to identify and address the reasons for non-reporting and delayed submissions. Appropriately completed annual returns for partner inseminations conducted in 2014 and 2015 should be submitted via the clinic portal.
- other areas that require improvement:
  - the PR should ensure that gas cylinders are secured in accordance with compressed gas safety guidelines
  - the PR should ensure that other than when in use, clinical waste storage bins should be locked at all times
  - the PR should ensure that the clinical indication for use of any medications in a manner that is different to their intended purpose should be documented in patient's records, and entries in the controlled drugs register are recorded correctly
  - the PR should ensure the development of a documented SOP for air quality testing and review the SOP for screening of sperm for treatment in a surrogacy arrangement. The PR should ensure that infection control procedures are audited at least every two years
  - the PR should ensure that the validation of the vitrification process and the frequency of and methodology for air quality testing is documented
  - the PR should provide evidence as to whether the counsellor is working towards BICA accreditation or can demonstrate training and experience to an equivalent standard

2.4. The committee further noted that following the renewal inspection, the PR was provided with a copy of the draft inspection report via email on 23 March 2016 and was asked to provide a response within 10 working days. The PR did not provide any responses to the draft report or the findings and/or recommendations contained therein.

2.5. The committee further noted that, when no response was received from the PR within the timescale identified, the PR was resent the draft inspection report on 12 April 2016 and asked to provide a response to the recommendations contained within the draft report within 5 working days. The PR did not provide any response within that timescale and had not done so as at the date of the committee meeting.

2.6. The committee noted the history of non-engagement by the PR with the inspectorate, which was detailed in the inspection report.

2.7. The committee expressed disappointment as to the lack of engagement by the PR with regard to responding to the draft inspection report and as a result the committee had deep concerns regarding the implementation of the recommendations contained in the report because the PR had provided no response to those recommendations and no assurances had been received as to the implementation of corrective actions. The committee's concerns about the continued critical non-compliance in relation to multiple birth rates were heightened by this lack of engagement by the PR with the executive.

2.8. The committee expressed disappointment as to the lack of engagement by the PR with regard to responding to the recommendations listed in the draft inspection report. Because the PR had provided no response the committee lacked adequate assurances that the recommendations would be implemented. The committee's concerns about the continued critical non-compliance in relation to multiple birth rates were heightened by this lack of engagement by the PR with the executive.

2.9. The committee noted the advice of its legal advisor who directed the committee to its guidance on licensing, which outlined the factors to consider when granting and determining the length of a licence.

2.10. The committee noted that section 2.4 of the guidance stated that where there has been a failure to take appropriate action with respect to alerts, advice or guidance then there may be good reason to undertake a focussed site visit to a centre outside of the normal inspection cycle.

2.11. The committee further noted that section 2.6 of the guidance stated that where the PR's response indicates a failure to commit to make improvements or a failure to appreciate the seriousness of the non-compliances, it may be appropriate to request a focussed site visit within a specified period of time so that evidence of the implementation of effective corrective action can be reviewed.

2.12. The committee noted that with respect to evidence of non-compliance with statutory requirements the committee will consider the following:

- the scale of non-compliance
- the PR's apparent understanding of the impact of the non-compliance(s)
- the PR's commitment (or otherwise) to implement corrective actions within agreed timescales; and, most importantly
- the risks to the safety of patients, their embryos or gametes, and/or the quality of service at the time that the licensing decision is made.

2.13. The committee noted from the guidance that two of the factors when considering to offer a four-year treatment licence included:

- a centre has taken appropriate and timely action in relation to any non-compliances identified as posing a risk to patients, their gametes or embryos
- there are no serious concerns about the quality of service based on observation of success rates; multiple pregnancy and birth rates; and patient feedback.

2.14. The committee noted from the guidance that the two factors when considering to offer a three-year treatment licence are:

- there is a history that indicates a previous failure to implement recommendations for improvement in the time since the last licence renewal
- there are concerns related to quality of service

2.15. The committee had regard to its decision tree. The committee was satisfied that the application was submitted in the form required and contained the supporting information required by General

Direction 0008. Furthermore, it was satisfied that the appropriate fees had been paid. The committee noted that the application was made by the PR for the centre.

2.16. The committee was satisfied that the PR possesses the required qualifications and experience and that the character of the PR is such as is required for supervision of the licensed activities. It was further satisfied that the PR will discharge his duties under section 17 of the Act. The committee noted that the inspectorate was satisfied that the PR had satisfactorily completed the PR entry programme.

2.17. The committee noted that the executive had recommended the renewal of the centre's Treatment (including embryo testing) and Storage licence for a period of three years without any additional conditions.

2.18. Having regard to its guidance on licensing and all the circumstances of this case, the committee determined that it would not be appropriate to grant a four-year licence. This was because the PR had not provided evidence and/or assurance that the centre had taken appropriate and timely action in relation to the non-compliances that had been identified and there remained serious concerns about the centre's multiple birth rate.

2.19. The committee determined that a three-year licence would be appropriate given the centre's history of failure to provide evidence that recommendations for improvement had been implemented in the time since the last licence renewal and the ongoing concerns relating to the centre's multiple birth rate.

2.20. The committee reminded the PR of his obligations to communicate effectively with the Authority pursuant to the General Directions and the standard conditions of the centre's licence.

3. Decision

3.1. The committee decided to renew the Treatment (including embryo testing) and Storage licence at centre 0157 for a period of 3 years with no additional conditions.

3.2. The centre also endorsed the recommendation from the inspectorate to undertake an announced inspection at the discretion of the executive.

