

# Executive Licensing Panel - minutes

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## Centre 0030 (Herts and Essex Fertility Centre)

### Executive Update – Investigation into Media Allegations

Friday, 25 August 2017

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Hannah Verdin (Chair) Anna Coundley Howard Ryan	Head of Regulatory Policy Information Access and Policy Manager Report Developer
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

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## Declarations of interest

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

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## The panel had before it:

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

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## 1. Background

- 1.1. The panel noted that 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 and 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. The panel noted 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.
- 1.3. The panel noted that the Herts and Essex Fertility Centre featured in this newspaper report, making allegations with regards to egg sharing and donation, counselling and costs of medication.

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## 2. Consideration of Investigation

- 2.1. The panel considered the papers, which included a report of an investigation into media allegations and licensing minutes for the last three years.
- 2.2. The panel noted the report focusses on an investigation into the allegations made in the Daily Mail report, namely in relation to:
  - Egg sharing and donation
  - Counselling
  - Costs of medicationand included a meeting with key members of staff at the centre on 18 May 2017.
- 2.3. The panel noted the HFEA's requirements in relation to each of these allegations.
- 2.4. The panel noted the aim of the investigation was to:
  - Discuss the newspaper article and review what happened from the centre's perspective.
  - Investigate whether there has been a breach of the law (HF&E Act 1990 (as amended)).
  - Review the centre's practices and procedures relating to egg sharing and/or egg donation and ensure compliance with the HFEA Code of Practice and General Directions.
  - Audit a sample of egg donor and recipient records to ensure compliance with statutory, regulatory and best practice guidance.
  - Ensure patients have received a proper offer of counselling.
  - Review the information given to same sex couples.
  - Review the centre's information regarding drug pricing.
- 2.5. The panel noted the findings of the investigation and the following recommendations made in the report that the centre must;
  - Review its practices, with attention paid to the marketing, and recruitment of patients wishing to donate or share some of their eggs. To ensure such acts are altruistic.
  - Review its website to ensure compliance with Code of Practice guidance regarding the marketing of egg share and/egg donation. Ensuring these aspects of the website remove

any undue emphasis on financial incentives and that the use of terms such as 'free IVF' are removed.

- Review its policy surrounding prescribing medication ensuring that patients are made aware that these may be dispensed at an alternative Pharmacy at a cheaper price.
- Review all documentation to ensure it clearly and accurately describes the processes within the clinic. With attention to egg sharing and donation, counselling and costs and medication.

- 2.6.** The panel noted that the inspectorate has no concerns with regards to the allegation concerning the targeting of lesbian couples for egg sharing, being satisfied that couples in the same sex relationship are provided with information relating to all available treatment options and decisions that they take are fully informed ones.
- 2.7.** The panel noted that inspectorate found no evidence to support there were inadequacies in the centre's counselling service. There was evidence that the centre's counsellors are appropriately qualified and experienced in the provision of fertility counselling. and in a sample of the patient records, it was evident that counselling had been offered.
- 2.8.** The panel noted that the Person Responsible (PR) has engaged effectively with this investigation and provided information promptly at the request of the centre's inspector. The centre's inspector will remain in close contact with the PR to ensure that the recommendations made in this report have been fully implemented.
- 2.9.** The panel noted the inspectorate recommends the continuation of the centre's treatment and storage licence without additional conditions.
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### **3. Decision**

- 3.1.** The panel noted the inspectorate's investigation and findings, regarding the media allegations, focusing on egg sharing, counselling and medications.
- 3.2.** The panel welcomed this Executive update, endorsing the inspectorate's recommendations, but expressing particular concern regarding information on the centre's website pertaining to the marketing of egg sharing and/or egg donation and undue emphasis on financial incentives. The panel also highlighted the importance of undertaking a shift in culture at the centre, ensuring more attention is given to the tone used in marketing materials for patients.
- 3.3.** The panel was satisfied for the centre's treatment and storage licence to be continued without additional conditions, requesting that the inspector report back to the panel, if the remaining recommendations are not implemented to the satisfaction of the inspector.
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### **4. Chair's signature**

