Licence Committee – minutes

Centre 0075 (London Women's Clinic, Darlington)

Interim Inspection Report & Media Allegations Report

Thursday, 13 July 2017

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

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

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

- Executive summary
- Annex 1 – Targeted interim inspection report with PR response
- Annex 2 – Report of investigation into media allegations

- Centre response to Executive summary report
- Letter from Licence Holder re new medical director for the LWC group
- Centre response to media allegations
- Licensing minutes from last three years:
  - 4 May 2017 – Interim inspection report (adjourned)
  - 9 March 2017 – Executive update
  - 14 July 2016 - Additional inspection following whistle blower report
  - 21 March 2016 - Interim inspection report
  - 12 March 2015 - Renewal inspection report
- Letter to Director of Compliance from PR - 3 February 2017
- Meeting notes from PR submitted as an additional response to inspection Report - 1 February 2017

1. Background

1.1. The London Women's Clinic, Darlington (centre 0075) holds a treatment and storage licence and provides a full range of fertility services. The centre has held a licence with the HFEA since 1992. The current licence was granted on 1 April 2015 for a three-year period instead of the usual four and expires on 31 March 2018.

1.2. The centre provided 354 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2016. In relation to activity levels this is a small centre.

1.3. The centre has been closely monitored since its licence renewal inspection in November 2014 and the inspectorate has visited the centre on a number of occasions since then to complete an announced interim inspection in November 2015, an unannounced inspection following a whistle-blower report to the HFEA in May 2016, an announced visit to provide an incident workshop, which also served to investigate a further whistle-blower report in August 2016, and a targeted announced interim inspection further to the previous inspections identifying new or recurring areas of concern in December 2016.

1.4. The Executive invited the Person Responsible (PR) and Licence Holder (LH) to a meeting on 26 January 2017 to discuss the regulatory record of the centre, the PR's role, the centre's response to the inspection report and expectations of the Executive in relation to regulatory compliance and sustained improvements. The Executive requested further information from the centre and considered it reasonable and proportionate to delay making any recommendations and to allow the PR a further opportunity to demonstrate regulatory compliance. The Licence Committee was informed of this decision, and at its meeting on 9 March 2017, discussed whether there would be any immediate risk to the safety of patients, gametes or embryos leading up to a full report being presented for later consideration at its meeting in May 2017. The committee was reassured that there would be minimal risks to the safety of patients, gametes or embryos and agreed to consider the full report at its meeting in May 2017. Before that meeting was convened, there was a press article published on the 2 May 2017 which raised serious allegations about several fertility clinics, including this centre.

1.5. At its meeting on 4 May 2017, the Licence Committee noted that the Executive had planned further engagement with the PR as a result of the press report and as such the Executive had requested that consideration of this matter be deferred and that a further report would be

presented to the committee in due course. The committee agreed to defer the consideration of this item.

2. Consideration of application

Report of inspection - targeted announced interim inspection further to the previous inspections identifying new or recurring areas of concern - 5 and 6 December 2016

2.1. The committee considered the report of an inspection of 5 and 6 December 2016.

2.2. The committee noted that the PR has provided evidence that all the recommendations made had been fully implemented and that evidence of training scheduled for May 2017 and a summary of follow up audits to assess the effectiveness of actions implemented was to be provided by 5 June 2017. However the PR did not submit these to the Executive within the required timescales and the Executive then requested immediate submission, to which the PR has responded.

2.3. The committee noted that there is a history of significant non-compliance at this centre and an inability to sustain compliance without the pressure and scrutiny of the Executive. The PR has had extensive opportunities to demonstrate and maintain compliance.

Report of Media Allegations – May 2017

2.4. The committee noted the details of the visit to the centre on 10 May 2017, to investigate allegations made by the Daily Mail newspaper, who published a report in May 2017 into the practices of some fertility clinics, and other matters relating to treatments for assisted reproduction more generally. There were several articles relating to, for example, the use of add on treatments, medication pricing, egg freezing and egg sharing and the incentives offered to patients in this process. The centre was particularly prominent in the report. The allegations included:

- the centre exploiting women to donate eggs for financial reasons
- having an inadequate counselling service that did not prepare women for the consequences of egg donation
- promoting high interest rate loans via a third party, to couples unable to finance their treatment by other means.

2.5. The committee noted the serious nature of the allegations made by the newspaper and that these allegations were clearly a breach of the HFEA Code of Practice (CoP) requirements. In order to address these issues the centre was required to:

- review its Counselling Standard Operating Procedure (SOP) to ensure it provides clarity on the provision of counselling
- review its practices, with attention to the marketing, and recruitment of patients wishing to donate or share some of their eggs
- revise its benefits in kind agreements to ensure they comply with CoP guidance
- review its website to ensure compliance with CoP guidance regarding the marketing of egg donation.

2.6. The report into the allegations made by the newspaper also stated that the PR has failed to ensure suitable practices were used in the course of activities, or that the conditions of the licence had been complied with.

2.7. The committee noted that the Executive considers that the PR has failed to demonstrate effective oversight of the day to day activities of the centre or fully discharge her duty under Section 17 of

the HFE Act 1990 (as amended). The Executive had considered a recommendation to revoke the centre's licence, but on balance felt that revocation of the licence at this stage would be disproportionate. The Executive gave further consideration to its options, given its concerns with the PR's suitability. Under Section 18A (1) and (2) of the HFE Act 1990 it is possible for the Authority to vary the licence to substitute another person for the PR provided the application is made with the consent of the other person (ie, the intended new PR) and if the Authority is satisfied that the other person is suitable to be in charge of a licenced clinic. Such an application for variation must be made either by the existing person responsible, or by the licence holder (LH) and the Authority is expressly not given any power to vary a clinic's licence to substitute a PR for another without an application. Under these circumstances the Authority could consider suspending the centre's licence with immediate effect, under section 19C of the HFE Act until the Executive is satisfied that a suitable PR has been appointed.

2.8. The committee noted the Executive's recommendation that, in seeking a voluntary undertaking, the Licence Holder will take all reasonable steps to ensure the new PR is in place by 1 October 2017, subject to HFEA approval. The committee noted that there are limited concerns about the safety of patients, gametes or embryos; the PR has engaged with all inspections and regulatory meetings and there have been some recent, noticeable improvements in staff communication and morale. The committee noted that the Executive recommends that the Licence Holder (an experienced PR within the LWC group) undertakes a greater support and supervisory role until a new PR is in post, and commits to doing so.

2.9. The committee noted that under section 16 (3) of the Act, where a Licence Committee has power to revoke a licence it may instead vary any terms of the licence. In relation to the findings the Executive recommends an additional condition be placed upon this licence prohibiting the practice of egg sharing. It recommends the PR must not provide treatment services where a patient donates her eggs to receive 'benefits in kind' until the Executive is satisfied that there are appropriate procedures in place to ensure that this process is compliant with requirements.

3. Decision

3.1. The committee had regard to its decision tree and the HFEA Compliance and Enforcement Policy.

3.2. The committee noted that the PR has responded to the inspection report and the report of the media allegations.

3.3. The committee noted that the PR has failed to demonstrate effective oversight of the day to day activities of the centre or fully discharge her duty under Section 17 of the HFE Act 1990 (as amended).

3.4. The committee noted that the PR and LH have agreed to replace the current PR and will take all reasonable steps to complete this process by 1 October 2017. The committee also noted that the LH has committed to undertake a greater support and supervisory role until this new PR is in post. The committee was satisfied that the PR and LH had made such a commitment and that it was no longer necessary to consider a suspension of the centre's licence at this time, however the committee agreed that, in the event that the PR and LH did not uphold these commitments and take all reasonable steps to replace the current PR, it would consider further enforcement action.

3.5. The committee noted that the PR has confirmed that the centre's egg sharing programme has been voluntarily stopped and that it will not resume until the Executive is satisfied with its suitability. The committee also noted that the PR has provided a copy of the centre's revised egg share agreement and counselling SOP for review by the Executive. The committee endorsed the

Executive's recommendation to add one additional condition to the centre's licence, under section 16(3) of the Act.

The condition reads:

> "The centre must not provide treatment services where a patient donates her eggs to receive 'benefits in kind' until the Executive is satisfied that there are appropriate procedures in place to ensure that this process is compliant with requirements."

3.6. The committee noted that significant changes to the management structure of the LWC group are planned, and expected to see substantial improvement over the next six months.

3.7. The committee agreed to publish the executive summary report and its two annex reports alongside the minutes of this meeting in line with the HFEA's 'Publication and disclosure' policy.

4. Chair's signature

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

Signature

Name

Bishop Lee Rayfield

Date

22 August 2017

Executive summary report to Licence Committee 13 July 2017 relating to: London Women's Clinic, Darlington (0075)

Purpose

This is a complex report following extensive monitoring and inspections undertaken by the HFEA Executive further to concerns, over some time, about the performance of London Women's Clinic, Darlington. In summary, our interventions are shown below:

- 23, 24 October and 7 November 2014: Licence renewal inspection
- 1 April 2015: Licence commenced
- 26 November 2015: Special interim inspection
- 29 April 2016: Whistle-blowing event
- 4 May 2016: Unannounced inspection of those concerns
- 14 July 2016: Licence Committee consideration of that inspection
- 12 August 2016: Further whistle-blowing event
- 16 August 2016: Announced visit, and investigation of further whistle-blowing event
- 5 and 6 December 2016: Interim inspection
- 26 January 2017 Meeting with the Licence Holder and Person Responsible
- 7 and 20 March, and 6 April 2017: Teleconference meetings with PR to provide the PR an opportunity to demonstrate compliance with the recommendations in the interim report
- 2 May 2017 Daily Mail allegations published
- 10 May 2017 Visit to investigate these allegations

Background

1. The London Women's Clinic, Darlington has held a Treatment and Storage licence with the HFEA since 1992 and provides a full range of fertility services. It provided 354 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2016. In relation to activity levels this is a small centre. The centre also stores gametes and embryos under licence.

2. The current licence was granted on 1 April 2015, for a three-year period and expires on 31 March 2018.

3. The licence renewal inspection in November 2014 identified several areas of non-compliance. The HFEA Licence Committee considering the application and report of the inspection expressed deep concern regarding the number and seriousness of those areas of non-compliance. The Committee also noted the good level of engagement of the PR with the Executive and agreed to renew the centre's licence for a period of three years, rather than the usual four, and required the Executive to undertake a 'targeted interim inspection' within nine months of the licence coming into force.

