

Licence Committee - minutes

Centre 0338 (Reproductive Health Group) Additional Inspection Report & Executive Update

Thursday, 12 July 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members	Andy Greenfield (Chair) Ruth Wilde Kate Brian	
Members of the Executive	Dee Knoyle Richard Chamberlain Catherine Burwood	Committee Secretary Temporary Committee Clerk (Observer) Senior Governance Manager (Observer)
Legal Adviser	Graham Miles	Blake Morgan 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:

Updates:

- Executive Summary - correspondence - Licence Committee on 12 July 2018
- Executive Summary - following PR responses to additional inspection report - Licence Committee on 12 July 2018
- Additional Report - Licence Committee on 12 July 2018

Additional inspection report

- Appendix 1: centre's records in relation to amendment of consent form.
- Appendix 2: centre's template letter sent to patients undergoing treatments with imported donor eggs from Ukraine - redacted.

Executive summary following PR responses to inspection report

- Appendix 3: letter from PR 'Response to HFEA Draft Report - June 2018'

Executive summary correspondence relating to non-compliant import of donor eggs from Ukraine.

- Appendix 4: correspondence relating to non-compliant import of donor eggs from Ukraine.

Previous licensing minutes up to the last licence renewal inspection:

- Licence Committee Minutes - 3 May 2018
- Licence Committee Minutes – 11 January 2018

1. Background

- 1.1. The Reproductive Health Group, centre 0338, is located in Warrington and has held a treatment and storage licence with the HFEA since April 2014. The centre provides a full range of fertility services, including embryo testing.
- 1.2. The HFEA undertook an unannounced interim inspection of the centre in November 2017, following which an additional inspection was recommended by the Executive and endorsed by the committee at its meeting in January 2018.
- 1.3. The committee was presented with an additional inspection report which focussed on reviewing all actions taken by the centre in response to the findings of the inspection in November 2017 and in consideration of further issues that emerged following audits of practice undertaken by the centre since that inspection.
- 1.4. In light of the findings in the inspection and the centre's recent performance, the Executive held a management review in accordance with the HFEA's Compliance and Enforcement Policy on 7 and 12 June 2018. Another management review was held following the submission of the Person Responsible's (PR) response to the report and the additional information provided on 28 June 2018.

2. Consideration

- 2.1. In the additional inspection report, the Executive concluded that the PR has failed to discharge his duty under section 17(1)(d) of the Act and is no longer considered suitable to supervise the licensed activities.
- 2.2. The committee noted that the evidence relied upon by the Executive in reaching this conclusion, included evidence that suggested that the PR had retrospectively altered a patient's WP (legal parenthood) consent form. In addition, in the view of the Executive, the PR did not ensure that all findings from the centre's audit of consent to legal parenthood undertaken in November 2017 were fully investigated and implemented.
- 2.3. In the light of these conclusions, the Executive recommended that the committee should issue a Notice of Proposal to revoke the licence under section 18(2)(b) and (g) of the Act. The committee noted that the Executive's concerns are focussed in most part on the suitability of the PR and his ability to discharge his statutory functions. Further, the committee noted that the Licence Holder (LH) and the centre staff have demonstrated an understanding of regulatory requirements and a willingness to engage with the Executive. However, in terms of proportionality, the committee noted that the Executive is unable to recommend a variation of the licence confined to the substitution of the PR in view of section 18(4) of the Act.
- 2.4. The committee noted tabled responses from the PR and from lawyers for the centre. In the latter document, it was submitted that it is not necessary, appropriate or proportionate to seek to achieve revocation through statutory enforcement action and that the PR and centre staff are happy to meet with the HFEA Executive to discuss the concerns in the report. Further, that the PR is also willing to consider transferring his role to another member of staff.
- 2.5. The committee considered that the additional inspection report raised serious concerns which need to be addressed promptly. However, the committee also noted that the additional inspection report did not contain a recommendation that the licence should be immediately suspended if a Notice of Proposal to Revoke the licence is issued. The committee noted that it was not suggested that there is an immediate risk to the safety of patients, gametes or embryos.

3. Decision

- 3.1.** The committee decided to adjourn consideration of the additional inspection report and related papers, without making any findings, to enable a meeting to take place between the PR and centre staff and the HFEA Executive, as requested in the submissions on behalf of the centre.
- 3.2.** The committee was satisfied as to the appropriate and proportionate nature of this approach. However, in view of the serious nature of the concerns raised, the committee require that such a meeting takes place as soon as possible and that an update be provided for consideration by the committee at its next meeting in September 2018.
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4. Chair's Signature

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

Signature



Name

Andy Greenfield

Date

31 July 2018

**Executive summary for Licence Committee
12 July 2018**

Centre number	0338
Centre name	Reproductive Health Group
Person Responsible (PR)	Mr Luciano Nardo