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

#### **Signature**



#### **Name**

Hannah Verdin

#### **Date**

5 September 2017

## Report of an investigation into media allegations: Herts & Essex Fertility Centre, 0030

**Date of meeting:** 18 May 2017

**Location of meeting:** Herts & Essex Fertility Centre

**Investigation team:** Louise Winstone and Sharon Fensome-Rimmer

Present		
HFEA	Louise Winstone Sharon Fensome-Rimmer	Centre Inspector Chief Inspector
Herts & Essex	David Ogutu Debbie Evans	Person Responsible (PR) Director of Clinical Services

### 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. Herts & Essex Fertility Centre (0030) featured in the press report. The article made the following allegations:
  1. **Egg sharing and donation:** exploiting desperate women on low incomes by targeting them to donate their eggs for financial reasons and using financial incentives to convince women to donate eggs because this allows the clinic to maximise its profits. An allegation was made that that there could be up to ten recipients for each egg donor thereby maximising the clinics profits. The clinic advertise on their website with the banner 'No NHS funding for your fertility treatment? There is another way. Our egg share programme

provides completely free IVF' and its Twitter headline is #FreeIVF. The article also referred to the centre minimising the very serious potential consequences of egg sharing while trying to sell the scheme. A member of staff was quoted 'You just think of them [eggs] as cells. I always think it's like donating blood isn't it?' 'An egg isn't a baby. Once it clicks most people don't have an issue with it. It just needs to click.' Most women find it okay because it's not like your baby. It's not fertilised. It grows in somebody else's tummy.' There was also an allegation that the clinic specifically targets lesbian couples for egg sharing.

**2. Counselling:** having an inadequate counselling service that did not prepare women for the consequences of egg donation. A member of staff was quoted as saying 'is not a pass or fail thing' and is quite routine, most people do it for the money'.

**3. Costs of medication:** 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 sharing and donation:**

In the UK, egg donation is permitted under the HFEA's Code of Practice (CoP) 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). CoP guidance states that if benefits in the form of licensed services are offered to an egg provider (including a mitochondrial donor), they should be given in connection with the cycle in which eggs are supplied for a recipient's treatment unless providing treatment to the egg provider at this stage could be harmful, or there is a clinical reason(s) to defer treatment to the egg provider.

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 of medication

The HFEA's powers are limited with regards to costs of medication for treatments as we do not set prices for treatments. 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 and this is appended in annex 1.

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## 2. Our investigation

This report focusses on an investigation into these accusations including a meeting with key members of staff at the clinic on 18 May 2017.

### 2.1 Aim of the investigation

- To discuss the Press article and review what happened from the clinic's perspective.
- To investigate whether there has been a breach of the law (Human Fertilisation and Embryology Act 1990 (as amended)).
- To review the clinic's practices and procedures relating to egg sharing and/or egg donation 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 same sex couples.
- To review the centre's information regarding drug pricing.

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

- Press accusations sent to the centre and the centre's responses
- Sample of egg donor records and their recipient records
- HFE Act 1990 (as amended)
- HFEA Code of Practice 8<sup>th</sup> Edition, revised May 2017

## **2.3 Egg sharing, donation and counselling**

### **i) Meeting with the PR and Director of Clinical services**

In a meeting with the PR, the Director of Clinical Services and the investigation team, the PR stated that the clinic policy is never to approach a couple to ask them to egg share. They said they have a marketing campaign to make patients aware of the service and then the patients contact the clinic for further information. The clinic said the marketing campaign was established when the local CCG withdrew funding from the area. The clinic said that egg share provides the only opportunity for some couples to undergo IVF. The Press made an allegation that there could be up to ten recipients thereby maximising the clinics profits, the PR's response to this was that one patient would never produce enough eggs to donate to ten couples. The clinic said this was a misunderstanding by the reporters as during the open evening one of the nurses told a patient that up to ten families can be created but she was referring to the ten-family limit.