4. An interim inspection took place in November 2015. This identified one 'critical', three 'major' and one 'other' areas where the centre was not compliant with HFEA

requirements. This was an improvement on the previous inspection in 2014, where there were four ‘critical’, two ‘major’ and three ‘other’ areas of practice requiring improvement, with medicines management non-compliance being a factor in both inspections. At that time of the interim inspection, there were no ongoing concerns relating to staff training and patient safety. The Executive Licensing Panel (ELP) considering this inspection report noted its concerns that despite it being an announced, targeted inspection the areas of non-compliances identified at the licence renewal inspection (in October and November 2014) remained an issue particularly those relating to concerns as to the management of medicines and patients providing consent appropriately. The panel noted that following the inspection, the centre had addressed all the non-compliances, to the satisfaction of the Executive. It also emphasised that it expected to see these improvements sustained. It agreed to the continuation of the centre’s licence.

5. On 29 April 2016, the HFEA was contacted by a whistle-blower regarding some practices at the centre. In accordance with the HFEA ‘Compliance and enforcement’ policy, a management review (held on 29 April 2016) considered that the concerns raised were sufficiently serious to warrant investigation. An unannounced inspection was conducted on 4 May 2016 to determine whether the whistle blower’s concerns were founded and if there was any risk to patients.

6. The focus of the whistle-blower’s concerns was a risk to patient safety due to the size, experience and competence of the centre’s nursing team. The inspection team concluded that the whistle-blower’s concerns were justified, to an extent. There were significant staffing issues at the centre at the time which were having an adverse impact on staff morale and the running of the centre. Overall, the inspection team considered that the staffing situation did not pose an immediate risk to patient safety. However, during a review of the two incidents highlighted by the whistle blower several additional areas of practice that required improvement were identified in relation to two critical and two major areas of non-compliance.

7. As such, the Executive could not initially make a recommendation for the continuation of the centre’s licence, given that the similar non-compliances had reoccurred. Nor was it assured of the PR’s ability to discharge her duty under Section 17 of the HF&E Act 1990 (as amended). Following assurance from the PR to implement the recommendations, the Licence Committee, at its meeting of 14 July 2016, agreed to the continuance of the licence but that a further inspection be conducted in nine months. It was also agreed that the HFEA clinical governance lead would provide a workshop to the centre team on the management and investigation of incidents, with a view to improving practice in that area.

8. On 12 August 2016, a (different) whistle-blower raised further concerns to the HFEA about the care of a specific patient at the centre. In accordance with the HFEA ‘Compliance and enforcement policy’ a management review meeting was held the same day. The Executive was due to visit the centre on 16 August 2016 to undertake the incident workshop (see 7. above) and it was considered appropriate to combine that visit, with the investigation of the whistle-blower’s concerns.

9. At that visit, the inspection team did not identify any concerns about the care of the specific patient. It was, however, concerned it was the second recent whistle-blowing incident, which in itself is suggestive of staffing discord. A further management review meeting was held, concluding that an additional inspection (targeted interim inspection) take place. This was carried out on 5 and 6 December 2016. The report of that inspection, and subsequent engagement with centre management, was due to be considered at the HFEA Licence Committee meeting of 4 May 2017.

10. On 2 May 2017, a newspaper published a report into the practices of some fertility clinics, and other matters relating to treatments for assisted reproduction more generally. There were several articles relating to, for example, the use of (add-on) treatments, medication pricing, egg freezing and egg sharing and the incentives offered to patients in this process.

11. The centre was particularly prominent in the press report. Further to 'undercover' reporting the article made several allegations. These included the centre exploiting women to donate eggs for financial reasons; of having an inadequate counselling service that did not prepare women for the consequences of egg donation; and promoting high interest rate loans via a third party, to couples unable to finance their treatment by other means.

12. In considering the press article, the Director of Compliance and Information requested that the Licence Committee adjourn its consideration of that report at its meeting of 4 May 2017 until further information could be gathered in relation to the newspaper's allegations. The Committee agreed to do so.

13. The investigation of those allegations was carried out by a visit to the centre undertaken on 10 May 2017.

14. As such there are two reports for consideration by the committee.

    1. Report of an inspection of 5 and 6 December 2016 – annex 1.
    2. Investigation report into media allegations – annex 2

Recommendation

The two reports set out actions necessary for the centre to demonstrate improvements to practice, for it to be compliant with HFEA requirements. This summary report considers whether additional and further steps should be taken to deal, in totality, with the range of issues presented in terms of the centre's licensing history; the report of the inspection of 5 and 6 December 2016, and the report of the investigation into media allegations. It concludes that further action is necessary and an appropriate recommendation is provided to Licence Committee.

In summary, the Executive recommends that action should be taken by London Women's Clinic to replace the current Person Responsible and that a condition be placed on the licence preventing the clinic from undertaking treatments involving

egg-sharing arrangements. The considerations the Executive have taken into account follow.

Firstly, it is necessary that the Committee has regard to the recommendation made by the Executive in its (original) submission to the Licence Committee at its meeting of 4 May 2017. Consideration of that report was postponed for the reasons set out above. This was as follows:

'Since the inspection, the PR has subsequently provided evidence that all the recommendations made in this report have been fully implemented. Evidence of training scheduled for May 2017 and a summary of follow up audits to assess the effectiveness of actions implemented are to be provided within the timescales specified.

The Executive now considers there is sufficient information on which to reach a conclusion regarding the centre's licence and recommends the continuation of the centre's licence without any additional conditions.

However, in doing so, the Executive is mindful of the licensing history of this centre and will continue to closely monitor the centre's performance and expects to see clear evidence of sustained improvements.

It is anticipated that the centre will be inspected for licence renewal in October 2017. The Executive expects to see evidence that the practices and processes put in place to date by the PR, have been effective in maintaining regulatory compliance and quality of care. If, however, the Executive have further concerns following this inspection, or non-compliances previously identified have reoccurred, it would seek to implement immediate formal regulatory action given the extensive opportunities the centre has had to demonstrate and maintain compliance'.

Since that recommendation was drafted there has been further interaction with the PR relating to some further follow-up of the inspection and of course relating to the investigation of the allegations made by the newspaper article. Both are material in the formulation of the recommendation. The Executive held a management review on 12 June 2017 to consider this. To summarise:

1. In relation to the inspection, the PR provided evidence that all the recommendations made in this report had been fully implemented, and the Executive accepted this. Further evidence was requested from the PR by the Executive to provide it with assurance. Evidence of training, scheduled for May 2017, and a summary of follow up audits to assess the effectiveness of actions implemented was required to be provided by 5 June 2017. The PR did not submit these to the Executive within the required timescales. The Executive issued a request on 9 June 2017 to the PR for their immediate submission, to which she responded.

2. Given the intense regulatory scrutiny the centre has been under for the past 18 months, the Executive was disappointed to note this. It expects that the PR is fully compliant with all the recommendations made in this and other reports

and demonstrates a commitment to compliance and an ability to fully discharge her duty under section 17 of the HFE Act 1990 (as amended).

3. The PR has had extensive opportunities to demonstrate and maintain compliance. There is a history of significant non-compliance and an inability to sustain that compliance without pressure from, and scrutiny of the Executive.

4. In addition, the actions of the centre, highlighted in the report of the investigation of the allegations made by the newspaper have the potential to bring the sector into disrepute and reduce public confidence in the fertility sector. The necessary improvements we require the centre to put in place (in section 5 of annex 2) relate to clear breaches to Code of Practice requirements and these breaches are of a significant and serious nature. The centre must:

- Review its Counselling SOP to ensure it provides clarity on the provision of counselling'.
- Review its practices, with attention to the marketing, and recruitment of patients wishing to donate or share some of their eggs.
- Revise its benefits in kind agreements to ensure they comply with CoP guidance.
- Review its website to ensure compliance with CoP guidance regarding the marketing of egg donation.

The report into the allegations made by the newspaper also states that the PR has failed to ensure suitable practices are used in the course of activities, or that the conditions of the licence have been complied with.

5. The Executive considers that the PR has failed to demonstrate effective oversight of the day to day activities of the centre or fully discharge her duty. Section 17 of the HFE Act 1990 (as amended) sets out the responsibilities of the PR:

   It shall be the duty of the individual (PR) under whose supervision the activities authorised by a licence are carried on

   (a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,

   (b) that proper equipment is used,

   (c) that proper arrangements are made for the keeping of gametes and embryos and for the disposal of gametes or embryos that have been allowed to perish,

   (d) that suitable practices are used in the course of the activities,

   (e) that the conditions of the licence are complied with,

(f) that conditions of third party agreements relating to the procurement, testing, processing or distribution of gametes or embryos are complied with, and

(g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

6. A Licence Committee can revoke a licence if it is satisfied that [amongst other things] the Person Responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under section 17 of this Act. The Executive is of the view that the PR has not ensured *that suitable practices are used in the course of the activities, nor that the conditions of the licence are complied with, and as such* ceases to be satisfied that the PR is suitable and, therefore, the Licence Committee has grounds to revoke the licence.

7. However, there are limited concerns about the safety of patients, gametes or embryos; the PR has engaged with all inspections and regulatory meetings and there have been some recent, noticeable improvements in staff communication and morale. The Executive is therefore of the view that revocation of the licence at this stage is disproportionate. The Executive gave further consideration as regards its options given its concerns with the PR's suitability.

8. Under section 18A (1) and (2) of the Act it is possible for the Authority to vary the licence to substitute another person for the PR provided the application is made with the consent of the other person [a new PR] and if the Authority is satisfied that the other person is suitable to be in charge of a licenced clinic. Such an application for variation must to be made either by the existing person responsible, or by the licence holder (LH).

9. In consideration of this, the Executive believes it is justified in seeking a voluntary undertaking from the LH and PR jointly to take steps to identify an alternative PR.

10. It further believes that the risks of destabilisation during such a step are real, and is mindful that the process to appoint a new PR, takes time. In the interim period, the Executive recommends that the Licence Holder (an experienced PR within the LWC group) undertakes a greater support and supervisory role until a new PR is in post, and commits to doing so. In making the undertaking, the Licence Committee will wish to be reassured that the Licence Holder will take all reasonable steps to ensure the new PR is in place by 1 October 2017, subject to HFEA approval.

