

Executive Licensing Panel - minutes

Centre 0044 (Centre for Reproductive and Genetic Health)

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		

Declarations of interest

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

The panel had before it:

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

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 Centre for Reproductive and Genetic Health featured in this newspaper report, making allegations specifically about its egg freezing programme.

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:
 - Inaccurate information is provided to prospective patients regarding the egg freezing programme and the statutory storage period for eggs
 - Poor advice was provided to a prospective patient regarding her reproductive choices
 - The centre provides free consultations to recruit patients to freeze eggs
- 2.3. The panel noted the HFEA's requirements in relation to each of these allegations.
- 2.4. The panel noted that the aim of the investigation was;
 - To investigate whether there has been a breach of the HF&E Act 1990 (as amended) or HFEA Code of Practice requirements.
 - To review the practices used by the centre to recruit patients to the egg freezing programme as well as the information provided to them, to ensure compliance with the HFEA Code of Practice and General Directions.
 - To discuss the newspaper article with relevant staff at the centre and review what happened from the centre's perspective.
- 2.5. The panel noted the findings of the investigation and the following recommendations made in the report that the PR should ensure that;
 - Verbal information provided to egg freezing patients includes appropriate success rate data, ideally live birth rates per thaw cycle started for egg freezing patients, for a recent treatment cohort. Any discussion about egg storage includes the statutory 10 year storage period and the conditions necessary for any extension of storage beyond 10 years. This recommendation should be implemented by 30 September 2017.
 - Written information provided to egg freezing patients includes appropriate success rate data, ideally live birth rates per thaw cycle started for egg freezing patients, for a recent treatment cohort. The information should also discuss the conditions necessary for any

extension of storage beyond 10 years. This recommendation should be implemented by 30 September 2017.

- Information on the CRGH website and in advertising materials is accurate and justified by treatment data which is less than three years old. This recommendation should be implemented by 30 September 2017.

3. Decision

- 3.1.** The panel noted the inspectorate's investigation and findings, regarding the media allegations, focusing on the centre's egg freezing programme.
- 3.2.** The panel welcomed this Executive update, endorsing the inspectorate's recommendations. The panel particularly noted the concern raised by the article that the centre 'even offers free consultations for those considering egg freezing', lasting around 15 minutes, but was reassured by the PR's communication that their use was to be reviewed.
- 3.3.** The panel noted the good practices shown by the centre and their effective engagement with the investigation, providing information promptly at the request of the centre's inspector. The centre had committed to treating patients fairly and in a manner compliant with HFEA requirements.
- 3.4.** 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 recommendations are not implemented to the satisfaction of the inspector, within the prescribed timescales.

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:

Centre for Reproductive and Genetic Health, Centre 0044

Investigation team: Andrew Leonard and Sharon Fensome-Rimmer

1. Background:

- 1.1. In the week of 1 May 2017, the Daily Mail newspaper published several reports into the practices of some fertility clinics relating to: the use of so-called treatment ‘add ons’, medication pricing, egg freezing, and egg sharing and the incentives offered to patients in this process.
- 1.2. The articles suggested 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. The Centre for Reproductive and Genetic Health (CRGH; HFEA licensed centre 0044) was featured in one article, specifically about the egg freezing programme at the centre. The Daily Mail article made the following allegations:
 1. **Inaccurate information is provided to prospective patients regarding the egg freezing programme and the statutory storage period for eggs.**
 - In a patient consultation on 2 December 2016, a 30 year old prospective patient (reporter) was advised by a consultant at the centre that her chances of having a baby at the age of 40 using eggs frozen now, were “very good”; “CRGH is highest in the country – 65 per cent is our success rate”... “because the eggs are frozen at the age of 30 years”.
 - In a patient consultation on 2 December 2016, a 30 year old prospective patient (reporter) was advised by a consultant at the centre that she could freeze her eggs until she is 40 and then ‘you can extend it again another ten years’.
 - In a poster at the clinic: ‘Highest number of live births using frozen eggs in the UK.’
 2. **Poor advice was provided to a prospective patient regarding her reproductive choices:** A 30-year-old prospective patient [reporter] told a consultant at the centre

during a 15 minute initial consultation that she definitely wanted children, but not for another decade and that she did not currently have a partner. The consultant advised her: “Then it’s a good idea to freeze the eggs”.