With regards to the allegation of the clinic minimising the very serious potential consequences of egg sharing while trying to sell the scheme, the PR and the Director of Clinical services both stated that these comments had been taken out of context. They said that the comment referring to egg donation being similar to blood donation was a comment made by a previous patient, which the Director of Clinical Services had used at the open evening with a view to reassuring patients rather than downplaying the seriousness of the procedures. Since the allegations, the PR confirmed that they have reflected on the importance of language used and the importance of staff being more mindful of how they communicate with patients.

The clinic was also accused of specifically targeting lesbian couples for egg sharing. The Director of Clinical services responded to this by explaining that during the open evening attended by the undercover reporters, there were five same sex couples in the audience which is why she had tailored some of her responses. She said she had discussed the different options available and that some are more complicated and not for everyone. She said that same sex couples are often happy to donate eggs as they will be recipients of donor sperm in treatment. The Director of Clinical Services said same sex couples are

provided with information about all of the options and will review the information following the consultation event(s).

The clinic says that counselling is mandatory for all egg share and/or egg donor patients, and that patients are not permitted to start treatment until the counselling report has been received. The clinic will fund as many sessions of counselling as the patients require. This includes the provision of mandatory 'implications' counselling or counselling of a supportive nature – and these sessions can be provided before, during or after treatment. The PR assured us that there have been occasions where patients have been declined for egg share if it is felt that they are struggling with the idea of donation and are motivated for what looks like financial reasons.

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

The inspection team reviewed a sample of egg sharer and recipient patient records from 2016. We saw that in all cases, eggs provided by the egg sharer were the subject of donation to one or two recipients only.

We also saw evidence that patients had received their benefits in kind in the same cycle and had been offered counselling. It is important that patients are not unduly subjected to further stimulation and egg collection.

In the 'Agreement for the recipient of eggs as part of an egg sharing programme' we were concerned to see that one of the clauses read 'if I receive no eggs due to the egg number collected being less than 6, I will have my treatment fee refunded minus the cancellation fee'. This information was also restated in the fees leaflet. We saw that the cancellation fee is £1000. This was raised with the clinic staff as it is inappropriate to charge a recipient for a cancelled egg share cycle. Clinic staff confirmed that no recipient has ever paid a cancellation fee and it is unclear why this was stated in the documents. The centre has since provided evidence that it has removed the cancellation fee from all documentation.

## **iii) Arrangements for counselling**

The clinic uses three independent counsellors and the patients can decide which counsellor they contact. Counselling sessions are mainly provided by a video conference facility. We reviewed a sample of patient records and we saw that counselling was offered and received by all patients.

## **2.4 Costs of medication:**

The PR stated that the clinic does not have the buying power of competitor pharmacies. They said that patients are always provided with the option of where to take their prescription. We saw this stated in information provided to patients and on the clinic's website. The clinic told us that some patients reported to them that on receipt of their prescription obtained elsewhere, the necessary needles and syringes were not included. This resulted in the patient having to contact the centre. It was also reported to us that,

further to such experiences, some patients, at their next treatment cycle, decided to collect the drugs from the centre for ease.

We were told that the price the clinic charges includes sharps bins, disposal, needles, syringes and top up medication if required. We were told they provide a bespoke service with patients able to access to drugs when they need them and there is a nurse on call if patients run out. The clinic is currently looking at a home delivery service which will serve to reduce costs. We emphasised that the option for patients to collect their prescription from elsewhere needs to be made much clearer in patient information.