4. Chair's signature

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

Signature

Name

Andy Greenfield

Date

28 June 2016

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) 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: 27 and 28 January 2016

Purpose of inspection: Renewal of a licence to carry out treatment (including embryo testing) and 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.

Inspectors: Vicki Lamb, Sara Parlett and Shanaz Pasha

Date of Executive Licensing Panel: 20 May 2016

Centre name	Assisted Reproduction and Gynaecology Centre
Centre number	0157
Licence number	L/0157/26/a
Centre address	13, Upper Wimpole Street, London, W1G 6LP, UK
Person Responsible	Mr Mohamed Taranissi
Licence Holder	Mr Mohamed Taranissi
Date licence issued	01/04/2013
Licence expiry date	30/06/2016
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Description of the centre and its licensing history:

The Assisted Reproduction and Gynaecology Centre (ARGC) has held a licence with the HFEA since 1995 and provides a full range of fertility services. The centre's current licence for treatment (including embryo testing) and storage was granted for a period of three years and one month, preceded by a short term licence.

The centre provided 700 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31/12/2015. In relation to activity levels this is a medium-sized centre.

Other licensed activities of the centre include storage of gametes and embryos.

Mr Taranissi is also PR for two other licensed centres: Reproductive Genetics Institute (RGI), (centre 0206) and London Fertility Centre (centre 0088). The centres all operate in the same way, with both the staff and standard operating procedures (SOPs) being common to all three centres.

Actions taken following interim inspection in March 2014

The centre's last inspection was an interim inspection conducted in March 2014. There were recommendations relating to one critical and four major areas of non compliance as follow:

Critical area of non-compliance:

- **The centre's multiple births minimisation strategy should be reviewed to ensure that the centre does not exceed a maximum multiple birth rate of 10%.**

Major areas of non-compliance:

- The PR should provide the HFEA with an update on the number of patients for whom embryos remain in store without effective consent. Where embryos remain in store without effective consent, a plan should be submitted to the HFEA documenting the centre's intended actions and the anticipated timescale for their implementation.

- The PR should ensure that witnessing is always fully documented to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process.

- The PR should submit missing consent to disclosure information and take action to correct the submissions that have been identified as being incorrect. The PR should audit procedures for submitting patients' consent to disclosure to researchers to the HFEA.

- The PR must ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Directions 0005

The report of this inspection was sent to the PR via email on 22 April 2014. The PR was asked to provide his response by 6 May 2014. An electronic delivery and 'read' receipt

was obtained for that email correspondence. The PR did not respond to the report as requested. The PR was further invited, by email, to provide a response on 13 and 23 May 2014. The centre's inspector also telephoned the PR on 21, 22, and 23 May 2014, and again on 3 June 2014. The inspector was unable to speak with the PR during any of these calls. A message was left on each occasion asking the PR to contact the inspector. The PR did not respond to these calls or contact the inspector as requested.

The report was presented to the ELP on 11 July 2014 without a response from the PR. The ELP agreed to the continuation the centre's licence with no additional conditions.

Since that time the PR has not provided information or evidence to demonstrate that the recommendations from this inspection were implemented either within or outside the timescales specified.

After the report was considered by the ELP the centre's inspector attempted to contact the PR to obtain an update on progress made to comply with the recommendations in the report. Emails were sent to the PR for this purpose on 4, 14 and 26 August 2014. The inspector telephoned the PR on 14 and 19 August 2014; messages were left on both occasions. A further email was sent on 25 September 2014 informing the PR that as the executive had not received any response from the PR regarding progress made in addressing the recommendations made following the inspection, the executive would now consider what further action to take. A 'read' receipt was obtained for this email but no response was received from the PR.

In accordance with the HFEA Compliance and Enforcement Policy, a management review was held on 30 September 2014 where the issues from the interim inspection of March 2014 were considered. The management review acknowledged that the non-compliances relating to witnessing and consent to disclosure were, due to their nature, neither serious nor urgent in relation to patient, gamete or embryo safety. The non-compliances relating to multiple births, storage without consent and data submission were considered to be serious but not urgent. There was agreement that as informal action had been unsuccessful so far, further informal action was not likely to be successful. The main concern was lack of dialogue with the PR to ascertain what action was being taken to address the non-compliances.

It was further acknowledged that other centres had higher multiple pregnancy rates than centre 0157 but these centres had engaged with the HFEA and provided assurance that action was being taken, whereas the PR for centre 0157 had provided no such assurance.

Risk tool alerts were not triggered for high multiple pregnancy rates for this centre in September or October 2014 and the multiple pregnancy rates appeared to show a marked reduction. The inspector emailed the PR on 7 November 2014 acknowledging this, but recognising that there had still been no contact from the PR regarding implementation of the recommendations from the inspection report. The PR was informed that formal action would be taken if, by 5 December 2014, there were still concerns in relation to the non-compliances identified in the interim inspection report.

However, during the renewal inspection of the centre's sister clinic, centre 0206 in November 2014 the inspectors were able to confirm that action had been taken to resolve some of the issues identified during the interim inspection of centre 0157 as follows.

While this recommendation had not been fully implemented, assurance was provided that the issues which gave rise to it had been fully resolved:

- The PR should provide the HFEA with an update on the number of patients for whom embryos remain in store without effective consent. Where embryos remain in store without effective consent, a plan should be submitted to the HFEA documenting the centre's intended actions and the anticipated timescale for their implementation.

A review of documentation, which was completed by the same staff following the same SOPs as at centre 0157, showed that the following issue had been resolved:

- The PR should ensure that witnessing is always fully documented to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process.