3. **The centre provides free consultations to recruit patients to freeze eggs:** The article stated ‘The clinic even offers free consultations for those considering egg freezing. They last around 15 minutes – perfect for a busy career woman on her lunch break.’

1.5. The centre was invited by the newspaper to submit a response to these accusations, which it did. The centre soon thereafter contacted their HFEA inspector to advise of the media story and their response, which was forwarded to the HFEA (Annex 1).

1.6. Context

Since 2005, the number of women storing their eggs has increased, with the most rapid growth occurring further to the introduction of egg ‘vitrification’ which became widely available around 2010. Vitrification is a cooling technique allowing the water inside and surrounding the egg to quickly cool into a solid state with no ice crystal formation at all, a problem with earlier, slow freezing, techniques. Despite growth of 25% to 30% year-on-year, egg storage cycles are still a relatively small proportion of fertility treatment performed in the UK. The live birth rate per thaw cycle started for women using their own thawed frozen eggs was 20.8% in 2012 and 13.9% in 2013 – albeit the actual difference is represented by only a small change in the number of births due to the small numbers involved. This is a lower rate of success than for fresh eggs or frozen embryo transfers (HFEA publication: Fertility Treatment 2014: Trends and figures).

2. Our investigation

This report focusses on an investigation into the allegations made in the Daily Mail report, namely: the provision of inaccurate information concerning the success rates of the egg freezing programme and the statutory storage period for eggs; the provision of poor treatment advice; and the provision of free consultation.

2.1. Aim of the investigation

- To investigate whether there has been a breach of the HF&E Act 1990 (as amended) or HFEA Code of Practice requirements.
- To review the practices used by the centre to recruit patients to the egg freezing programme as well as the information provided to them, to ensure compliance with the HFEA Code of Practice and General Directions.
- To discuss the newspaper article with relevant staff at the centre and review what happened from the centre’s perspective.

2.2. The HFEA's requirements in each area of allegation are:

a. Information provision

The HFEA expects patients in fertility clinics to be provided with appropriate information prior to providing any consent to licensed activities. This is required by statute (Human Fertilisation & Embryology (HFE) Act 1990 (as amended), Schedule 3,3,1b) and by SLC T58: 'Prior to giving consent gamete providers must be provided with information about:

- a. the nature of the treatment
- b. its consequences and risks
- c. any analytical tests, if they are to be performed
- d. the recording and protection of personal data and confidentiality
- e. the right to withdraw or vary their consent, and
- f. the availability of counselling.

The HFEA considers that 'proper' information is accurate, complete and easily understood. Specific information on success rates on centre's websites is covered by HFEA Code of Practice (CoP) Guidance 4.5 and information for gamete storers by CoP Guidance 17.13.

b. Treatment advice

The HFEA expects patients in fertility clinics to be provided with the best possible treatment, and advice about treatment, in terms of its actual quality and it being correct for the patient's circumstances. Standard Licence Condition (SLC) T2 requires, for example, 'Suitable practices must be used in the course of activities authorised by this licence and in other activities carried out in the course of providing treatment services that do not require a licence.'

To support this, the HFEA requires via SLC T14 that: 'Personnel carrying out licensed activities or other activities carried out for the purposes of providing treatment services that do not require a licence must, where appropriate, be registered in accordance with the appropriate professional and/or statutory bodies (eg, General Medical Council, Health Professions Council, Nursing and Midwifery Council)'. Such personnel must be appropriately qualified and competent, SLC T12 stating that: 'Personnel in the centre must be available in sufficient number and be qualified and competent for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals.'

c. Free consultations

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. This extends to the costs of consultations and services provided in support of the provision of treatment. However, we have considered 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.