### **iii) The Person Responsible**

Shortly after the allegations were made, the PR responded to the HFEA by saying 'We are confident that we have at all times adhered to HFEA regulations, guidance notes as well as the whole Code of Practice in providing an egg sharing and/or egg donation programme. There have been no concerns from previous inspections from HFEA and CQC about our interpretation of guidance as well as practice and this has been our response to the Daily Mail'.

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## **3. Findings:**

### **3.1. Egg sharing and/or egg donation arrangements and marketing:**

The clinic was found to be compliant with the information provided to donors and recipients. However, we were concerned about the reference to the recipient cancellation fee. On 13 June 2017, the centre provided us with copies of revised documentation. This included the agreements for both the donor and the recipient. We reviewed these and noted the recipient cancellation fee has now been removed from these documents and the treatment price list.

The PR provided explanations for the comments made by staff during the open evening. We accept that for several of the comments, it is possible that these were taken out of context and prompted by specific and potentially leading questions asked by the reporters. The clinic is of the view that its marketing campaign serves to promote their egg sharing and/or egg donation service but is not targeted to actively recruit egg sharers and donors for purely financial incentives. Further the clinic is confident that all potential egg sharers and donors undergo counselling where the motives for donating are discussed and documented.

The clinic states that it does not place an undue emphasis on financial incentives in the way that it markets its egg sharing and donation programme. We do not accept this. At the time of this investigation, the clinic promoted egg sharing on its website using terms such as 'free IVF' and 'Our egg sharing and sperm sharing schemes reward donors with free fertility treatment'.

The information on the clinic website is not compliant with the HFEA Code of Practice guidance at 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 clinic’s website information clearly identifies egg sharing/donation as a way of cutting the costs of IVF treatment.

In relation to the allegation that the clinic specifically targets lesbian couples for egg sharing, we do not have concerns. We are satisfied that couples in a same sex relationship are provided with information relating to all available treatment options and the decisions that they take are fully informed ones.

### **3.2. Counselling arrangements:**

In relation to the adequacy of the counselling service, for example that it did not prepare women for the consequences of egg donation, we found no evidence to support this. We saw evidence that patients attending the clinic for egg sharing and/or egg donation are offered and encouraged to receive counselling. We are aware that the number of sessions that a patient accesses is dependent on the specific requirements of each patient. We saw evidence that the centre’s counsellors are appropriately qualified and experienced in the provision of fertility counselling. We saw evidence in a sample of the patient records that counselling had been offered, and we were reassured to see that it had also been received by all the patients.

### **3.3. Costs of medication:**

The HFEA do not have the powers to regulate the costs of medication for treatment cycles. The clinic provides patients with some information that necessary medication can be obtained from alternative sources and which may be considerably cheaper. We found that this information could be made much more clearly, and the PR committed to this, for example ensuring that posters are available in the waiting room. On the 27 June 2017, the PR provided evidence that the price list on the clinic website informs patients that they can source medication externally. He also confirmed that patients are informed at their first appointment with a consultant that they can source medication externally, and that this point has been added to the checklist of information provided to patients.

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## **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, the inspection team conclude that:

- Whilst clinic staff provided explanations for comments made to the undercover reporters, which they believe have been taken out of context by the newspaper, they are suggestive of an overly informal culture as regards the provision of information to patients in relation to donation treatment.

- Whilst there was no evidence of active recruitment of egg sharers and/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 share/donate some of their eggs.
- The clinic is promoting egg sharing as a scheme to enable patients to afford their fertility treatment, potentially to the centre's financial benefit. The centre's website was in breach of CoP guidance 13.1 as it referred to egg share ('a similar advantage') as '...free fertility treatment'. This also goes against the principle of altruistic donation.
- The clinic documentation in relation to egg share and/donation are compliant with Code of Practice guidance.
- The clinic's counselling service is suitable and compliant with regulatory requirements.
- The clinic provides patients with information that their medication can be obtained from alternative sources which may be considerably cheaper.