Also during the inspection at centre 0206, the PR was asked about action taken to address the non-compliances identified during the interim inspection at centre 0157, as requested in the email of 7 November 2014. The PR stated that he had not received the email of 7 November 2014. He was given a hard copy of the email during the inspection of centre 0206 and given 20 working days to respond to it. No response was received and therefore a management review was held on 6 January 2015.

The review acknowledged that:

- the consent to storage issue was resolved;
- the witnessing issue was resolved;
- the multiple pregnancy rate appeared to be reducing although it remained high (no risk tool alerts for high multiple pregnancy rates were triggered for September, October, November and December 2014 or January 2015);
- although there continued to be improvements to be made relating to register returns, data was signed off by the verification dates required and so all information that is relevant for patients and offspring was eventually provided;
- improvements were still needed regarding consent to disclosure to researchers. However information submitted to the HFEA always states the patients do not consent to disclosure, and so, although a patient's wishes may not be accurately recorded on the HFEA register, there is no risk of inadvertent disclosure.

In view of the findings considered by the management review, monitoring was considered to be a sufficient action at that time. The PR was informed of the decision by email on 2 February 2015.

Alerts sent to the PR relating to success rates

Since the last inspection in March 2014, the PR has been sent 17 alerts triggered by the HFEA risk tool relating to success rates, and as a consequence was asked to review:

- procedures for the provision of ICSI treatment in patients aged under 38. A review was requested on each occasion relating to alerts issued in October 2014, January, February, June, July, August and September 2015;
- procedures for the provision of ICSI treatment in patients aged 38 and over in response to an alert issued in July 2015;
- multiple pregnancy rates. Once again, a review was requested on each occasion relating to alerts issued in April, June, July, August 2014, February, March, April, May 2015 and January 2016.

Where an alert is raised, PRs are required to respond to the centre's inspector, informing them how the issue is being addressed. The PR did not respond to any of these alerts.

However, average success rates for ICSI in both age groups for the period October 2014 – September 2015 are above average at a statistically significant level and the apparent low success rates in those months were due to late reporting of treatment outcomes by the centre. Where the outcome of treatment is reported late or is absent, the risk tool considers this to be a negative outcome and therefore calculates a reduction in success rates until this is corrected. The executive is satisfied that procedures for the provision of ICSI treatment are not a cause for concern.

The centre's multiple pregnancy rates remain high, but are reducing steadily year on year (see multiple births in section 2).

Actions prior to this renewal inspection

On 3 November 2015, although the centre had not received an alert for multiple pregnancy rates since May 2015, the PR was contacted to suggest he review his multiple birth minimisation strategy in preparation for the licence renewal inspection. He was also informed that if there were similar discrepancies in consent to disclosure to researchers as were found at the previous inspection it would be likely to cause a licensing panel concerns when considering renewal of the licence.

In preparation for a licence renewal inspection PRs are asked to complete and submit a self assessment questionnaire (SAQ) via the HFEA clinic portal to assess the centre's compliance with standard licence conditions. Although the PR completed a SAQ this document was not submitted and therefore the inspector could not be sure that the completed SAQ was a finalised version. A previously submitted SAQ was therefore used to inform this inspection.

In order for a licence to be renewed, the PR must complete and submit a licence renewal application form also via the HFEA clinic portal. Prior to this inspection a licence renewal application form was completed by the PR but again was not submitted. Therefore the inspector could not be sure that the completed renewal application form was a finalised version. It should be noted that only the PR can submit an application and that submission indicates acceptance of a standard declaration by the PR.

On 27 October 2015 the executive wrote to the PR proposing a date for the licence renewal inspection but did not receive a response. As a SAQ and licence renewal application form were seen to have been completed on the clinic portal (but not submitted) the executive took the completion of these documents to indicate that the PR intended to renew the centre's licence. On a visit to the centre on 7 December 2015 (see legal parenthood section) the centre's inspector requested and received verbal confirmation from the PR that the date proposed for the licence renewal inspection was suitable.

As no renewal application had been submitted by the time of the inspection, during the inspection the centre's inspector twice offered the PR assistance in logging on to the clinic portal and submitting the form. The PR declined this offer.

As an alternative, the centre's inspector gave the PR a printed version of the completed renewal application and asked the PR to sign it to indicate that he accepted the standard declaration. The PR did not sign the form. The PR said that he would submit the form later, either later in the week of the inspection or the following week, but he stated that he did

not have his login details to submit the form. Therefore the centre's inspector wrote down the login details and gave these to the PR. No renewal application form was submitted by 12 February 2016 so the centre's inspector emailed and wrote to the PR to say that if she heard nothing to the contrary she would accept the application that he had completed on the portal as an application to renew his licence. No response was received and the inspector submitted the renewal application on behalf of the PR on 2 March 2016.

Following discussion with the Director of Compliance and Information the completed SAQ was also submitted by the centre's inspector on 11 March 2016.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period October 2014 – September 2015 show the centre's success rates are in line with national averages with the following exceptions:

- success rates following IVF and ICSI in women of all ages are higher than average at a statistically significant level.

In 2015, the centre did not submit an annual return for partner insemination that was performed in 2014.