2.3. Documents/papers reviewed during the investigation:

- HFE Act 1990 (as amended)
- HFEA Code of Practice 8th Edition, revised May 2017

- The article on the Daily Mail website and video recording: <http://www.dailymail.co.uk/news/article-4467352/Desperate-women-duped-freezing-eggs.html>.
- Accusations made by the Daily Mail and sent to centre 0044 intercalated with the centre's response to those allegations (Annex 1).
- A research publication submitted by centre 0044 to Reproductive Biomedicine Online 'several weeks' prior to the allegations emerging, referred to by centre 0044 in their responses to the Daily Mail and provided along with supporting data to the HFEA.
- The centre's information sheet provided to patients before consenting to egg freezing (ISP015 version 6).
- HFEA response to 'Freedom of Information' request F-2013-03311: Questions regarding egg freezing and egg thawing in UK clinics, until recently available on the HFEA website and still available at: <http://hfeaarchive.uksouth.cloudapp.azure.com/www.hfea.gov.uk/8597.html>
- HFEA publication, Fertility Treatment 2014: Trends and figures, available at: <http://ifqtesting.blob.core.windows.net/umbraco-website/1783/fertility-treatment-2014-trends-and-figures.pdf>.
- The PR's written response in support of his belief that it was reasonable to advise a 30 year old patient that their chance of having a baby in 10 years, using eggs frozen now, was the same as the centre's current success rate using frozen eggs in treatment.
- The centre's website success rate data.

2.4. Interview with the staff at CRGH

CRGH was visited on 31 May 2017 by prior arrangement with the Person Responsible (PR). The allegations made in the Daily Mail article and the centre's response to them were discussed with the PR (Dr. Paul Serhal) and with the consultant who leads the egg freezing programme and who undertook the consultation with the journalist, Dr. Vidya Atluri (VA).

3. Findings:

3.1. Information regarding success rates

The PR noted to the inspectors that information on the HFEA website regarding egg freezing and its likelihood of success is out of date and not centre-specific. This information comprises Fertility Treatment 2014: Trends and figures, published in March 2016, which reviews validated data for treatments in 2013 and 2014, and a Freedom of Information response (F-2013-03311: Questions regarding egg freezing and egg thawing in UK clinics), which cites data for treatment in 2009-2011. The PR considered that this data had caused some of the allegations, because the information on egg freezing success rates used by the Daily Mail article appeared to be based on it ('just 13 per cent of cycles lead to a live baby and only one in every 57 eggs defrosted results in a live baby'). In contrast, the PR considers the centre advises its prospective patients about

success rates using data which are more contemporaneous and specific to the centre's activities and that this explains the discrepancy highlighted in the Daily Mail article. The PR advised the Daily Mail in its response to the allegations about success rate data specific to CRGH (Annex 1).

When asked about the source of the centre's data, the PR advised the inspectors that the centre's egg freeze/thaw programme success rate was calculated recently by staff for treatments using thawed donated eggs in 2014 (a total of 28 cycles), as stated in the PR's response to the Daily Mail allegations:

'Our pregnancy rate based on 2014 data is 64.3% for patients using frozen donor eggs. Donors are 35 and under so this would be representative of a 30 year old woman seeking treatment with her own frozen eggs.'

The PR also discussed a wider analysis of 110 cycles of treatment with thawed donated eggs performed at CRGH between 2010 and 2015. This analysis was submitted by the centre in an academic paper to Reproductive Biomedicine Online¹ several weeks before the Daily Mail allegations were published. The academic paper was provided to the inspectors: the 2010-2015 treatment data analysis involved 1127 donor eggs being thawed in 110 cycles provided to 87 patients. Fifty one pregnancies and 44 live births occurred, i.e. a clinical pregnancy rate per patient of 59% and a live birth rate per patient of 50.6%. The data for 2014 specifically was obtained from the PR: 29 cycles of treatment involving thawed donor eggs were commenced in 2014, leading to 28 embryo transfers and 18 pregnancies, a clinical pregnancy rate per embryo transfer procedure of 64.3% and per cycle started of 62%.