11. If the centre is of the view that it is unable to take such action the Licence Committee is advised that under section 18A(4) of the Act, the Authority is expressly not given any power to vary a clinic's licence to substitute a PR for another, other than on the application of either the PR or the LH.

12. In these circumstances the Committee is invited to consider suspending the clinic's licence with immediate effect, under section 19C of the HFE Act. The Executive is mindful that storage of gametes and embryos will need to continue, and that patients may be partway through treatment

13. It is clearly important that those patients are cared for appropriately and to make provision for continuity of treatment and storage services in relation to these patients alone, the Executive recommends that Special Directions are issued to the PR under s24 (5A) of the Act.

14. Suspension should usually result in the cessation of all activity which requires a licence and the Executive considers that to act as a compliance tool it must include an immediate ban on taking on any new patients and initiating any new treatment cycles. However, it is appropriate to permit the centre to store gametes and embryos currently in storage, (and the transfer of gametes and embryos to licensed centres for licensed activity to take place) and the continued treatment of patients for whom an 'Intention to Treat' form has been submitted to the HFEA, or patients whose gametes or embryos have been thawed in preparation for treatment.

15. In reaching its decision the Licence Committee should refer to the Compliance and Enforcement Policy and the factors to consider in relation to suspending a licence (paragraphs 3.7 and 3.8). The Executive's recommendation is the suspension remain in place until the Executive is satisfied that a suitable PR has been appointed.

16. A decision to suspend a licence takes effect immediately on provision of the appropriate Notice. A decision to suspend is subject to the right of reconsideration (appeal) exercisable by giving the Authority notice within 14 days. However the giving of any notice to the Authority does not affect the continuation of the suspension of the licence (s19C(4)-(6)).

17. In addition, the Executive notes that under section 16 (3) of the Act, where a Licence Committee has power to revoke a licence it may instead vary any terms of the licence. In relation to the findings (summarised in paragraph 4. above) the Executive recommends a condition be placed upon this licence prohibiting the practice of egg sharing. It recommends the PR must not provide treatment services where a patient donates her eggs to receive 'benefits in kind' until the Executive is satisfied that there are appropriate procedures in place to ensure that this process is compliant with requirements. If such a condition is placed on the licence this would be reviewed at the time of the application to renew the centre's licence, the report of which, will be presented to Licence Committee for consideration.

21 June 2017

Executive update following PR response to this summary report

- A copy of this executive summary report and the report of the media allegations were provided to the PR on 22 June 2016. The PR provided a response to the report on 30 June 2017. This response is included in the attached papers.

- The PR and LH have agreed to the executive's request to replace the current PR and will take all reasonable steps to complete this process by 1 October 2017.

- The LH has provided a commitment to undertake a greater support and supervisory role until this new PR is in post.

- Significant changes to the management structure of the LWC group are planned. The executive welcomes this commitment to improving leadership of this group and expects to see substantial improvement over the next six months.

- The PR has confirmed that the centre's egg sharing programme has been voluntarily stopped and that it will not re-commence until the executive is satisfied as to its suitability. The PR has provided a copy of the centre's revised egg share agreement and counselling SOP. These have not yet been reviewed by the executive.

Final Executive recommendation

It is recommended that the Licence Committee:

- formalises the request for the current PR to be replaced;
- places the following additional condition on the centre's licence:
  "The centre must not provide treatment services where a patient donates her eggs to receive 'benefits in kind' until the Executive is satisfied that there are appropriate procedures in place to ensure that this process is compliant with requirements". In recommending this, it is noted that the PR has already voluntarily agreed to comply with this requirement.

The committee is asked to note that as per the HFEA's 'Publication and disclosure' policy, the executive requests that this summary report and its two annex reports are published alongside the minutes of this meeting.

Annex 1

Targeted Interim Inspection Report

Centre name: London Women's Clinic, Darlington
Centre number: 0075
Date licence issued: 1 April 2015
Licence expiry date: 31 March 2018
Additional conditions applied to this licence: None
The centre has applied to add the following activities: None
Date of inspection: 5 and 6 December 2016
Inspectors: Polly Todd (Lead), Susan Jolliffe
Date of Licence Committee: 13 July 2017

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

This is a report of a scheduled (rather than unannounced) inspection and provides information on the centre's performance and level of compliance from what is now, the fourth visit to this centre since November 2015.

The inspection focussed on key areas of risk and on-going areas of concern as follows:

- staff communication;
- the quality management system;
- patient safety;
- medicines management;
- reporting, and learning from, adverse incidents and;
- the PR's ability to fully discharge her duty under Section 17 of the HF&E Act 1990 (as amended).

As part of the HFEA's ongoing activities relating to 'legal parenthood' this area of practice is currently a focus for all inspections.

The inspection team also takes into account the progress made in implementing the actions from all inspections conducted since the renewal of the centre's licence in 2015, and ongoing monitoring of the centre's performance.

The centre had made an application to change the Person Responsible (PR), but this has subsequently been withdrawn. The centre had also applied to vary its licensed activities to include preimplantation genetic screening (PGS). This application has also subsequently been withdrawn (see report for further information).

The aim of this report is to provide the Authority's Licence Committee (LC) with information on which to make a decision about the continuation of the centre's licence.

Brief description of the centre and licensing history

The London Women's Clinic, Darlington has held a licence with the HFEA since 1992 and provides a full range of fertility services.

The centre provided 354 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 September 2016. In relation to activity levels this is a small centre.

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

The centre has been subject to considerable regulatory scrutiny since their licence renewal inspection in November 2014 which, prior to this inspection includes three visits to the centre by the HFEA as follows:

- November 2015 – an announced interim inspection;
- May 2016 – an unannounced investigation inspection following a whistle-blower report to the HFEA;
- August 2016 – an announced visit to provide an incident workshop which also served to investigate a further whistle-blower report.

As described below, these inspections identified new or recurring areas of concern and non-compliance which resulted in the recommendation that a further inspection be conducted to assess the effectiveness of corrective actions implemented.

A Licence Committee renewed the centre's licence in March 2015, but expressed deep concern regarding the number and seriousness of the areas of non-compliance noted on inspection, especially those in relation to staff training and patient safety. The committee did however note the engagement of the PR with the Executive and agreed to renew the centre's licence for a period of three years rather than the usual four and strongly endorsed the Executive's proposal to undertake a targeted interim inspection within nine months of the licence coming into force.

That inspection took place in November 2015 and found one critical, three major and one 'other' areas of non-compliance. At that time, there were no ongoing concerns relating to staff training and patient safety.

The Executive Licensing Panel (ELP) that considered this interim inspection report agreed to the continuation of the centre's licence but did note their concerns that despite this being an announced, targeted inspection, non-compliances were identified that had also been an issue at the licence renewal inspection, in particular, those relating to medicines management and consent. However, the panel noted that since the inspection, the centre had addressed all the non-compliances. The panel stressed that it expected to see these improvements sustained.

On 29 April 2016, concerns were raised with the HFEA by a whistle-blower regarding certain practices at the centre. In accordance with the HFEA 'Compliance and enforcement' policy, a management review considered that the concerns raised were deemed serious and warranted investigation. An unannounced inspection was conducted in May 2016 to determine whether the whistle blower's concerns were founded and if there was any risk to patients.

The whistle blower's focus was a risk to patient safety due to concerns over the centre's nursing team in terms of complement, experience and competence. The inspection team concluded that the whistle blower's concerns were justified, to an extent. There were significant staffing issues at the centre at the time which were having an adverse impact on staff morale and the running of the centre. Overall, the inspection team considered that the staffing situation did not pose an immediate risk to patient safety. However, during a review of the two incidents referenced by the whistle blower several additional areas of practice that required improvement in relation to two critical and two major areas of non-compliance were identified.

As a result of this inspection the Executive could not initially make a recommendation for the continuation of the centre's licence, given that non-compliances had reoccurred, nor was it assured of the PR's ability to discharge her duty under Section 17 of the HF&E Act 1990 (as amended). Following assurance from the PR to implement the recommendations the Licence Committee agreed to the continuance of the licence with a further inspection in nine months. It was also agreed separately that, in response to the findings of that inspection, the HFEA clinical governance lead would provide a workshop to the centre team on the management and investigation of incidents.

The Licence Committee considering this inspection report made it clear that due to the systemic issues at the centre, they wanted an update on progress to be provided to the committee in November 2016. This was unintentionally overlooked by the Executive, for which we apologise. The committee can be reassured that the Executive has been in continuous close contact with the centre and the required update forms part of this report.

On 12 August 2016, further concerns were raised with the HFEA by another whistle blower about the care of a patient at the centre. In accordance with the HFEA 'Compliance and enforcement policy' a management review meeting was held the same day. As the HFEA were due to visit the centre to provide the incident workshop that month, it was considered appropriate to combine the visit and investigate the whistle blower's concerns at that time.

On investigation, the inspection team had no concerns about the care of the specific patient but were concerned that this was the second whistle blowing incident in six months. A further management review meeting was held and it was decided that an additional inspection should take place with a focus on staff communication. This is the report of that inspection visit.

Summary for the Licencing decision

The Licence Committee is asked to note that this inspection concluded that recommendations for improvement in relation to two critical, one major and one 'other' area of non-compliance was warranted as follows:

Critical areas of non-compliance

- **The PR should comply with the recommendation of the May 2016 inspection report and commission an external investigation of the adverse incidents detailed within.**

- **The PR should review the quality management system to ensure it is effective and provides assurance of compliance of the range of activities carried out in the course of providing treatment services, against regulatory requirements, the centre's SOPs and quality indicators and that learning from incidents can be demonstrated.**

Major area of non-compliance

- The PR should ensure that procedures for the management of medicines at the centre are compliant with all relevant regulatory requirements and best practice guidance.

'Other' area of non-compliance:

- The PR should ensure that all TPAs are in date and compliant with regulatory requirements.

Since the time of the May and August 2016 inspections, there have been some significant staff changes, including the appointment of an experienced lead nurse. There has been a noticeable improvement in how nursing staff communicate with each other and this appears to have had a positive impact on staff morale. The lead nurse now in post, has a good understanding of the importance of safe procedures and practices, but the centre's incident investigation and audit practices still required significant improvement. Although the HFEA provided staff with a brief workshop on incident reporting and investigation in August 2016, there appeared to be little evidence that this had had an impact on practice.