Multiple births[2]

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

Between October 2014 and September 2015 the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups is 25%: this represents performance that is likely to be greater than the 10% multiple live birth rate target for this period.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

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), the inspection team considers that it has sufficient information to conclude that:

- the application has been provided;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has broadly discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are broadly suitable;
- the application contains the supporting information required by General Directions 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one critical, five major and six 'other' areas of non-compliance which have resulted in the following recommendations:

Critical areas of non compliance:

- **The PR should arrange to have the effectiveness of the centre's multiple births minimisation strategy reviewed by an independent expert, and establish, and ensure the accurate use of, summary logs for treatment cycles in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer.**

Major areas of non compliance:

- The PR should take immediate action to ensure that witnessing is completed and recorded at all critical points of the clinical and laboratory process.
- The PR should provide written confirmation that the export of embryos outside the European Economic Area that was reviewed during the inspection met the requirements of General Directions 0006, schedule 4 (b), (c) and (i).
- The PR should review the efficacy and appropriateness of the centre's procedures for obtaining patient consent to storage of gametes and embryos, including where consent may be considered to be fettered to payment of storage fees.
- The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms.
- The procedures used to submit licensed treatment data, including the number of cycles of partner insemination, should be reviewed to identify and address the reasons for non-reporting and delayed submissions. Appropriately completed annual returns for partner inseminations conducted in 2014 and 2015 should be submitted via the clinic portal.

'Other' areas that requires improvement:

- The PR should ensure that gas cylinders are secured in accordance with compressed gas safety guidelines.

- The PR should ensure that other than when in use, clinical waste storage bins should be locked at all times.
- The PR should ensure that the clinical indication for use of any medications in a manner that is different to their intended purpose should be documented in patient's records, and entries in the controlled drugs register are recorded correctly.
- The PR should ensure the development of a documented SOP for air quality testing and review the SOP for screening of sperm for treatment in a surrogacy arrangement. The PR should ensure that audits infection control procedures are audited at least every two years.
- The PR should ensure that the validation of the vitrification process and the frequency of and methodology for air quality testing is documented.
- The PR should provide evidence as to whether the counsellor is working towards BICA accreditation or can demonstrate training and experience to an equivalent standard.

The PR has not provided a response to these recommendations. The inspector sent the PR a copy of the draft report on 23 March 2016, requesting a response to the recommendations within 10 working days. When no response was received the inspector sent the PR the draft report again on 12 April 2016, and asked for a response to the recommendations within 5 working days. Both these communications were sent by email, with delivery receipts obtained, and by letter, with proof of delivery obtained.

Recommendation to the Executive Licensing Panel

The centre has one critical and five major of areas of concern.

The inspection team notes that the success rates are above the national average but the centre's multiple clinical pregnancy rates are unlikely to meet the current multiple live birth rate target.

The PR is encouraged to continue to use the Quality Management System (QMS) to best effect to implement an effective strategy to reduce multiple birth rates to meet the target so as to improve the quality of the service offered to patients. The inspector will continue to monitor the centre's performance in this regard.

Taking into account the 'Guidance on periods for which new or renewed licences should be granted', the indicative sanctions guidance, the licence renewal report and the centre's licensing history, the inspection team recommends renewal of the centre's treatment (including embryo testing) and storage licence for a period of three years without additional conditions.

Given that the PR has a demonstrable history of failing to communicate effectively with the centre's inspector or respond to correspondence, the inspection team also recommend that as the PR has not:

- responded to this inspection report; nor
- provided updates to the centre's inspector to demonstrate that appropriate action is being taken by the recommended timescales, some of which have now elapsed, to address the non-compliances;

an additional inspection be conducted at the discretion of the executive in 2016.

This inspection will focus on the non-compliances identified in this report. The executive acknowledges that recommendations are sometimes addressed by the PR without

notifying the centre's inspector, but considers that, except where informed by data submitted to the HFEA, in the absence of effective communication from the PR there is no other mechanism for the executive to establish whether the recommendations made are being implemented, and therefore a further inspection is warranted.

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

What the centre does well

Witnessing (Guidance note 18)
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.

What the centre could do better
Five sets of patient records were reviewed. In one record the date and time of witnessing the identity of the sperm provider was missing, and the signature of the practitioner and time of witnessing the disposal of gametes/embryos was also missing. One other record showed that in two out of the three sperm preparation steps the signature of the practitioner was recorded but only the initials, and not the signature, of the witness. The inspector was assured that the preparation steps had been witnessed and this was a documentation error only (SLC T71) (recommendation 2).

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors 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; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important

that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better
Nothing identified at this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are broadly suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

Laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are accredited and therefore considered suitable.

The centre is compliant with HFEA requirements to process gametes and embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are broadly compliant with guidance.

Medicines management
It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed by the Medicines and Healthcare Products Regulatory Agency (MHRA) as an intravenous nutritional supplement for adults and children.

Some healthcare professionals consider intralipid therapy has an effect on the immune system and may be beneficial to a particular subset of women having IVF. Intralipid is not licensed for use in fertility treatment. If prescribed in this context, this represents 'off-label' use.

Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence. In April 2015 the President of the Royal College of Obstetricians and Gynaecologists (RCOG), published concerns regarding the evidence base for the use of this medicine in IVF in terms of its safety and efficacy. In July 2015 the HFEA published guidance to centres regarding the prescribing of intralipid or other 'off label' therapies to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about this therapy to ensure that the reasons for prescribing this medicine 'off-label' are explained, including that there is currently little evidence to support its use in this application;
- recording the reasons for prescribing this medicine in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The clinic's processes for medicines management and the safe storage, disposal and administration of medicines are broadly compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Directions 0003)

The single biggest risk of fertility treatment is a multiple pregnancy. To reduce this risk, the HFEA sets a maximum multiple live birth rate that centres should not exceed and since October 2012, this has been 10%.