Executive summary following PR responses to additional inspection report

Background

1. A report of an additional short notice inspection report for this clinic is being considered by the Licence Committee at this meeting.
2. The draft report of the inspection findings was provided to the PR on 15 June 2018 and, as requested by the executive, the PR provided his response by 28 June 2018.
3. The response includes the PRs response to the draft inspection report (at Annex 1 of the inspection report) and a letter dated 28 June 2018 from the PR to Dr Karen Conyers, the centre's inspector.
4. In addition, the PR provided a suite of 14 policy and other operational documents and the executive has had regard to these. In the opinion of the executive these provide information on the centre's processes, and on the actions, that have been taken in response to the inspection findings, but have no impact on the extant recommendation.
5. The focus of the executive has been on (where necessary) addressing any points raised in the documents referenced in paragraph 3, above.
6. In addition to the PR's responses to the report, the Licence Committee is invited to consider the PR's letter to the centre's inspector (Appendix 3). The executive notes several points, set out below.
7. The PR states in paragraph 3 of his letter:

'We acknowledge the critical and major areas of non-compliance identified in the inspection report, as presented in the Summary for the LC (page 2 of the draft Interim Licensing Report). However, we are surprised that these were not presented to the team during the post-inspection feedback meeting, nor to the PR during the meetings arranged at the time of the visit. This would have enabled us to respond to some of the concerns raised and may have avoided the need for them to be raised as non-compliances in your report. In our opinion the report does not fully reflect what presented by the inspectors.'

On the 8 June 2018, the PR wrote to the centre's inspector, confirming: 'We endeavour to be fully compliant with all the aspects of practice and will work as hard as possible to address the other issues we discussed during the feedback

session on Tuesday afternoon. I am planning to write to you with a summary of actions and supporting documentation within the next 7-10 days.'

Several actions in relation to the two cases noted in the area of critical non-compliance in the inspection report have been recorded in the documents provided by the PR as being undertaken by the centre on 8, 13 and 14 June 2018, that is before the PR was provided with the inspection report. Furthermore, on 15 June, the centre's quality manager submitted in-house consent documents that had been revised on 8 June 2018. Therefore, the executive is assured that the PR and/or his staff were aware of these issues identified during the inspection in order for the actions to be taken.

8. The PR states on page 2 (second paragraph):

'With regard to the one, isolated instance of a critical non-compliance identified in the draft report, the PR acknowledges that this should not have occurred.' and that the consent form was 'altered retrospectively after receiving verbal permission from the patient at the time of a telephone conversation'.

The executive assert the PR failed to ensure that suitable practices are used in the course of the clinic's activities. In its evidence the executive relied upon to form this conclusion, the committee's attention is drawn to the range of factors taken into account (including the instance referenced above).

In relation to the specifics of the referenced instance (case A), at the time of the inspection there was no information in the patient's medical records to support this position, nor did the PR provide this explanation to the inspector during discussions about this issue. The centre's records of the communication in relation to this case are included in the papers presented to Licence Committee (Appendix 1). These records were provided to the inspection team in response to their request during the inspection and indicate that the patient was unaware of what had been amended on the consent form until it had been sent to her. This is discussed on page 11 of the inspection report, from paragraph 2 onwards.

9. The PR states at page 3 (first paragraph):

'Legal parenthood As confirmed by the inspectors during the visit, all the cases in the audit relating to legal parenthood had been followed up. They accepted that historic cases had been dealt with, with the exception of one in relation to which the centre was still waiting to receive the marriage certificate; coincidentally the document arrived in the evening of day 2 of the inspection and it was forwarded to the centre's inspector.'

The inspection team do not accept that all historic cases had been dealt with, as stated by the PR in this letter. The inspection report highlights the finding that one case (case B) was identified in the centre's audit of legal parenthood in November 2017, but that the required corrective action to contact the couple and establish marital status had not been captured in the audit report nor acted on by the centre (see 'Audit of centre's records' on page 13 of the inspection report).

Therefore, as the executive noted, this issue had not been followed up by the centre until identified by the inspection team.

This is not the same case as indicated by the PR where a marriage certificate had been requested and was awaited (case C, see paragraphs 2 and 3 on page 12 of the inspection report). The arrival of the marriage certificate in response to the PR's request on the second day of inspection and the PR's previous actions taken in relation to this are also discussed on page 12 of the inspection report.

10. The executive has considered the PR's responses to the report and the information in the 'Response to HFEA Draft Report'. These submissions do not provide sufficient additional assurance to the executive that would cause it to reconsider the recommendations made in the report.
11. Therefore, the executive is of the view that the PR has failed to discharge his duty under section 17(1)(d) of the Act and is no longer considered suitable to hold a licence. The PR has failed to ensure that suitable practices are used in the course of the clinic's activities.
12. The Licence Committee is invited to make findings in this regard.

Karen Conyers
Inspector
28 June 2018.