At the time of the inspection, an application had been made to appoint a new PR. This was discussed on inspection with the proposed PR who described that, whilst he is the only clinician working at the centre on a daily basis he assured the inspection team that recruitment was underway to provide him with substantive clinical support to allow him time to devote to his duties as PR. The inspection team considered that to have a PR on site would be a positive step as the current PR is based in London and may therefore be somewhat remote from the day to day workings of the centre. The inspection team was initially reassured by the proposed PR's assurance that he would be provided with the clinical support to free up sufficient time to dedicate to the role. However, discussions with the current PR since the inspection, were unable to confirm the availability of this additional support. The application to change PR has subsequently been withdrawn.

Following the May 2016 inspection, it was recommended that the incidents discussed at that inspection should be fully investigated. In her response to the report the PR stated *'I have also arranged for the 2 reportable incidents described in your report to be independently reinvestigated as part of the learning process for all staff'*. The Executive requested that copies of the investigation reports be provided to the HFEA when completed. Copies of the investigations had not been provided up to the time of this inspection.

On inspection, the PR was asked to provide a copy of the investigation reports however she was unable to recall any investigation having taken place and was unable to provide evidence of this to the inspection team on the day.

As a consequence of the areas of concern noted at this inspection that had also been noted at previous inspections; the mismatch of information received about the additional clinical support for the proposed PR and the absence of evidence in support of previous recommendations having been implemented, a management review meeting was held on 19 December 2016 in accordance with section 3.1 of the HFEA's 'Compliance and enforcement policy' to discuss the implications of these findings. It was considered that whilst these issues were of great concern, there was no apparent or immediate risks to patients, staff, gametes or embryos and that the PR should be contacted in the first

instance, to provide clarification regarding the clinical support to be made available to the proposed PR and to provide copies of the external investigation reports that had been required since the May 2016 inspection.

The PR responded to the request within the given timeframe. She was unable to provide confirmation of the reported clinical support provision and subsequently withdrew the application to appoint a new PR. On 22 December 2016, the PR provided a copy of an external investigation report into both incidents. The report was dated 'July 2016', there was no author attributed to the document, and some corrective and preventative actions described were not scheduled to be implemented until January 2017, some six months after the report is said to have been completed. It is unclear why, at the time of inspection, the PR and other staff could not recall any investigation having taken place, when the primary reason for the investigation was staff learning.

In light of this information and the evidence provided, the inspection team could not be assured of the PR's ability to ensure regulatory compliance. There were current and historical concerns about the PR's ability to fully discharge her duty under Section 17 of the HF&E Act 1990 (as amended) due to the lack of assurance of the centre's ability to learn from incidents; non-compliances that have been cited in previous reports noted again at this inspection and failure to implement recommendations and submit evidence within agreed timescales. The PR has previously had discussions with the Executive and provided commitment and assurance of sustained improvements, but despite the regulatory scrutiny the centre has been under since the renewal inspection in 2014, repeated non-compliance with regulatory requirements continued to occur.

As a consequence of these concerns, a further management review meeting was held on 3 January 2017 to discuss whether formal sanctions were required under the HFEA's 'Compliance and enforcement policy'. The Executive referred to the HFEA's guidance on licence length. Where there is a history that suggests serious concerns about a PR's ability to ensure regulatory compliance, a licence decision may be adjourned until the PR can 'demonstrate that improvements have been implemented and are effective in preventing recurrence of the non-compliance'. It was agreed that at this stage the Executive could not confidently recommend continuation of the centre's licence. This was of grave concern as this was the second instance in recent times whereby the Executive has felt unable to recommend the continuation of the centre's licence. However, the inspection team noted that at this inspection there had been some improvement and considered it proportionate to endeavour to seek robust assurance and engagement with the PR, at what is now, a critical part of the centre's licence consideration process. To this end, the Executive and senior members of the HFEA's Compliance team met with the PR and Licence Holder (LH) on 26 January 2017 and had frank discussions with them, regarding the regulatory record of the centre and the PR's role and response to this report.

In addition, when responding to this inspection report, the PR provided a copy of a recent legal parenthood audit that was unavailable for review during the inspection. The audit had identified two legal parenthood consenting anomalies. At the meeting with the Executive and senior members of the HFEA's Compliance team, the PR was asked to provide the Executive with full details of these anomalies and the actions taken by the centre. The PR was unable to provide this information. Given the potential impact of legal parenthood anomalies, the Executive was surprised that the PR could not provide further details of these cases or her actions in response to the audit's findings. The PR was subsequently given a further 24hrs to provide the Executive with the information requested. This she did,

within the agreed timescale and provided evidence of appropriate actions, to the Executive's satisfaction.

Whilst the PR gave verbal assurance of improved compliance and engagement at the meeting on 26 January 2017, she was unable to provide robust assurance of substantive engagement, improvement or ongoing regulatory compliance. Additionally, when questioned, the PR was unable to give firm details of the appointment of another fertility consultant to support the existing clinician, whom, she had indicated as being 'on staff' in her response to this report. Consequently, the Executive could not confidently recommend a continuation of the centre's licence at this stage, and invited the PR to provide a further response and evidence of the implementation of the recommendations within this report prior to it being presented to the Licence Committee.

Following receipt of this additional response from the PR, a management review meeting was held on 6 February 2017 to discuss whether a licence recommendation could be made in light of this information. On the basis of the PR's response to this inspection report, the meeting held with the PR and LH and the additional information received from the PR since the meeting, the Executive considered that there was insufficient evidence of the PR's ability to fully discharge her duty under Section 17 of the HF&E Act 1990 (as amended) by ensuring compliance with the required standard licence conditions. However, it was agreed that it was reasonable and proportionate to delay making any recommendation to a Licence Committee at this point and to afford the PR a further opportunity to demonstrate regulatory compliance.

Some areas for improvement required evidence to be submitted by 5 March 2017, once in receipt of this, it was anticipated that the Executive would have sufficient information on which to make a recommendation to Licence Committee. This information would not however be available in time for the report to be considered by Committee at its meeting in March. The Executive did not have any significant concerns regarding the safety of patients, gametes or embryos, therefore an Executive update was provided to committee at that meeting proposing that the full report would be considered by the committee at its meeting in May. The Committee agreed to this proposal.

The Executive expected to receive robust and substantive evidence of regulatory compliance and ongoing improvement of practice within this centre.

Between 7 March 2017 and 6 April 2017, the Executive has held fortnightly teleconference meetings with the PR to provide support and to provide the PR with an opportunity to demonstrate progress towards implementing the recommendations of this report; regulatory compliance; and her ability to fully discharge her duty under Section 17 of the HF &E Act 1990 (as amended).

Over the course of these meetings, in addition to the evidence required for submission by 5 March 2017, the Executive has requested and reviewed additional evidence of compliance to corroborate verbal assurances given by the PR. The PR has engaged with the Executive throughout this process and provided the required information within agreed timescales. The 'Executive response' section of this report has been updated to reflect the progress made.

Following the conclusion of these meetings a management review meeting was held on 7 April 2017 to discuss the outcome of the meetings, the evidence provided to date and to consider the recommendation to be made to Committee.

A recommendation was made and the report was subsequently submitted to the LC for consideration at the meeting scheduled for 4 May 2017. However, on 2 May 2017 a tabloid newspaper published a report into the practices of a number of fertility clinics. There were several articles relating to, for example, the use of (add-on) treatments, medication pricing, egg freezing and egg sharing and the incentives offered to patients in this process.

LWC Darlington (0075) was particularly prominent in the press report. The article accused the centre of exploiting women to donate eggs for financial reasons; of having an inadequate counselling service that did not prepare women for the consequences of egg donation, and promoting high interest rate loans via a third party, to couples unable to finance their treatment by other means.

In light of the press article, the Director of Compliance and Information requested that the LC adjourn their consideration of this report at the 4 May 2017 meeting until further information could be gathered on the newspaper's allegations. A report of the findings of the investigation into the press article has been submitted with this report for consideration by the LC.

The Executive has considered this report together with the report of the investigation into the newspaper article when making its recommendation.

Recommendation to the Licence Committee

Since the inspection, the PR has subsequently provided evidence that all the recommendations made in this report have been fully implemented.

However, evidence of training scheduled for May 2017 and a summary of follow up audits to assess the effectiveness of actions implemented were due to be provided by 5 June 2017. The PR did not submit these to the Executive within the required timescales. A further request for their immediate submission was sent to the PR on 9 June 2017, to which she responded.

These issues in different circumstances would seem insignificant or trivial, but given the intense regulatory scrutiny the centre has been under for the past 18 months, the Executive expects that the PR is fully compliant with all the recommendations made in this report and clearly demonstrates a commitment to compliance and an ability to fully discharge her duty under section 17 of the Act. The PR has had extensive opportunities to demonstrate and maintain compliance. However, the Executive remains concerned that the PR is unable to sustain improvements or maintain regulatory compliance without pressure from the Executive to do so.

A management review was held 12 June 2017 with the Director of Compliance and Information to consider the Executive's final recommendation to licence committee. The Executive's full recommendation to the LC is documented in the *'Executive summary report to Licence Committee 13 July 2017 relating to London Women's Clinic, Darlington (0075)'* submitted with this report.

Details of Inspection findings

Quality of Service

Pregnancy outcomes[1]
HFEA held register data for the year ending June 2016 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages.

Multiple births[2]
The single biggest risk of fertility treatment is a multiple pregnancy.

HFEA held register data for the year ending June 2016 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 17%. This represents performance that is not likely to be significantly different to the 10% multiple live birth rate target for this period.

Staffing and staff communication
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 with the exception noted in this report (see adverse incidents section and recommendation 1).

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.

In the last seven months four nurses and one business manager have left the centre, however, the centre has since recruited an experienced lead nurse and other nursing staff to add to the staffing complement. Staff training, induction and comprehensive competency records were seen during the inspection. Communication systems have been introduced with monthly 'all staff' meetings and monthly nursing team meetings. There are also individual one to one meetings for staff, but these are not formalised yet. It was clear on inspection that staff morale had noticeably improved, with staff reporting that communication within the team had improved, they were happy to come to work, felt supported in their roles and told the inspection team that team relations were positive.

Quality Management System (QMS)
It is important that centres audit all their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following prescribed standard operating procedures (SOPs) and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.
On inspection, the inspection team noted the following issues:

- There is no SOP for record keeping and quality indicators have not been established for record keeping.
- The consent to legal parenthood SOP does not indicate what to do if a nominated legal parent withdraws their consent.