The centre's procedures are not compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer and conducting regular audits and evaluations of the progress and effectiveness of the strategy.

However, the inspection team recognises that the centre's multiple pregnancy rate has reduced to 25% from 29% at the last inspection in 2014, and the multiple birth rate for treatments between 1 October 2014 and 30 September 2015 is likely to be approximately 20%[1] compared to a multiple birth rate of 33% between 1 July 2013 and 30 June 2014.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes/embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are partially

[1] The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- 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.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre doe not have any transport or satellite centres, therefore this is not applicable at this centre.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. 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.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are broadly compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre has not reported any adverse incidents since the last inspection. On inspection of the centre's adverse incidents log the inspector was satisfied that no reportable incidents had occurred since the last inspection. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities

Gas cylinders in the gas store were not adequately secured to ensure that they were not at risk of toppling (SLC T17, Health Technical Memorandum.02-01: medical gas pipeline systems part B: Operational management) (recommendation 7).

Infection control
The large clinical waste bins located outside the recovery area were not locked at the time of the inspection. This area is accessible to the general public from the main road and therefore is a potential infection hazard (SLC T2) (recommendation 8).

Medicines management
The clinical rationale for prescribing intralipid therapy is not documented in the patient's record (SLC T2) (recommendation 9).

The centre does not record alterations in the controlled drugs register in accordance with regulations. There were numerous errors in the controlled drugs register that were scribbled out and a new entry overwritten, rather than written as an explanatory foot note with a record of the date the error was corrected (SLC T2, SLC T47 and Misuse of Drugs Regulations 2001, schedule 20 (c)) (recommendation 9).

Multiple births
Between 1 October 2014 and 30 September 2015, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 25%: this represents performance that is likely to be statistically higher than the 10% multiple live birth rate target for this period. Additionally, between 1 July 2013 and 30 June 2014 the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 33%: this is higher than the 10% multiple live birth rate target for this period (General Directions 0003 and SLC T2) (recommendation 1).

Although the PR confirmed that he is following professional body guidelines when advising women on how many embryos should be transferred, these guidelines are not proving sufficient to ensure the centre does not exceed the HFEA multiple birth rate target.

Centre staff were not able to provide a summary log for treatment cycles in which multiple embryos had been transferred to patients who meet the criteria for single embryo transfer (General Directions 0003) (recommendation 1).

Imports and exports
Centre staff were not able to demonstrate that an export of embryos outside the European Economic Area met the requirements of General Directions 0006, schedule 4 (b), (c) and (i) (recommendation 3).

Quality management system
The SOP for testing laboratory air quality does not reflect current practice despite having been reviewed on 19 January 2016. The SOP for screening of sperm for treatment in a surrogacy arrangement implies that the quarantine period may be waived if the patients wish, although no evidence was seen to suggest that this has actually occurred (SLC T33b) (recommendation 10).

An audit of infection control procedures has not been undertaken within the last two years (SLC T36) (recommendation 10).

Process validation
Validation of the vitrification process and the frequency of and methodology for air quality testing has not been documented. However, from discussions with centre staff, the inspector is satisfied that validation has been performed (SLC T72) (recommendation 11).

Staff engaged in licensed activity

Person Responsible (PR)

Staff

What the centre does well

Person Responsible (Guidance note 1)
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 (PREP number T/1075/7).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better
Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA requirements.

Safeguarding
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better
Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening

Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
These procedures have not been performed at the centre since the last inspection, as these procedures are usually provided at the associated centre 0206. Therefore it was not possible to inspect these areas. The PR would like to retain embryo testing on the licence for this centre to enable embryo testing to be performed at centre 0157 if there is not capacity to perform it at centre 0206. The same staff will perform these procedures at both centres.

What the centre could do better
Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to one patient who provided feedback on her experience. A further 12 patients also provided feedback directly to the HFEA in the time since the last inspection. Seven of these individuals had 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 and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF& E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)

The centre's counselling procedures are broadly compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg and sperm sharing arrangements (Guidance note 12; General Direction 0001)

Egg and sperm sharing is not undertaken at this centre, therefore this is not applicable at this centre.

Surrogacy (Guidance note 14)

The centre's procedures for treatment involving surrogacy are broadly compliant with HFEA requirements (see quality management system section). This is important to protect the surrogate and any children born as a result of the treatment.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are 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

Counselling
The counsellor for the centre is not British Infertility Counselling Association (BICA) accredited. Centre staff were not able to provide evidence as to whether the counsellor is working towards accreditation or that her experience and training demonstrates an equivalent standard (SLC T12) (recommendation 12).

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and/or donors are compliant with HFEA requirements. 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.

What the centre could do better
Nothing identified at this inspection.

Consent

Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are partially 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 (General Direction 0005)
The HFEA Register is a rich source of information about treatment using assisted

reproductive technologies (ART). It can be used by researchers and linked to other health registers to improve knowledge about the health of patients who have undergone ART and those born following ART treatment. The HFEA is permitted to disclose non-identifying information to researchers but can only provide patient identifying information with the consent of the patient. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA.

The centre's procedures for taking consent to disclosure to researchers are partially compliant with HFEA requirements.

What the centre could do better

Consent
A review of patient consent to treatment and storage forms showed that in one set of patient records there were inconsistencies in the period for which consent to storage was provided by the patient and her partner. In one other record, the consent form was ticked for two different storage consent periods, therefore making it difficult to ascertain the intended storage consent decision. Some of the patient records showed that changes had been made to the consented storage period. Following discussion with the PR it appeared that this could be due to payment for storage being linked to the consented storage period (SLC T38 and CH(15)01) (recommendation 4).