The inspectors reviewed data in the HFEA register for treatments at centre 0044 involving thawed donor eggs in 2014. This analysis validated the number of cycles and the success rate data provided by the centre for thawed donor egg treatments in 2014.

The centre's data for thawed donor egg treatment in 2014 provides a success rate, albeit a clinical pregnancy rate per cycle started, which is considerably higher than that cited by the Daily Mail. This is perhaps because the centre's data is specific to their activities and is from a more recent timeframe. It is good practice to provide information to patients which is specific to the centre's activities and is from recent treatments. There are however certain problems with the success rate information provided to the prospective patient:

- a) The centre's data supports a clinical pregnancy rate of 64.3% per embryo transfer procedure not a 65% chance of a future live birth for the prospective patient, which is what the prospective patient asked about. It is potentially inaccurate to assume a clinical pregnancy rate is equivalent to a live birth rate.
- b) The validity of using the success rate for treatments using thawed donated eggs in 2014, as an equivalent to the possibility of success if a 30 year old patient freezes

¹ The inspection team note that the Reproductive Biomedicine Online is a reputable peer review research journal, published by Elsevier. It is the official journal of several learned societies in the area of reproductive medicine and currently has an impact factor of 3.249.

her eggs now, then uses them in her own treatment in 10 years time, is questionable.

- c) Why is data for 2014 (28 cycles) used to inform a patient in January 2017 of their chance of success? The academic paper describes a larger cohort of 110 cycles of treatment with thawed donor eggs which might be considered more statistically valid. Data for treatments with thawed donated eggs in 2015 could also have been used which would be a more recent alternative.

The inspectors remain concerned regarding item a) above, a clinical pregnancy rate per embryo transfer was used by VA to advise the prospective patient of the chance of a live birth. A live birth rate will, in general, be lower than a clinical pregnancy rate because of the risk of pregnancy loss.

Regarding point b), the PR advised the inspectors that the success rate for treatments with thawed donor eggs was used for information, because the eggs were frozen when the donors were less than 35 years old and were then used some years later in treatment. This was considered analogous to when women freeze their own eggs in their early 30s for later use in their own treatment. The PR provided a body of academic papers after the centre visit, to justify that the chance of success when using thawed eggs was strongly determined by the age of the egg provider when the eggs were stored rather than the age of the recipient when treated with them. The inspectors consider that these papers are reliable evidence and accept this specific point, however they note that VA and the PR seem to interpret the prospective patient's question as being: what was the chance of success for the embryo transfer in the future using embryos derived from thawed eggs? Review of the video evidence of the consultation, available on the Daily Mail website, supports this.

An alternative interpretation, which seems to be that adopted by the Daily Mail, is that the prospective patient was asking for her chance of success now, if she was to undertake all the treatment and storage necessary to use her thawed eggs in her treatment some years in the future. Assuming this interpretation, the information provided by VA is potentially inaccurate: the prospective patient's chance of a live birth at the age of 40 using thawed eggs, will not be equal to the centre's clinical pregnancy rate per embryo transfer when treating patients with thawed donor eggs in 2014. The inspectors accept that future success rates can only be estimated from recent treatment data and have noted above the inaccuracy of using clinical pregnancy rate as a surrogate for live birth rate. However the success rate provided by VA is likely to be an inaccurate response to the patients question for additional reasons: it ignores events during egg collection, storage, thawing and culture (e.g. failure of ovarian stimulation, recovery of low egg numbers, poor freeze survival, poor embryo development) which, if they occur as is likely in some cases, will lower the chance of success. The success rate provided focusses only on the embryo transfer at some time in the future and is specific to treatments using thawed donor eggs. Ideally a prospective patient for the egg freezing programme should be supplied with live birth rate data for previous patients who have been treated with their own thawed eggs, rather than thawed donated eggs.