[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%.

- The legal parenthood consent audit only records the presence of consent forms. The inspection team was informed that a comprehensive legal parenthood audit had been completed but this was not available for review on inspection.

The centre's quality management system is found to be partially compliant with requirements (SLC T33(b); T35, see recommendation 2).

The inspectors also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture, then it is important that they act to review their practices when guidance is issued. The centre has recently implemented processes for effective learning and improvement through, regular team meetings (where HFEA guidance and information is an agenda item); engaging staff in audit processes and having a board where staff can add items to meeting agendas. The impact of these measures on learning and continuous improvement will require evaluation and review at future inspections to see that they are effective and have been fully embedded.

Third party agreements

On inspection, the third party agreement (TPA) for 'The Doctor's Laboratory' (TDL) was out of date (review date June 2015). A letter had been sent (seen on inspection and dated the day of the inspection, 5 December 2016) to the third party renewing the agreement (SLC T111, see recommendation 4).

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. Whilst it is noted that the centre had addressed medicines management concerns raised in previous inspections, during the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be partially compliant with requirements because:

- In the controlled drugs register, the time of administration of the controlled drug had not been recorded in 15 of 16 entries reviewed, contrary to the centre's SOP.
- In three of the five records audited during the inspection, the full name of the controlled drug administered to the patient had not been recorded on the anaesthetic chart. In these records an unofficial abbreviation had been used.
- In one patient record the date had not been recorded on the anaesthetic chart.

(SLC T2, Safer Management of Controlled Drugs 2007 (DH), NICE guideline [NG46] 1.7.4 April 2016, see recommendation 3).

Safety and suitability of premises and facilities

The centre's premises are 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 so that patients and staff are in safe surroundings that prevent harm.

Infection control

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

Record keeping
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained with the exception noted in the quality management and medicines management sections of this report. Good medical records are essential for the continuity of the patient's care (see recommendations 2 and 3).

Adverse incidents
It is important that centres investigate adverse incidents thoroughly to ensure lessons are learned from incidents and to be able to continuously improve the services offered. On inspection, the PR was asked to provide the external investigation reports into two adverse incidents at the centre, that she had committed to commissioning in her response to the inspection report of May 2016. The PR was unable to recollect any requirement for an investigation or of an investigation having taken place and therefore the recommendation has not been implemented.

On inspection, a review of the centre's incident log raised concerns with the inspection team. An incident had been reported on 16 November 2016 as a 'near miss' on the centre's own data base and staff reported that they had briefly spoken with the HFEA clinical governance lead as to whether this constituted an incident reportable to the HFEA. From the information provided verbally to the HFEA it was considered that it was not necessary to report the incident. However, information available on inspection showed that this incident was a 'near miss' but the potential impact had the error not been identified, could have had serious consequences as the incident involved a failure to adequately confirm a patient's identity before being scanned and provided with medicines for her treatment. This was only picked up when the patient was asked to settle her account for her medicines on leaving, where it was discovered that it had been assumed that the patient was someone else, fortunately following the same treatment protocol. Had sufficient detail of the 'near miss' been provided to the HFEA the centre would have been required to report this and to conduct a proper investigation.

The inspection team found that the internal incident report lacked the detail of the discussion of what had happened; there was a lack of thorough investigation and no root cause analysis (RCA) completed, consequently the corrective and preventative actions were not sufficiently robust to prevent reoccurrence of the incident. Although the HFEA delivered a brief workshop in August 2016 at the centre on incident reporting and investigation, there is little evidence that this has had an impact on practice or that the centre has provided further, bespoke training for staff, suitable to their needs as recommended (SLC T119, see recommendation 1).

Compliance with HFEA standard licence conditions
From the pre-inspection assessment and observations during the visit to the centre, the inspection team identified no further areas of practice that could be improved.

Compliance with recommendations made at the time of the last inspections in 2015 and 2016

Following the interim inspection in November 2015, recommendations for improvement were made in relation to one critical, three major and one 'other' areas of non-compliance or poor practice.

In responding to the report the PR provided evidence that all of the recommendations have been implemented:

'Critical' areas of non-compliance:

- **The PR should ensure that a suitably trained and competent controlled drugs accountable officer (CDAO) is appointed.**

  The PR should review practices relating to the management of medicines, including safe and secure transport, to ensure compliance with legislation and best practice guidance.

'Major' areas of non-compliance:

- The PR should ensure that audits are effective and should review barriers to implementing learning from guidance or recommendations provided by the HFEA and other sources.
- The PR should ensure that patient consent is recorded clearly and accurately.
- The PR should ensure that all standard operating procedures (SOPs) accurately describe the procedures used at the centre.

'Other' areas of practice that require improvement:

- The PR should ensure that all notices fixed to walls in clinical areas are 'wipe clean' and that clinical areas are cleaned thoroughly to ensure compliance with infection control best practice guidance.

Following the inspection in May 2016 there were several areas of practice that required improvement in relation to two critical and two major areas of non-compliance.

In responding to the report the PR provided a commitment to implement the following recommendations:

'Critical' areas of non-compliance:

- **The PR should ensure that detailed, accurate and clear records are kept for all patients at all times.**
- **The PR should ensure that all significant adverse events are reported to the HFEA. The PR should ensure that incidents are investigated thoroughly, including a case review and root cause analysis.**

'Major' areas of non-compliance:

- The PR should ensure that the centre has personnel available in sufficient number and that are appropriately qualified and competent in the tasks they perform.
- The PR should ensure that audits are performed by trained and competent staff and that audit of activities against compliance with the centre's own approved protocols are performed.

Whilst the PR provided assurance that all the recommendations have been implemented some areas were still found to be non-compliant at this inspection.

Ongoing monitoring of centre success rates

Since the current licence came into force in 2015 the centre has not received any performance related risk tool alerts.

Legal parenthood

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

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided the report of the audit to the HFEA within the required timeframe and took appropriate action with respect to the issues identified by the audit.

As part of the HFEA's ongoing activities relating to 'legal parenthood', in October 2015 all PRs were asked to confirm that specific actions had been undertaken; that there are effective methods for assessing the on-going competence of staff to take this consent; and that effective audit procedures are in place to ensure on-going compliance with consent taking requirements. The PR responded to this communication and provided the required reassurances to the satisfaction of the Executive.

At this inspection, to provide further assurance of the effectiveness of the centre's procedures, the inspection team reviewed five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required. Effective consent to legal parenthood with a prior offer of counselling was seen to be in place before treatment in all cases.

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

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 the Code of Practice or professional practice guidance, 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. Incident Reporting On inspection: • the PR was asked to provide the external investigation reports into two adverse incidents at the centre, that she had committed to commissioning in her response to the inspection report of May 2016. These reports have not been provided to the Executive. • Staff have not received training to undertake	The PR should comply with the recommendation of the May 2016 inspection report and commission an external investigation of the adverse incidents detailed within. The PR should provide a summary report of this investigation to the centre's inspector by 5 March 2017. The PR should provide an explanation of why this investigation has not taken place despite assurances to	1. The investigation review was carried out and dated July 2016. The report should have been clearer in that the implimentation of a number of corrective actions will be completed by January 2017. Clearly, we would not have waited for 6 months to begin the process of correction. The corrective actions have been implimented as part of the overall operational development and	Since the inspection and prior to this report being completed, the PR has provided a report of the external investigation of the adverse incidents detailed in the May 2016 inspection report. The PR reports that this investigation had been undertaken as requested following the May 2016 inspection, but was unaware of the requirement to submit the report to the Executive. The report was dated 'July 2016', there is no author attributed to the document and

audits and investigations as recommended. • Reports of adverse incidents demonstrated: a lack of detail in the report about what had happened; a lack of thorough investigation and RCA and consequently the corrective and preventative actions were not sufficiently robust to prevent reoccurrence of the incident. SLC T119. Lack of meaningful investigation of incidents was cited as a non-compliance in both the November 2015 (renewal) and May 2016 inspections and lack of staff training was cited in the May 2016 report. This non-compliance was escalated to a critical non-compliance in the 2016 report.	the Executive after the May 2016 inspection, that an investigation had been commissioned. The PR should provide this explanation when responding to this report. The PR should ensure that all staff who undertake incident investigation and audit receive appropriate training in addition to that provided by the HFEA. Confirmation that training has been completed should be provided to the centre's inspector by 5 March 2017. The PR should review the process and procedures for reporting and investigating incidents and investigate why this non-compliance continues to occur. The PR should provide a summary report of this review and investigation, including corrective actions taken to prevent recurrence of this non-compliance to the centre's inspector when responding to this report. Three months after this review the PR should audit the	improvements. Please see the ammended review report. 2. The external investigation report provided to you did not include a signature. For this I apologise and have corrected the administrative oversight. All staff have received training by the HFEA incident inspector with an additional half day training by the QA team in July 2016. This training will be repeated and confirmation provided to the inspector by the 5th of March 2017. A review will be provided to the HFEA by the 5th of March 2017 For further information please see page 19.	some corrective and preventative actions described are not scheduled to be implemented until January 2017, some six months after the investigation report is said to have been completed. The Executive remains concerned that the PR lacks insight into the seriousness of this non-compliance; has overlooked the requirement stated in the May 2016 report to provide this evidence previously, and has not been proactive in implementing the necessary corrective and preventative actions in a timely manner. Further action required. <u>Update following PR's second response to report:</u> The Executive acknowledges the PR's response and receipt of a further investigation report from 2016. Evidence of completion of staff training in July 2016 was not available at the inspection and

	reporting and investigation of adverse incidents to ensure that the corrective actions implemented have been effective in maintaining regulatory compliance. A copy of this audit should be provided to the centre's inspector by 5 March 2017.		has not subsequently been provided to the Executive. The Executive questions the effectiveness of this training (if it has taken place) as the quality of incident reporting and investigation seen on inspection was below the required standards to achieve compliance, therefore, repeating this training may not be the most appropriate course of action to achieve competence in conducting incident investigation and reporting. The Executive expects the PR to implement suitably effective training. The Executive has not received a review of the centre's incident investigation processes and procedures as required on receipt of this report. The Executive remains concerned that the PR has once again overlooked a requirement to fully comply