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## 5. Recommendations

The clinic has some improvements to make to be acting appropriately and to be compliant with Code of Practice guidance and the principles of gamete donation. We make the following recommendations: The clinic must:

- Review its practices, with attention paid to the marketing, and recruitment of patients wishing to donate or share some of their eggs. To ensure such acts are altruistic.
- Review its website to ensure compliance with CoP guidance regarding the marketing of egg share and/egg donation. Ensuring these aspects of the website remove any undue emphasis on financial incentives and that the use of terms such as 'free IVF' are removed.
- Review its policy surrounding prescribing medication ensuring that patients are made aware that these may be dispensed at an alternative Pharmacy at a cheaper price.
- Review all documentation to ensure it clearly and accurately describes the processes within the clinic. With attention to egg sharing and donation, counselling and costs and medication.

**5.1.** The PR has engaged effectively with this investigation and provided information promptly at the request of the centre's inspector. The centre's inspector will remain in close contact with the PR to ensure that the recommendations made in this report have been fully implemented. The inspection team recommends the continuation of the centre's Treatment and Storage licence without additional conditions.

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## 6. References

1. Human Fertilisation and Embryology Authority (HFEA) Code of Practice 2017 section 3 8<sup>th</sup> edition.
2. Human Fertilisation and Embryology Authority (HFEA) Code of Practice 2017, section 4.3, 8<sup>th</sup> edition.
3. Human Fertilisation and Embryology Authority (HFEA) Code of Practice 2017, section 12.5, 8<sup>th</sup> edition.
4. Human Fertilisation and Embryology Authority (HFEA) Code of Practice 2017, section 13.1, 8<sup>th</sup> 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].

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## 7. Annex 1 – Clinic response to the Daily Mail allegations

Herts and Essex fertility Centre is a Human fertilisation and Embryology authority (HFEA) licenced fertility clinic. We adhere to the HFEA code of practice to the letter in the provision of fertility treatments using patients own gametes as well as donor gamete where applicable. Our HFEA inspection reports which are publicly available attest to this.

The HFEA code of practice (12.1)states that:

Where relevant, the possibility of donating gametes for fertility treatment, mitochondrial donation or research should be raised before a potential donor's treatment begins. Patients should not be put under pressure or unduly influenced to donate gametes or embryos.

Our advertisements and the information available on our website as well as the HFEA website inform patients that altruistic as well as egg sharing donation is a service provided at Herts and Essex Fertility Centre. Interested patients will then approach the clinic for further information. They must have independent implications counselling (provided by external independent counsellors) before we can provide egg donation.

Egg share cycles involve treatment of only one recipient and one egg donor. Half the eggs received from an egg share donor is used to treat only one other patient, the recipient. The payment received from the recipient covers the donor's cost. The information you have about one egg share donor's eggs being used to treat up to 10 others is certainly not true if not clinically impossible (one patient could not produce enough eggs to keep half and the other half be shared between 10 others).

At Herts and Essex fertility Centre we are proud to help hundreds of couples to have babies, who cannot afford fertility treatment and who through no fault of theirs, are not eligible for NHS funded treatment. Only through egg sharing can some couples have a loving family and we have nothing to be ashamed of. We are equally helping hundreds of women who need donor eggs, many of whom have run out of eggs and in early menopause or who have low number of poor quality

eggs. They now can have a family where otherwise they would have had to go abroad for treatment often in unregulated clinics like Cyprus, Romania, Latvia, Russia, Ukraine etc. or endure waiting lists of 1 – 2 years in the UK for altruistic donors.

Very importantly research has clearly shown that egg sharing women have similar success rates to that of comparable non- egg sharing women undergoing IVF treatment. So those women are not compromising their chances of success and on top of that, are getting their treatment free.

As far as counselling is concerned, we do not dictate how many sessions egg sharing couples have. This is purely between the counsellors and the couples to decide if they require more sessions as we have no limit as to the number of sessions.