

# Executive Licensing Panel - minutes

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**Centre 0339 (CREATE, St Pauls, London)**

## **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 CREATE, St Pauls London featured in this newspaper report which states that after waiting two hours for a private appointment, undercover reporters (posing as prospective patients interested in egg donation) met with a clinician at the centre. The article alleges that the doctor's attitude towards donation focused on financial rather than altruistic motivations.
- 1.4. The panel noted that the article also refers 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.

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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 focuses on an investigation into the allegations made in the Daily Mail report, namely: respect for the primary principle of altruism when donating eggs. This included a meeting with key members of staff at the centre on 15 June 2017. 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 donation and egg sharing and ensure compliance with the HFEA Code of Practice and General Directions.
  - Audit a sample of egg donor records to ensure compliance with statutory, regulatory and best practice guidance.
  - Review the centre's information regarding drug pricing.
- 2.3. The panel noted the findings of the investigation. The panel noted that the centre was found to be compliant with regulatory requirements for their egg donation practices and the inspection team concluded the following:
  - Without a transcript of the conversation, the inspection team cannot determine what was said during the meeting with the reporters, or the context in which it was said. There is no suggestion that centre staff acted inappropriately during the meeting with the reporters. Irrespective of this, the investigation was primarily concerned with the centre's general practice and policy with respect to egg donation.
  - The centre's egg donation practices are compliant with regulatory requirements.
  - There is much notable practice at the centre including;

The PR informing the Director of Compliance and Information as soon as she was made aware that an article would be published by the Daily Mail;

The allegations were investigated as an incident by the centre and although the centre considers that they have done nothing wrong, the PR still initiated a full review of protocols and staff understanding of the relevant requirements.

The centre's processes have a clear theme of altruism running through their SOPs and patient information.

- No concerns were noted about fees for medication or patient choice in purchasing medication from sources other than the centre.

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### **3. Decision**

- 3.1.** The panel noted the inspectorate's investigation and findings regarding the media allegations, particularly noting that the PR had informed the Director of Compliance and Information as soon as she was made aware of the allegations being made in the Daily Mail's article. The panel also noted the centre's continuing high level of engagement with the investigation
- 3.2.** The panel welcomed this Executive update and endorsed the inspectorate's conclusions, being satisfied the centre was compliant with regulatory requirements for their egg donation practices.
- 3.3.** The panel was satisfied for the centre's treatment (including embryo testing) and storage licence to be continued without additional conditions

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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: CREATE, St Paul's London, Centre 0339

**Date of meeting: 15 June 2017**

**Location of meeting: CREATE, St Paul's London**

**Investigation team: Sara Parlett and Paula Nolan**

Present		
HFEA	Sara Parlett Paula Nolan	Centre Inspector Clinical Governance Lead
CREATE, St Paul's London	Professor Geeta Nargund	Person Responsible (PR) and Lead Consultant
	Praful Nargund	Managing Director

### 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 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.
- 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. CREATE, St Paul's London featured in the newspaper report. The report states that after waiting two hours for a private appointment, undercover reporters (posing as prospective patients interested in egg donation) met with a clinician at the centre. The article alleges that the doctor's attitude towards donation focussed on financial rather than altruistic motivations.

**1.5.** The article also refers 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.

**1.6.** The HFEA's requirements on egg donation are as follows:

In the UK, egg donation is permitted under the HFEA's Code of Practice and compensation is permitted. Patients are also allowed 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 for donation, 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

**1.7.** The HFEA's requirements on drug pricing are as follows:

Our powers are limited with regards to costs as we do not set prices for treatments. However, we wanted to explore this aspect, 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.

- 1.8.** The HFEA's Director of Compliance and Information wrote to all centres involved on 26 April 2017, requesting a response to the accusations that were due to be published. This request and the centre's response is set out in annex 1.

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## **2. Our investigation**

This report focusses on an investigation into the allegations made in the Daily Mail report, namely: respect for the primary principle of altruism when donating eggs. This included a meeting with key members of staff at the centre on 15 June 2017.

### **2.1. Aim of the investigation**

- To discuss the newspaper article and review what happened from the centre's perspective.
- To investigate whether there has been a breach of the law (HF&E 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 records to ensure compliance with statutory, regulatory and best practice guidance.
- To review the centre's information regarding drug pricing.

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

- Communication between HFEA Director of Compliance and Information and the PR
- The centre's standard operating procedures (SOPs) and patient information directing processes for egg donation and egg sharing
- Sample of egg donor records
- HF&E Act 1990 (as amended)
- HFEA Code of Practice 8<sup>th</sup> Edition, revised May 2017

### **2.3. Egg donation**

#### **i) Actions of centre staff – allegations made in the report**

The PR was asked why the 'couple' had been kept waiting for two hours for a private appointment. The PR explained that this was an open evening event that is run free of charge on a regular basis for prospective patients. The main focus is on natural/mild IVF and not egg donation. At the end of these events, prospective patients can have a brief chat with one of the clinicians to see if the centre best suits their needs.

Following the publication of the Daily Mail article, the PR launched an incident investigation to review what happened during the meeting with the reporters.