			with this recommendation within the given timescales. Further action required. **<u>7 April 2017 Update following regulatory meetings:</u>** The Executive has been provided with assurances that additional processes have been implemented to ensure that incidents are appropriately investigated and reported to the HFEA where appropriate. The Executive acknowledges that staff training is due to take place in May 2017. No further action beyond submission of evidence of completion of staff training, due by 5 June 2017.
2. Quality management system: On inspection, the inspection team noted the following issues: • There is no SOP for record keeping and quality	The PR should review the quality management system to ensure it is effective and provides assurance of compliance of the range of activities carried out in the course of providing treatment	There is a Record Control SOP, however this was in the process of review (as per the SOP review process) at the time of inspection. For the purposes of clarity In future when a document is in review	The Executive acknowledges the PR's response to this recommendation. On inspection, previous versions of the Record Control document were not available

indicators have not been established for record keeping. • The consent to legal parenthood SOP does not indicate what to do if a nominated legal parent withdraws their consent. • The legal parenthood consent audit only records the presence of consent forms. The inspection team was informed that a more comprehensive legal parenthood audit had been completed but this was not available for review during the inspection. SLC T33 (b); T35. QMS non-compliance was cited at the centre's inspections in November 2015 and May 2016. It was escalated to critical in the 2016 report.	services, against regulatory requirements, the centre's SOPs and quality indicators and that learning from incidents can be demonstrated. The PR should provide a summary report of the review and an action plan for the timescales for implementation of corrective actions, to the centre's inspector when responding to this report. The PR should provide a copy of the legal parenthood audit that was unavailable to the inspection team when responding to this report. The PR should address the non-compliances within the QMS identified in this report. It is anticipated that this will be completed by 5 March 2017. The centre's inspector will then request a sample of documents to review including, audits, SOPs, quality indicators to ensure	this will be indicated on the central intranet. The quality indicators for record keeping have been defined and will form part of our mandatory audit shedule. * The patient records will contain all the requirements described in the HFEA Licence Conditons T39 and T46. * The day surgery patient record will be fully completed as per checklists. The SOP is also provided with this report. 2. The Consent SOP V8 which, contains guidance on taking consent for legal parenthood has been clarifed to include information should the nominated legal parent withdraws their consent. SOP has been provided with this report 3. The original audit on legal parenthood as required by the	to the inspection team. It would be expected that these versions would be available for staff use until the updated versions are ratified. The PR has not submitted the newly reviewed document to the Executive. Since meeting with the Executive, the PR has provided further information regarding quality management. Whilst the Executive acknowledges the organisational plans for a group-wide approach to the QMS, it remains concerned that the PR's reliance on these proposed plans will not focus attention on the centre's current system or facilitate compliance with this recommendation within the specified timescales. Further action required. The Executive acknowledges receipt of the recent legal

	they are compliant with regulatory requirements. QMS non-compliances have been noted in previous inspections at this centre. This raises concerns that the QMS is not being used to best effect to ensure that services are provided in accordance with the conditions of this licence. The PR should investigate why this non-compliance has not been appropriately addressed previously despite assurances to the Executive. The PR should ensure that changes made to centre practices to resolve non-compliances are maintained by using the centre's QMS effectively.	HFEA (2014/15) has been previously provided to the HFEA. An uptodate audit report is included with this response. As discussed at the inspection and detailed in this report the clinic has faced considerable challenges with staffing. These have been fully addressed, the clinic has in place a new leadership team and clear identification of roles and responsibilities for the Quality Lead which, will ensure that the QMS is used to its best effect. (See futher comments on page 19)	parenthood audit with this report. However, the Executive is concerned that the PR was not proactive in highlighting the anomalies found during the audit, to the Executive until a request for further information was made. The Executive remains concerned that the PR does not appreciate the requirements to fully discharge her duty under Section 17 of the HF&E Act 1990 (as amended). **7 April 2017 Update following additional regulatory meetings:** The Executive has had extensive discussions with the PR regarding the QMS at the centre and is satisfied that the locally implemented processes will enable the centre to achieve ongoing regulatory compliance. No further action required.

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
3. Medicines management On inspection, the following issues were noted: • In the controlled drugs register, the time of administration of the controlled drug had not been recorded in fifteen out of sixteen entries reviewed, which is contrary to the centre's SOP. • In three of the five records audited during the inspection, the full name of the controlled drug administered to the patient had not been recorded on the anaesthetic chart. In these records an unofficial abbreviation had been used.	The PR should ensure that procedures for the management of medicines at the centre are compliant with all relevant regulatory requirements and best practice guidance. The PR should investigate why controlled drug record keeping is not consistent with the centre's own SOP and state what measures will be taken to ensure ongoing, sustainable, compliance with this recommendation The PR should provide a copy of the review, including an action plan for the implementation of identified	I acknowledge my responsibilities as PR for medicines management at the clinic. The recording of medicines used at the time of conscious sedation for an egg collection is the professional and corporate responsibility of the anaethesist in charge of each case. Actions: a) In July 2016 the lead nurse wrote to the aneasthetists concerned to reinforce documentation requirements. b) the lead clinician has met with the aneasthetist concerned to reiterate record keeping requirements.	The Executive acknowledges the PR's response to this recommendation and awaits receipt of the review required by 5 March 2017. Further action required. **7 April 2017 Update following additional regulatory meetings:** The Executive acknowledges receipt of the review of medicines management practice and additional substantive evidence that should ensure ongoing compliance with this recommendation.

• In one patient record the date had not been recorded on the anaesthetic chart. SLC T2. DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' 4.11.1.2. NICE [NG46] (2016) 'Controlled drugs: safe use and management' 1.7.4 April 2016.	corrective and preventative actions to the centre's inspector by 5 March 2017. The PR should audit medicines management practice and record keeping to ensure that corrective actions implemented have been effective in maintaining compliance with regulatory requirements, practice guidance and the centre's own SOPs. A summary review of this audit should be provided to the centre's inspector by 5 June 2017.	c)The anaesthetic nurse will conduct a daily review of medicines record keeping before the aneasthetist leaves the theatres post procedure list. A further review will be provided to the inspector by the 5th of March 2017. A further audit of medicines management will be provided to the inspector by the 5th of June 2017.	No further action beyond submission of the audit due by 5 June 2017.

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
4. Third Party Agreements On inspection, the TPA for the TDL was out of date. SLC T111.	The PR should ensure that all TPAs are in date and compliant with regulatory requirements. The PR should provide a copy of the TPA identified in this report, demonstrating compliance, to the centre's inspector by 5 March 2017.	The completed Third Party Agreement for The Doctors Laboratory (TDL) has been completed and attached to this report.	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required.

Reponses from the Person Responsible to this inspection report

Thank you for this report. There are a number of areas reported by the Executive that I am very pleased to read.

Patient safety:
As a doctor with many years of experience I lead a multidisciplinary team who are committed to ensuring high quality and safe care for our patients. I am pleased to read that you make clear in this report, during this challenging time, that you have no patient safety concerns. Your reassuring comments are echoed in relation to the safe storage of our patient's gametes and embryo's.

Teamwork:
After carefully restructuring our team I am pleased to read that the report has note that the Executive consider the staff are competent and in sufficient number to provide safe activity. And importantly, that there has been noticeable improvement in how nursing staff communicate with each other and as a result improved the morale of the clinic. I agree with your report that the lead nurse has a good understanding of the importance of safe procedures and practices. She has extensive experience and a long history with clinic and I am delighted she as chosen to return. As the Executive has advised she will complete the PREP programme this spring.

Provision of information: Not providing information to the inspection team in a timely manner. In particular, the report of a review of the investigation of two incidents I commissioned in July of 2016. This was completed and a reported provided to me. However, I acknowledge that I did not send the inspector copies of the report. And indeed the report could have been clearer in the timing of the identified corrective actions. I have attached a clearer copy of the review including confirmation of the already implemented corrective actions. I apologise for the administrative error of omitting a signature; this has now been corrected.

Mismatch of information: In particular additional clinical support for the doctor. We have been working for two years to develop a PGS service for our patients. At the present time patients have to travel to London for this treatment and we are keen to provide a less burdensome experience. We already have the necessary protocols, staffing, counselling and genetic support in place and I think it desirable that I retain the role of Person Responsible and provide, as required, additional clinical support until I am content that the improvements are proven sustainable and that we are able to add PGS to our services. In addition, I can confirm that we now have on staff an additional senior fertiity consultant who will be supporting Dr Ashour.

We have carefully and with great consideration implemented substantial improvements in the clinic and I would like to thank my staff for all their hard work to date. It has taken some time however; I feel that change is more sustainable where it is made with care and attention.

I am grateful that the HFEA have recognised and acknowledge that a great deal of progress has been made and I am sure that this will reassure the Executive that this progress will be sustained.

Mrs S Nair
Person Responsible

Executive response to additional comments provided by PR

At the meeting (26 January 2017) between the PR, LH and the Executive the following points were discussed:

It is not within the remit of the Executive to advise on suitable personnel for the role of PR. It was made clear to the PR and LH that at no time had any such advice of this nature been given during or since the inspection.

The PR states in her response that the centre now have 'on staff an additional fertility consultant' to support the existing clinician. The PR was unable to provide confirmation of this appointment to the Executive at the meeting and indicated that discussions with the consultant was still in progress.

The PR has been unable to provide any further information to the Executive regarding the mis-match of information highlighted in this report.

Annex 2

Report of an investigation into media allegations: London Women's Clinic Darlington, Centre 0075

Date of meeting: 10 May 2017

Location of meeting: LWC Darlington (North East)

Investigation team: Polly Todd, Centre Inspector; Sharon Fensome-Rimmer, Chief Inspector.

Present		
HFEA	Polly Todd Sharon Fensome-Rimmer	Centre Inspector Chief Inspector
LWC Darlington	Dr Shailaja Nair Dr Safwat Ashour Ellie Suthers	Person Responsible (PR) Lead Consultant LWC Quality Lead

1. Background:

1.1. On 2 May 2017, the Daily Mail newspaper published a report into the practices of some fertility clinics. There were several articles relating to, for example, the use of add-on treatments, medication pricing, egg freezing - in particular, egg sharing and the incentives offered to patients in this process.

1.2. The article suggests the fertility sector (or those parts subject to the investigation) is 'cashing in' on women desperate to have a child, on patients who cannot afford the costs of treatment, and that clinics are profiting unreasonably from patients.

1.3. These are serious allegations and have the potential to bring the sector in to disrepute and reduce public confidence in the integrity of the fertility sector, and the clinicians and other professionals working in licensed clinics.