Disclosure of information, held on the HFEA Register, for use in research
Nineteen individual patient records were reviewed and two discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register (CH(10)05 and General Directions 0005). Therefore the centre's procedures have failed to ensure that the HFEA holds an accurate record of patient and partner consent to disclosure decisions. In both cases the patient and partner had consented to the release of their identifying information but the consent data provided to the HFEA indicated that the patient and partner did not consent. Although this would not lead to the HFEA releasing patient identifying information to researchers without consent, it would mean that the patient's/partner's wishes were not being complied with (recommendation 5).

(NB. The centre's designated HFEA Form Returnee has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected).

Legal parenthood

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure

they are suitable, to notify their inspector when the audit was completed and to discuss what, if any, action should be taken. The PR did not provide notification that the audit had been completed, nor discuss what, if any, action would be taken.

Interrogation of treatment data submitted to the HFEA showed that the centre had not provided treatment with donor sperm to couples who were neither married nor in a civil partnership at the time of treatment and whose treatment resulted in a live birth. As a result, the HFEA decided not the take any further action at that time.

However, by October 2015 there had been a number of treatments reported by the centre where donor sperm had been used but no outcome form had been submitted. This meant that, without knowing whether there were any live births or ongoing pregnancies resulting from these treatment, the HFEA could not be assured that parenthood issues did not apply to these cases.

On 15 October 2015, the Chief Inspector wrote to the PR requiring that he submit a copy of his legal parenthood audit findings and provide assurance that:

- his methodology for identifying any treatments where consent to parenthood was relevant were robust;
- treatments that had been provided since 6 April 2009 where consent to parenthood was relevant, had been audited in accordance with the methodology prescribed in the Chief Executive's letter CH(14)01;
- his procedures for taking consent to parenthood are robust, that training for new staff is effective and there are effective methods for assessing the on-going competence of staff to take this consent;
- he has effective audit procedures to ensure on-going compliance with consent taking requirements.

These actions were to have been completed by 2 November 2015.The PR did not respond to this correspondence.

The centre's inspector wrote to the PR on 16 November 2015 to remind him that he had not responded to the Chief Inspector's letter and to require him to provide the information by 20 November 2015 otherwise formal action may be taken. The PR did not respond to this correspondence.

On 27 November 2015 the centre's inspector wrote to the PR to inform him that she and a fellow inspector would visit the centre on 2 December 2015 to perform an audit of consent to legal parenthood in patient records. The inspectors visited the centre as planned but the PR would not allow the inspectors access to the records. The inspectors therefore left the centre without having performing the planned audit.

On 3 December 2015 the centre's inspector wrote again to the PR to inform him that she and a fellow inspector would visit the centre on 7 December 2015 to perform an audit of consent to legal parenthood in patient records. The inspectors visited the centre as planned. On this occasion the PR was accompanied by his legal advisor. The inspectors were not permitted access to the records. Once again the inspectors were not able to perform the planned audit. The PR did, however, provide verbal assurance that all patients complete the WP/PP consent to legal parenthood forms, that records are regularly audited to confirm that relevant consent forms are present and correctly completed and that he was satisfied the audit methodology was robust. The PR also informed the inspectors that no

anomalies had been found. On 16 December 2015 the centre's inspector wrote to the PR to summarise the outcome of the visit on 7 December 2015.

As the assurances received from the PR were adequate to fulfil the requirements of the Chief Inspector's letter of 15 October 2015, the executive accepted that legal parenthood consent was, and is, being obtained in a compliant manner.

On inspection the inspectors were able to review one patient record where donor sperm was used and the patient couple were neither married nor in a civil partnership. The centre's procedure for ensuring proper consent to legal parenthood was compliant with HFEA requirements.

What the centre could do better
Nothing identified at this inspection.

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 and
- 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 identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

The centre's procedures for screening patients are compliant with HFEA requirements. 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.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. 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 treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)
Embryos are not currently used, and have not been used since the last inspection, for training staff, therefore this guidance note was not inspected.

What the centre could do better
Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are 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 ; General Direction 0005)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities. In order to do this, centres 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.

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

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Obligations and reporting requirements
1% (1/104) of the IVF treatments reviewed at inspection had not been reported to the HFEA (General Directions 0005 and SLC T41). This treatment notification was subsequently sent to the HFEA during the time of the inspection. 78% (81/104) of the IVF and 86% (6/7) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Directions 0005 (SLC T41) (recommendation 6).

The PR did not provide written notification of the number of cycles of partner insemination performed in 2014 or 2015 (General Directions 0005 and SLC T41) (recommendation 6).

The PR did not submit a renewal application or SAQ in support of this inspection despite several reminders to do so (SLC T4). The renewal application was submitted by the inspector after correspondence to the PR notifying him that this would be done unless he stated he did not wish it to be submitted for him. The SAQ was submitted by the inspector after discussion with the Director of Compliance and Information (recommendation 6).

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2014, recommendations for improvement were made in relation to one area of critical non-compliance and four areas of major non-compliance as described earlier in this report. Actions taken following this inspection are also described in this section (see pages 3, 4, 5 and 6).

No significant improvements were noted during this inspection regarding the other three non-compliances and therefore continue to be reported as non-compliances at this inspection for which recommendations for improvement have been made.

