

Licence Committee Meeting

15 December 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

Royal Surrey County Hospital (0159) Interim Inspection

Members of the Committee:

David Archard, Lay Member – Chair
Jennifer Hunt, Senior Infertility
Counsellor, IVF Hammersmith

Present via conference telephone:
Sally Cheshire, Lay Member

In Attendance:

Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice to the
Committee:
Mary Timms, Field Fisher Waterhouse

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

The following papers were considered by the Committee:

- papers for Licence Committee (29 pages)
- no papers were tabled.

1. The papers for this item were presented by Gill Walsh, HFEA Inspector. Mrs Walsh informed the Committee that this small, storage only centre offers semen storage, largely to oncology patients. Mrs Walsh summarised the areas for improvement identified at the interim inspection. These were:

- the centre's failure to monitor air quality during processing of gametes
- the requirement to ensure the availability of appropriately qualified counsellors for all patients wishing to store semen
- the requirement to establish one third party agreement still outstanding
- the requirement to validate the flow hood cabinet
- the requirement to establish documented procedures for the receipt and release of gametes
- the requirement to revise patient information and witnessing documentation

2. Mrs Walsh directed the Committee to the response by the Person Responsible, who, she suggested, had responded positively to the issues raised in the report.
3. On the issue of air quality testing, Mrs Walsh informed the Committee that the centre have confirmed that procedures are now in place to test the air quality as required and an ongoing schedule of monitoring is being implemented. The Executive has requested to be informed of the outcome of recent air quality testing. Currently this information has not yet been received.
4. Mrs Walsh informed the Committee that the centre has entered into an agreement with Woking Nuffield for the availability of qualified counselling for all patients. This step was welcomed by the Committee. On the basis of the inspection report, the Committee requested that the centre preserve the term “counsellor” for fully qualified counsellors thereby maintaining a clear distinction between the specialist advice and support provided by the oncology nurses and the availability of qualified counselling outside of the medical process. The Committee agreed that this move would result in greater clarity for patients.

The Committee’s Decision

5. The Committee noted the areas for improvement identified in the inspection report and agreed that they would expect the Person Responsible to address the recommendations in accordance with the timescales set out in the report.
6. The Committee noted the report and welcomed the fact that her response indicated an intention by the Person Responsible to comply with the recommendations of the inspection team.
7. The Committee noted, however, that there was no mention in this response of the requirement to revise the written procedures for the receipt of gametes. The Committee agreed that all the improvements required to the centre’s documentation should be completed in the timescales suggested in the report and should then be submitted to the Executive for inspection. The Committee asked that this be followed up by the Executive.
8. The Committee noted the response by the Person Responsible on the issue of air quality and decided to draw to the centre’s attention the following requirements:
 - (a) the requirements of Licence Condition A.10.19 that “the processing of gametes and embryos while exposed to the environment must take place in an environment...of at least Grade C air quality, with a background environment of at least Grade D air quality” and that “it

must be demonstrated and documented that the chosen environment achieves the quality and safety required”; and

(b) guidance in the Code of Practice (G.9.4.5) that “where the environmental air quality has dropped below Grade D in the course of a procedure involving the manipulation of gametes or embryos, those gametes or embryos should only be used in treatment if the centre can assure itself that no additional risk to the woman to be treated or to any resulting child is entailed as a result”.

9. The Committee agreed that the centre’s licence should continue with no additional conditions.

Signed..... Date.....
David Archard (Chair)