1.4. LWC Darlington (0075) was particularly prominent in the press report. The article made the following allegations:

1. **Egg donation:** Exploiting women to donate eggs for financial reasons and using financial incentives to convince women to donate eggs coaching them not to disclose

this in writing, thereby allowing the centre to maximise profits, and targeting 'lesbian' couples for egg sharing, who may only need treatment to access sperm;

2. **Counselling:** Having an inadequate counselling service in place leaving women unprepared for the consequences of egg donation;
3. **Costs and finance:** Promoting high interest loans via a third party, Zebra Finance, to couples unable to finance their treatment by other means. It also referred to centres charging high prices for treatment medication that patients could obtain from local pharmacy providers at a lower price, and not informing patients of this.

The HFEA's requirements on each is as follows:

1. Egg donation:

In the UK, egg donation is permitted under the HFEA's Code of Practice and to be compensated. It also allows patients to receive treatment services in exchange for donation of their gametes (eggs and sperm) to treatment or research. The policy is known as 'benefits in kind' or, more commonly, egg sharing.

The parameters regarding compensation to donors are set by the European Union Tissues and Cells Directive (EUTCD) and egg sharing arrangements fall within these parameters as they support the objective of increasing tissue and cell availability for donation (HFEA 2011).

HFEA policy allows clinics to offer both sperm and egg donors, undergoing fertility treatment, the option of having free or reduced treatment in exchange for donation to research or another patient (HFEA General Direction 0001).

There has been much debate about the ethics of donating eggs or sperm in exchange for a benefit, especially as that benefit may exceed the compensation available to 'altruistic' donors (those that are not undergoing any fertility treatment, and only wish to donate their gametes (eggs or sperm)), which is currently £35 per visit for sperm donors and up to £750 per egg donation cycle. However, evidence suggests that there are positive outcomes for both the recipient and the donor in egg sharing arrangements and the practice is widespread across the fertility sector, with many patients benefiting from receiving donated gametes (HFEA 2011).

When considering compensation under a 'benefits in kind' arrangement it is expected that centres respect the following principles:

- Altruism
- Fairness
- Free choice
- Welfare of future child
- Safety of donors, patients and the donor conceived
- Family autonomy/respect for family life

2. Counselling

The Human Fertilisation & Embryology (HFE) Act 1990 (as amended) requires counselling to be offered when patients seek treatment with donated gametes or embryos; wish to donate or store their gametes or embryos or wish to nominate, or be nominated as, a legal parent. The HFEA considers that the offer and provision of counselling is an important part of the decision-making process for any potential donor. Counselling provides the opportunity for a donor to have time with an informed guide who is independent of the medical treatment process. It is important that donors take this opportunity to explore and discuss the wider implications of donating, such as the potential impact on the donor; their family (including any future children), and the potential for a future contact from a person(s) born following that donation. The existence of compensation or a benefit in kind for the donation should be a secondary consideration to the intention to donate, not the principle reason for donating. Therefore, centres should not be promoting egg sharing/donations as a way of reducing the cost of fertility treatment.

3. Costs and finance

The HFEA's powers are limited with regards to costs and financing of treatments as we do not set prices for treatments or rules relating to financial arrangements. However, we wanted to explore this aspect of the allegation, as patients can be vulnerable, by their circumstances, and we are committed to ensuring high quality care for people affected by assisted reproduction. The HFEA expects that patients are provided with enough information on which they can make an informed decision about their treatment, and this includes the costs involved. The centre was invited by the newspaper to submit a response to these accusations, which it did so (annex 2 (a)) and also posted on its website (see attached hyperlink) *http://www.londonwomensclinic.com/north-east/*daily-mail-response

2. Our investigation

As indicated in the summary paper, the centre has been under intensive regulatory scrutiny over the past 18 months. The HFEA Director of Compliance and Information requested that the HFEA Licence Committee adjourned its consideration of a further report relating to the centre's performance whilst an investigation into the matters covered in this report takes place. It is expected the Licence Committee will now consider that report, together with this report, at its meeting scheduled for 13 July 2017.This report focusses on an investigation into these accusations including a meeting with key members of staff at the centre on 10 May 2017.

2.1 Aim of the investigation

- To discuss the Press article and review what happened from the centre's perspective.
- To investigate whether there has been a breach of the law (Human Fertilisation and & Embryology Act 1990 (as amended)).
- To review the centre's practices and procedures relating to egg donation and egg sharing and ensure compliance with the HFEA Code of Practice and General Directions.
- To audit a sample of egg donor and recipient records to ensure compliance with statutory, regulatory and best practice guidance.
- To ensure patients have received a proper offer of counselling.
- To review the information given to patients regarding financing treatments.
- To review the centre's information regarding drug pricing.

2.2 Documents/papers reviewed or referred to during the investigation:

- Press accusations sent to centre (appended at annex 2 (a)) and the centre's responses
- Sample of egg donor records and their recipient records
- Zebra Finance information leaflet
- HFE Act 1990 (as amended)
- HFEA Code of Practice 8th Edition, revised May 2017

2.3 Egg donation and counselling

i) Actions of the lead Consultant

Dr Ashour, lead consultant, was video recorded by the reporters (posing as prospective patients) at one of the centre's open days saying that the centre profits from egg sharing arrangements, and informing the reporters that they should not indicate in writing that they were donating for financial gain.

In a meeting with Dr Ashour, the PR and the investigation team, Dr Ashour reported that the article had taken his comments out of context. He said that when he had told the reporters that they wouldn't be accepted (for the egg sharing scheme) if they state they are donating for financial reason he said this was in relation to the 'good will message' (provided by the donor) that can be read by the donor conceived person or their family, saying it wouldn't be positive for them to read that someone only donated for money. He did not say, however, that they should not be donating for financial reasons, but that they should not say they are.

Dr Ashour added that he was asked a direct question on several occasions about the centre making a profit from the egg donation and sharing activities. He said that he answered 'yes' [they do], but added that egg sharing activity accounts for 1% of the centre's cases.

The centre says it offers counselling to patients donating gametes (as part of the package of treatment) and if they choose not to take up the offer they are asked to sign a form confirming they decline. We were told that most patients take up this offer. Dr Ashour told us that when he gave the example of a patient having received donor eggs to then terminate the subsequent pregnancy, he was providing an example of how important it is to have counselling in these situations, and he also said that the case he quoted was from a considerable number of years previously. He claimed the reporters had taken his comments out of context and he was not saying that the centre's counselling service was not good.

Dr Ashour has apologised to the centre team and gave his apology to the investigation team and HFEA for the trouble caused.

ii) Review of patient records; information provided to patients and benefits in kind agreements:

The inspection team reviewed a sample of egg donor/sharer and recipient patient records from 2015 to 2016. The PR reported that they had not undertaken any egg sharing treatments or had any egg donors in 2017 to date.

In all the records reviewed, counselling had been offered and received by all patients. Records showed that the counselling appointment is scheduled for one hour and up to three sessions are available to patients as part of their treatment package. There was some ambiguity among staff as some staff members said that counselling was 'mandatory', whilst others said it was not. A review of the centre's counselling SOP did not give clarity on this.

Screening of patients was completed within the required timeframes and the records showed that patients had received verbal and written information about egg sharing/donation as appropriate. All donors were encouraged to write a 'pen portrait' and this was seen in the records.

'Benefits in Kind agreements' were seen in the records in the form of 'consent' forms. The 'agreements' did not clearly outline the terms and conditions, for example, they did not specify the benefit the patient would be receiving, the full costs involved or the number of treatment cycles covered by the agreement. The centre reported that they refer the patients to a price list that states the price of treatment with and without donation. In addition, the centre's revised 'donor agreement' informs the donor they may withdraw consent, but does not indicate to what point consent may be withdrawn.

iii) Arrangements for counselling

The centre's counsellor is British Infertility Counselling Association (BICA) accredited; an accredited member of the British Association of Counselling and Psychotherapy; and is an Executive member of BICA and Co-chair of the BICA training group, offering training to counsellors.

Whilst upset by this event the counsellor reported to have been well supported by the centre team and her BICA colleagues. The centre's inspector reassured her that at no time were there any doubts as to her practice or competence. Previous inspections had not identified any concerns with the service offered to patients. The counsellor reported that she undertakes full implications counselling with the patients considering egg donation or sharing and informs patients that they can access her services at any point of their treatment should they wish further support.

It was noted by the inspection team that the centre has a very good uptake of counselling by its patients and donors. This is thought to be because the service is promoted well and that up to three sessions with the counsellor are included in their treatment package without any additional charge.

2.4 Costs and Finance:

i) 'Zebra Finance'

The centre informed the inspection team that when patients make an initial enquiry they are sent an information pack containing a leaflet from 'Zebra Finance,' a company independent of London Women's Clinic and authorised and regulated by the Financial Conduct Authority. Once the patients have been seen and have a known treatment plan they can, if they wish, apply to Zebra Finance for funding for their treatment. Patients contact Zebra Finance directly to confirm that they have a treatment plan in place and make an application. It is not known at the time of investigation, what information Zebra Finance require from the patient, other than to confirm that they have a bank account that accepts direct debits, and deposit £1000 per calendar month into their bank account.

Once an application has been made, Zebra Finance, reportedly contact the accounts team at LWC London who email LWC Darlington to confirm an application has been made.

At the time of the investigation, it was not known what information is given to Zebra Finance by LWC London, or what information the patient is given, regarding confidentiality and sharing of information with other third parties. Our starting point is even though patients contact Zebra Finance directly it is not safe to assume that they have consented to the centre disclosing confidential information covered by the HF & E Act 1990 (as amended). It is the centre's responsibility to ensure that this consent has been given by the patient.

On further investigation and dialogue with LWC's finance manager (25 May 2017), it was confirmed that the finance department at LWC London receive daily notifications from Zebra Finance of patients who have made an application/been approved for finance. No other information is given by Zebra Finance and no information is requested from LWC. The investigation team conclude that there has been no breach of requirements concerning disclosure of information.

The finance manager informed the investigation team that as of 24 May 2017 the contract between LWC group and Zebra Finance had been terminated.

Discussions with Zebra Finance after the investigation visit, have found that the LWC group were in breach of their contract with Zebra as detailed below by Zebra's head of Compliance.