On-going monitoring of centre success rates

As described earlier in this report, in the last year the PR was asked to review:

- procedures for the provision of ICSI treatment in patients aged under 38 in February, June, July, August and September 2015;
- procedures for the provision of ICSI treatment in patients aged 38 and over in July 2015;
- multiple pregnancy rate in February, March, April, May 2015 and January 2016.

The PR did not respond to these requests. However, average success rates for ICSI in both age groups for the period October 2014 – September 2015 are above average at a statistically significant level and the apparent low success rates in those months were due to late reporting of results by the centre.

The multiple pregnancy rate remains high. The PR was contacted about this issue in February 2015. As it appeared that the trajectory of the CUSUM plot was beginning to flatten at that time, following a management review it was decided to continue to monitor the situation and the PR was not required to take any additional action.

Areas of practice requiring action

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, General Direction or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or 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. **Multiple births** Between 1 October 2014 and 30 September 2015, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 25%: this represented performance that was likely to be statistically higher than the 10% multiple live birth rate target for this period. Additionally, between 1 July 2013 and 30 June 2014 the centre's multiple live birth rate for all IVF,	The inspection team recognises that the centre's multiple pregnancy rate has reduced from 29% at the last inspection in 2014, and the multiple live birth rate will be lower than the 33% seen between 1 July 2013 and 30 June 2014. The PR should arrange to have the effectiveness of the centre's multiple births minimisation strategy reviewed by an independent expert by 28 April 2016.		The PR has not responded to the inspection report to date. The centre's multiple pregnancy rate remains high with no indication of a reduction in multiple pregnancies.

ICSI and FET cycles for all age groups was 33%: this is higher than the 10% multiple live birth rate target for this period (General Directions 0003 and SLC T2). This was identified as an area for improvement at the last two inspections.	A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 28 May 2016.		
Centre staff were not able to provide a summary log for treatment cycles in which multiple embryos had been transferred to patients who met the criteria for single embryo transfer (General Directions 0003).	By 28 March 2016, the PR should establish, and ensure the accurate use of, summary logs for treatment cycles in which multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. Six months after the establishment of the logs the PR should conduct an audit of the documentation of cases where multiple embryos have been transferred to a patient who meets the criteria for single embryo transfer. A summary report of the audit findings including corrective		

	actions and the timescale for their implementation should be submitted to the centre's inspector by 28 October 2016.		

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/her legal duties
- a combination of several 'other' areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
2. Witnessing Five sets of patient records were reviewed. In one set the date and time for witnessing the identity of the sperm provider was missing, and also the signature of the practitioner and time was missing for witnessing the disposal of gametes/embryos. In another record, two out of the three sperm preparation steps had the signature of the practitioner but only the initials, and not the signature, of the witness (SLC T71). This was identified as an	The PR should take immediate action to ensure that witnessing is recorded at all critical points of the clinical and laboratory process. The inspector should be advised of the measures taken to ensure that this happens by 28 March 2016. Within three months of the inspection the PR should conduct an audit of witnessing and a summary report of the findings of the audit should be provided to the inspector by 28 May 2016.		The PR has not provided evidence that action has been taken in response to this non-compliance.

area for improvement at the last inspection.			
3. Imports and exports Centre staff were not able to demonstrate that an export of embryos outside the European Economic Area met the requirements of General Directions 0006, schedule 4 (b), (c) and (i).	The PR should provide written confirmation that the export of embryos outside the European Economic Area that was reviewed during the inspection met the requirements of General Directions 0006, schedule 4 (b), (c) and (i). This information should be submitted to the HFEA by 28 April 2016.		The PR has not provided evidence that action has been taken in response to this non-compliance.
4. Consent A review of patient consent to treatment and storage forms showed that in one set of patient records there were inconsistencies in the consent to storage periods for one couple and one of the consent forms was ticked for two different storage consent periods, therefore making it difficult to ascertain the intended storage consent decision. Some of the patient records showed that changes had	The PR should review the efficacy and appropriateness of the centre's procedures for obtaining patient consent to storage of gametes and embryos, including where consent may be considered to be fettered to payment for storage. The centre's inspector should be provided with a summary report of the findings of this review, including corrective actions and the timescale for their implementation by 28		The PR has not provided evidence that action has been taken in response to this non-compliance.

been made to the consented storage period and following discussion with the PR it appeared that this could be due to storage payment being linked to the consented storage period (SLC T38 and CH(15)01).	April 2016. Within six months of the inspection the PR should conduct an audit of consent to storage of gametes and embryos and a summary report of the findings of the audit should be provided to the inspector by 28 August 2016.		
5. Disclosure of information, held on the HFEA Register, for use in research Two discrepancies were found between completed patient/partner disclosure consents on patient files and the related consent data submitted for inclusion on the register (CH(10)05 and General Directions 0005). This has been escalated to a 'major' non-compliance as this was identified as an area for improvement at the time of the last two inspections, and the PR has not corrected previous	The PR should review procedures and take appropriate corrective actions to ensure that the disclosure consent information supplied to the Authority accurately reflects that given and recorded on disclosure consent forms. The PR should also correct the submissions that have been identified as being incorrect. These recommendations should be implemented by the time the PR responds to the inspection report and the inspector informed of the results of the review and actions taken. The PR should conduct an audit six months after		The discrepancies identified at the inspection have not been corrected and the PR has not provided confirmation that the procedures have been reviewed.