A full transcript of the footage was requested from the Daily Mail, but was not provided. The clinician involved made a statement as part of the incident investigation process and explained that she remembered the meeting well, because of the “strange feeling of manipulation towards the financial implications of a possible IVF treatment at our clinic rather than a real interest in exploring fertility options from the clinical point of view”. However, the couple were insistent on discussing financial implications of the egg donation pathway and she explained to them donors recruited at the centre are altruistic donors. When discussing the payment for a donor cycle, with hindsight, the clinician considers she could have used the word compensation rather than money during the meeting.

An extraordinary meeting was held with all centre staff on 2 May 2017 where the Daily Mail article was discussed and the PR checked everyone’s understanding of the process for recruitment of egg donors and sharers, in particular the altruistic nature of donation and compensation. The PR was satisfied with the staff’s familiarity with the regulatory requirements and guidance in this area.

At the centre’s regular clinical meeting on 4 May 2017, centre staff were tasked with reviewing the centre’s SOPs and the Code of Practice relating to egg donation and egg sharing.

**ii) Review of SOPs, information provided to patients and patient records**

The centre performs a small number of egg donor and egg share cycles: there have been four egg share cycles since the centre opened and approximately ten egg donation cycles take place each year.

The centre’s SOPs were reviewed and are compliant with regulatory requirements. The centre’s ‘egg donation and egg sharing patient pathway’ lists the selection criteria before a potential donor can be accepted – the first requirement listed is that they must have an altruistic motivation for donating. An additional area of good practice established at the centre is that following obtaining consent to donation, the centre enforces an additional ‘cooling off’ period of 7-14 days for donors to have further time to reflect before any treatment commences.

The centre’s patient information clearly describes the altruistic nature of donation. For example, the egg sharing information states: “Giving the gift of motherhood by donating some of your eggs collected during the course of your own treatment is the ultimate gift and act of kindness you can make towards women who would not otherwise be able to realise their dream of achieving motherhood.”

The inspection team reviewed a sample of egg donor/sharer patient records from the last three years. These demonstrated compliance with regulatory requirements. Goodwill messages from the donors – which are written for children born from their donation – clearly demonstrated that altruism was the primary motive for donation in these specific cases.

## 2.4. Costs

The PR explained that all patients are made aware that they are free to purchase their medications elsewhere. However, it was explained that the medications can be cheaper to purchase via the centre.

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## 3. Findings

- 3.1.** The centre was found to be compliant with regulatory requirements for their egg donation practices.

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## 4. Findings and Conclusions

- 4.1.** From our investigation, including meetings with centre staff, review of documentation, review of the centre's website, the inspection team concludes that:
- In summary, without a transcript of the conversation, the inspection team cannot determine what was said during the meeting with the reporters, or the context in which it was said. There is no suggestion that centre staff acted inappropriately during the meeting with the reporters. Irrespective of this, the investigation was primarily concerned with the centre's general practice and policy with respect to egg donation.
  - The centre's egg donation practices are compliant with regulatory requirements.
  - Furthermore, there is much notable practice at the centre including:
    - The PR informing the Director of Compliance and Information as soon as she was made aware that an article would be published by the Daily Mail.
    - The allegations were investigated as an incident by the centre and although the centre considers that they have done nothing wrong, the PR still initiated a full review of protocols and staff understanding of the relevant requirements.
    - The centre's processes have a clear theme of altruism running through their SOPs and patient information.
  - No concerns were noted about fees for medication or patient choice in purchasing medication from sources other than the centre.

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## 5. References:

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

Human Fertilisation and Embryology Authority (HFEA). General Directions 0001 Gamete and embryo donation Version 4; October 2015.

HFEA 2011 Authority Paper; 'Donation review: compensation of donors and benefits in kind'. [HFEA (19/10/11) 612].

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## Annex 1

### Communication between Director of Compliance and Information and PR

Dear Geeta

The HFEA has recently been contacted by the Daily Mail, about some specific allegations in relation to activities undertaken at your licensed centre. Thank you for your courtesy call yesterday alerting me to contact you have had from the newspaper.

At this stage I am seeking your initial written reaction to the allegations that have been put to you as well as the nature of those allegations, and any actions you have taken to date.

I will be following up with you further, following the publishing of information (or the receipt of further information) relating to activities in your clinic.

In the meantime I look forward to your response to me, by 12 noon tomorrow (27/04/17).

Kind regards,

Nick Jones

Director of Compliance and Information

Dear Nick

Here are my comments in response to your email. Let me reassure you that our centres are fully compliant with HFEA regulations and no illegal or improper activity has taken place. The protocols and procedures consistent with HFEA regulations are used at all times. No patient or gametes and embryos have been put at risk and absolutely no improper financial activity has been carried out.

We are deeply concerned that, without receiving a substantive response from us, the Daily Mail has sent unfounded allegations to you about our clinic. There are some serious mistakes and misunderstandings of not only fertility treatment, but also the HFEA regulations in their allegations. We reserve all rights to robustly defend our reputation.

One allegation is in relation to undercover footage recorded during a free one to one chat with one of Doctors at a free educational open evening on 11<sup>th</sup> April 2017. It was important to note that this was not a medical consultation, treatment was not offered, and no licensed activity was undertaken. The allegation is in relation to a conversation initiated by the journalist on becoming an egg donor and payment.

We have requested for a copy of the full recording so that we can investigate it fully as we have an obligation to ensure that our doctor has complied with HFEA and GMC obligations during her informal conversations. However, the Daily Mail has only released to us a small extract. [REDACTED]