We gave them [Introducer Appointed Representatives) status – that is a named organisation including LWC (Darlington) written notice of termination yesterday and recorded this on the FCA Firms Register yesterday. Grounds given for termination are breaches of contract around advertising and promotion and bringing us into disrepute. They have also been given notice that they must cease all Regulated Activities immediately and we shall be checking from time to time that they have complied and if not then we shall report them to the FCA Enforcement Division. Engaging in such introductory activities as they apparently have done and without FCA authorisation or under an agency of IAR is a criminal offence under the Consumer Credit Act 1974.

ii) **Post inspection investigation:**

The newspaper also made the following allegations relating LWC Darlington:

'The LWC North East markets egg sharing differently outside London – targeting women who are struggling with their finances. On the Darlington and Welsh clinic web pages, potential patients are told that if their 'minds are on the recent recession and the impact of NHS cutbacks' they may be interested in egg sharing. But on the London page, there is no reference to NHS cutbacks or the recession.'

The LWC (Darlington) website includes the following on its 'low cost packages' page

Here at the London Women's Clinic North East we understand that fertility treatment can be an expensive time; our minds are on the recent recession and the impact of the NHS cutbacks. The cost of fertility treatment can prove to be a financial burden for those of us looking to start a family.

With this in mind, the LWC North East has produced a range of low cost price packages to fit every budget and every patient looking to start a family. Egg-sharing provide free IVF treatment to eligible women by donating some of their eggs.

A review of the LWC London website shows the Daily Mail to be correct, in that no mention is made of the recession or NHS cutbacks, although it does offer egg sharing as an option to reduce treatment costs. Similarly, the price of treatments is clearly outlined on the LWC London website (for example, IVF £3450), with no such costings available for patients to see on the Darlington site, which only provides an email and telephone contact. As Darlington is part of the corporate London Women's Clinic group, it is unclear as to

why, when the websites look identical in their design and all other aspects, that there are these subtle differences.

The PR's response to this allegation, was insufficient in that it did not explain the difference in the way the LWC group advertises low cost treatments to different patient groups (see annex 2(a)).

There was a further allegation that:

'LWC specifically targets lesbian couples for egg sharing' with the implication that this is inappropriate on the basis that women in same-sex relationships do not necessarily have fertility problems and only need treatment because of access to sperm, therefore other forms of treatment (such as insemination) may be more suitable.

We concluded that the PR's response was not unreasonable (see point 5 annex 2(a)).

iii) The Person Responsible

The PR reported that she had sent a response to the Daily Mail and visited the centre as soon as she was able, to speak to staff and offer support. The PR was confident that the centre's practices are appropriate and the counselling service is good. The lead for quality for the LWC group of clinics informed the investigation team that the pricing for the treatment medication was in line with that of local pharmacy providers. The investigation team received information that indicated the centre's costs for IVF treatment medication was £1100 in comparison to Boots which is £876.The PR confirmed that the centre did not inform patients that they could get their medication from alternative sources but if patients asked they were told they could get them from elsewhere.

The PR also noted that she was aware that the interim inspection report had been removed for consideration at the LC at the 4 May meeting.

3. Findings:

3.1. Egg sharing arrangements and marketing:

The centre was found to be compliant with the screening of egg donors, and the information provided to donors and recipients appeared to be appropriate. The centre's egg sharing agreements were in the form of 'consents'. It was not clear from these, what the patient was 'consenting to', in that the terms and conditions of the agreement were not clear; there was a lack of information regarding the benefit in kind offered to the patient, the number of treatment cycles covered by the agreement, and costs of the treatment, for example. The centre reported that they refer the patient to a separate price list for this information. The investigation team regard this as unsuitable and not compliant with CoP guidance which states that the agreement should contain all the terms of the

arrangements and a full description of what benefits in kind are to be expected and the number of treatment cycles or length of storage covered by the agreement.

The centre places an emphasis on financial incentive rather than altruism, in the way that it markets egg donation/sharing. At the time of this investigation, the centre advertised egg sharing as a 'low-cost packages' option. This is in breach of Code of Practice (CoP) guidance which states that advertising or publicity should not refer to 'financial gain or similar advantage'. The media report also alleged that LWC were targeting women who are struggling financially, because of the subtle differences in advertising between the LWC Darlington website and the LWC London site. These differences were noted when the investigation team reviewed the centre's website after the investigation visit. The PR's response to this allegation was found to be lacking in providing a suitable explanation for these differences.

The inspection team believe that this website information is not in line with CoP guidance 13.1 which states: 'Advertising or publicity aimed at recruiting gamete or embryo donors, or at encouraging donation, should not refer to the possibility of financial gain or similar advantage, although it may refer to compensation permitted under relevant HFEA Directions.'

The LWC website information clearly identifies egg sharing/donation as a way of cutting the costs of IVF treatment.

3.2. Counselling arrangements:

The media article implied that the counselling at the centre was inadequate, and did not prepare patients for donation. The inspection team found strong evidence to refute this allegation. The centre's counsellor is appropriately qualified and very experienced in fertility counselling. There was evidence in the patient records that counselling had not only been offered, but had been received by all the patients, whose records we reviewed. Counselling sessions were scheduled for an hour; up to three sessions are included in all patients' treatment packages, and the centre has a very good uptake of counselling.

3.3. Financing of licenced treatment:

As previously noted, the HFEA do not have the powers to regulate the arrangements for funding treatment cycles. However, the allegations made by the media that the LWC group market their treatments differently, were found to be correct at the time of this investigation. Subsequent discussions with the finance provider (Zebra Finance) found that LWC Darlington were in breach of the provider's terms and conditions of their contract. Zebra Finance have since terminated their contract with the LWC group citing breach of contract around advertising and promotion and bringing them (Zebra) into disrepute.

Additionally, the centre confirmed that they do not make patients aware that they could purchase their treatment medication from local pharmacies, which may be cheaper. This,

the investigation concludes, is not in line with the requirements to give patients all the information they may require to make an informed decision (CoP 4.3).

4. Conclusion:

4.1. From our investigation including meetings with clinic staff and the Person Responsible at the investigation visit; review of documentation, review of the centre's website following the visit, and the discussions with the financial services provider, the inspection team conclude that:

- It is inconclusive whether Dr Ashour has acted inappropriately. He provided explanations for his comments, which he believes have been taken out of context by the newspaper and seemed feasible to the investigation team. The investigation team did not have access to the Daily Mail's recordings of the conversation to corroborate their allegations.
- That said, Dr Ashour has apologised for his actions and it is easy to see that Dr Ashour's actions have the potential to bring the sector into disrepute and affect public confidence in the sector.
- It is a fact that Zebra Finance has terminated its contract with LWC on the grounds of breach of contract and for bringing the company into disrepute. This constitutes a serious step taken by the finance provider and is suggestive of a casual approach to compliance taken by LWC. The HFEA has no powers in this area.
- Whilst there was no evidence of active recruitment of egg sharers/donors by the clinic, the information provided to patients on the centre's website, does refer to an advantage to the patient (financial or similar) if they donate/share some of their eggs. It is noted that the centre has not undertaken egg sharing treatments this calendar year to date.
- The centre's website was in breach of CoP guidance 13.1 as it referred to egg donation ('a similar advantage') as a 'low-cost treatment' package option. This also goes against the principle of altruistic donation.
- The PR's response does not explain why there is a difference in the marketing of egg sharing between the two websites (LWC North East and London) and therefore there is the potential for inference of the centre exploiting less affluent women.
- The centre does not provide patients with information that informs them they could obtain their medication from alternative sources which may be considerably cheaper and this does not provide patients with information to enable them to make an informed decision (CoP 4.3).
- The centre's counselling service is suitable and compliant with statutory and regulatory requirements.
- The centre's 'benefits in kind' agreements are non-compliant with CoP guidance and require revision in order that the terms and conditions of the agreement are clear to donors and recipients. Referral to a price list is not considered suitable practice.

- The revised donor agreement (V2 November 2016) informs the donor that they may withdraw their consent but does not say up to what point the consent may be withdrawn (point 2).
- It can be concluded that the centre is promoting egg donation as a scheme to enable patients to afford their fertility treatment, potentially to its financial benefit. This option is marketed differently on the LWC group's websites, which suggests the allegation the centre is *'exploiting desperate women on low incomes'*, is accurate, especially in the absence of any substantial explanation from the PR to the contrary. That said, given the volume of egg sharing activity the centre is not benefiting substantially.

5. Recommendations

5.1. The centre has several improvements to make if it is to be perceived to be acting appropriately and be compliant with Code of Practice guidance and the principles of gamete donation. Based on these findings we make the following recommendations: The centre must

- Review its Counselling SOP to ensure it provides clarity on the provision of counselling.
- Review its practices, with attention to the marketing, and recruitment of patients wishing to donate or share some of their eggs.
- Revise its benefits in kind agreements to ensure they comply with CoP guidance.
- Review its website to ensure compliance with CoP guidance regarding the marketing of egg donation.

5.2. Furthermore, and given the weight and depth of the conclusions and recommendations, the Executive consider the PR has failed to ensure suitable practices are used in the course of activities, or that the conditions of the licence have been complied with. As such, the centre must review its arrangements for ensuring a suitable PR is in place.

5.3. Given the intense regulatory scrutiny the centre has been under, this report is to be submitted with the 'Targeted interim inspection report' (annex 1) to the HFEA Licence Committee (LC). The findings of both reports will be taken into consideration in the recommendations to the Licence Committee as to the continuation of the centre's licence, or other recommendations, in the '*Executive Summary to Licence Committee 13 July 2017 – London Women's Clinic, Darlington (0075).*'

6. References:

1. Human Fertilisation and Embryology Authority (HFEA) Code of Practice 2017 section 3 8th edition.
2. Human Fertilisation and Embryology Authority (HFEA) Code of Practice 2017, section 4.3, 8th edition.
3. Human Fertilisation and Embryology Authority (HFEA) Code of Practice 2017, section 12.5, 8th edition.
4. Human Fertilisation and Embryology Authority (HFEA) Code of Practice 2017, section 13.1, 8th edition.
5. Human Fertilisation and Embryology Authority (HFEA). General Directions 0001 Gamete and embryo donation Version 4; October 2015.
6. HFEA 2011 Authority Paper; 'Donation review: compensation of donors and benefits in kind'. [HFEA (19/10/11) 612].
7. London Women's Clinic North East (Darlington) website: http://www.londonwomensclinic.com/north-east accessed 17.5.17.