errors. *(NB. The Centre's designated HFEA Form Returnee has been provided with the relevant patient and partner numbers so that the form data can be reviewed and corrected).*	implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the inspector by 28 October 2016.		
6. Obligations and reporting requirements 1% (1/104) of the IVF treatments reviewed at inspection had not been reported to the HFEA (General Directions 0005 and SLC T41). 78% (81/104) of the IVF and 86% (6/7) of the DI treatments reviewed at inspection had been reported to the HFEA outside the period required by General Directions 0005 (SLC T41). Late data submissions were identified as an area for improvement at the time	The missing treatment notification was subsequently sent to the HFEA during the time of the inspection. The procedures used to submit licensed treatment data, including the number of cycles of partner insemination, should be reviewed to identify and address the reasons for non-reporting and the delayed submissions. The centre's inspector should be provided with a summary report of the findings of this review, including corrective actions		Late submission of forms is still an issue. The PR has still not notified the HFEA of the number of cycles of partner insemination performed in 2014 and 2015. Additionally, the PR has not provided confirmation that the procedures used to submit forms have been reviewed.

of the last two inspections. The PR did not provide written notification of the number of cycles of partner insemination performed in 2014 and 2015 (General Directions 0005). The PR did not submit a licence renewal application or SAQ in support of this inspection despite several reminders to do so (SLC T4). The licence renewal application was submitted by the inspector after correspondence to the PR notifying him that this would be done unless he stated he did not wish it to be submitted for him. The SAQ was submitted by the inspector after discussion with the Director of Compliance and Information.	and the timescale for their implementation by 28 March 2016. The PR should conduct an audit six months after implementing any corrective actions, to confirm that the actions have had the desired effect. A summary of the audit should be provided to the inspector by 28 October 2016.		

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
7. Safety and suitability of premises and facilities Gas cylinders in the gas store were not secured. (SLC T17, Health Technical Memorandum.02-01: medical gas pipeline systems part B: Operational management).	The PR should ensure that gas cylinders are secured in accordance with compressed gas safe storage guidance. The PR should provide confirmation of the action taken by 28 April 2016.		The PR has not provided evidence that action has been taken in response to this non-compliance.
8. Infection control The large clinical waste bins located outside the recovery area were not locked at the time of the inspection. This area is accessible to the general public from the main road and therefore is a potential infection hazard (SLC T2).	The PR should ensure that other than when in immediate use, clinical waste storage containers should be locked at all times. The PR should provide confirmation of action taken to ensure this when responding to this report.		The PR has not provided evidence that action has been taken in response to this non-compliance.
9. Medicines management The clinical rationale for prescribing intralipids	The PR should ensure that the clinical indication for use of any medications in a manner		Evidence to demonstrate that the first part of this recommendation has been

therapy is documented in the patient's medical record (SLC T2).	that is different to their licenced intended purpose should be documented in patient's records. Within six months of the inspection the PR should conduct an audit of medical records for patients who have been treated with intralipids to ensure that the clinical indication is being documented in patient records and a summary report of the findings of the audit should be provided to the inspector by 28 August 2016.		implemented is not yet due. The PR has not provided evidence that the second part of this recommendation has been implemented.
The centre does not record alterations in the controlled drugs register in accordance with regulations. There were numerous errors in the controlled drugs register that were scribbled out and a new entry overwritten, rather than written as an explanatory foot note with a record of the date the error was corrected (SLC T2,	The PR should review how entries and corrections are made in the controlled drugs register to ensure compliance with Misuse of Drugs regulations. A summary of the findings of this review, any corrective actions and timescales for implementation should be provided to the centre's inspector by 28 April 2016.		

SLC T47 and Misuse of Drugs Regulations 2001, schedule 20 (c)).	Within six months of the inspection the PR should carry out an audit of the controlled drugs register and a summary report of the findings of the audit should be provided to the inspector by 28 August 2016.		
10. Quality management system The SOP for testing laboratory air quality does not reflect current practice despite having been reviewed on 19 January 2016. The SOP for screening of sperm in a surrogacy arrangement implies that the quarantine period may be waived if the patients wish, although there is no evidence that this has actually occurred (SLC T33b).	The PR review the SOP for air quality testing to ensure that it accurately reflects current practice. The PR should review the SOP for screening of sperm to be used in treatment requiring surrogacy to ensure that it accurately reflects the requirement for a suitable quarantine period or alternative testing procedure that does not require a quarantine period. Copies of the SOPs should be provided to the centre's inspector by 28 April 2016.		The PR has not provided evidence that action has been taken in response to this non-compliance.

An audit of infection control procedures has not been conducted within the last two years (SLC T36).	The PR should ensure that an audit of infection control procedures is conducted by 28 April 2016. A copy of the most recent infection control audit should be provided to the centre's inspector by 28 May 2016.		
11. Process validation The validation of the vitrification process and the frequency of and methodology for air quality testing has not been documented. However from discussions with staff, the inspector was satisfied that validation has been performed not documented (SLC T72).	The PR should ensure that the validation of the vitrification process and the frequency of and methodology for air quality testing is documented. A copy of the validation documents should be submitted to the centre's inspector by 28 April 2016.		The PR has not provided evidence that action has been taken in response to this non-compliance.
12. Counselling The counsellor for the centre is not BICA accredited. Centre staff were not able to provide evidence as to whether the counsellor is working towards BICA accreditation or can meet the	The PR should provide evidence as to whether the counsellor is working towards BICA accreditation or can meet the equivalence of BICA accreditation. This information should be submitted to the centre's inspector by 28 April 2016.		The PR has not provided evidence that action has been taken in response to this non-compliance.

equivalence of BICA accreditation (SLC T12).			

Reponses from the Person Responsible to this inspection report