The inspectors note and understand VA and the PR's discussion that the time pressures of a 15 minute mini-consultation mean that the intricacies of success rates cannot be discussed and that this may also explain the misunderstandings concerning success rates which occurred during the mini-consultation. VA and the PR also discussed with the inspectors that the video evidence shows that VA attempted to clarify the success rate she provided and what it referred to. The inspectors agree but also note that VA subsequently concurred with an incorrect summary by the reporter of what the 65% success rate meant, as she attempted to move the discussion onto another matter.

In summary on point b), the inspectors consider that VA did not deliberately attempt to mislead the patient. However potentially inaccurate information was provided and the necessary caveats were not included, such that misunderstandings occurred, which were not clarified because of the time constraints of the mini-consultation. The inspectors are mindful that the mini-consultation is only the prelude to the treatment pathway and that much fuller information should be provided to a patient progressing towards egg freezing treatment, which should resolve any misconceptions regarding success rates before consent is sought.

Regarding point c), the compliance of the success rate information provided is considered in the context of the compliance of the patient information sheet and the centre's website discussed below in 3.4.

3.2. Information regarding storage periods

In the consultation, the 30 year old prospective patient was advised by VA that she could freeze her eggs until she is 40 and then 'you can extend it again, another ten years'.

This is potentially inaccurate as VA did not discuss that extension of storage of eggs beyond 10 years is only possible under certain circumstances, defined by The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. Again the inspectors note the PR and VA's comments regarding the time constraints of the 15 minute mini-consultations and that much fuller information about the extension of storage periods should be provided to patients progressing towards treatment, well before storage consent is given.

3.3. The CRGH poster 'Highest number of live births using frozen eggs in the UK.'

The reporter noted a poster at the centre stating the above and the Daily Mail article queried the accuracy of the statement.

The PR advised that it was based on data within the HFEA response to 'Freedom of Information' request F-2013-03311: Questions regarding egg freezing and egg thawing in UK clinics, until recently available on the HFEA website and still available at: <http://hfeaarchive.uksouth.cloudapp.azure.com/www.hfea.gov.uk/8597.html>.

This response was almost three years old at the time of the reporter's mini-consultation and discusses validated treatment data from 2009 – 2011. It is reasonable to question

whether such a statement can be made in advertising literature and on the centre's website, given the data used to support it was for treatments performed almost five years and more before the mini-consultation. Indeed CoP Guidance 4.5 requires that website success rate data is less than three years old.

3.4. The provision of information to egg storers

The PR noted that if prospective patients indicate they wish to have treatment after the mini-consultation, proper information is provided to them verbally and in writing, prior to them giving any consent for treatment. They are also provided with opportunities to ask questions of staff about their treatment and are offered counselling and receive it if they so wish. When the patients enter the treatment pathway, and this is considered by centre staff to be subsequent to the mini-consultation stage, information is provided to the patients to ensure effective consent is provided and the statutory compliance of the centre's licensed activity.

The patient information sheet about egg freezing was provided to the inspectors and was reviewed. It discussed the egg freezing treatment generally and states regarding success rates:

'What are the chances of my eggs being successfully defrosted and used in Treatment? Not all eggs will survive the freezing/thawing process. Reports have estimated a live birth rate of 7-8% per oocyte vitrified-warmed. This data is applicable to patients 35 years and under so women over this age would generally have a lower success rate.'

The inspectors felt further information was necessary to ensure compliance with CoP Guidance 17.13c: the information sheets should include centre-specific live birth rates per cycle for the egg freeze/thaw programme at CRGH. It will also promote transparency further if this success rate data is provided to prospective patients in the mini-consultation, if they continue.

Regarding egg storage time limits, the patient information sheet states:

'How long can eggs be stored? Once eggs have been frozen, their quality will not deteriorate dependent on how long they are in storage. However, eggs cannot be stored indefinitely as the HFEA have set a limit of 10 years on the storage of eggs. This period can be exceeded in certain circumstances in periods of 10 years up to 55 years.'

The inspectors felt this statement accurately portrayed the legal situation but it could be considered non compliant with CoP Guidance 17.13b because the 'certain circumstances' are not further discussed, i.e. that to extend storage beyond 10 years a medical practitioner has to find that the gamete provider is at risk of, or exhibits, premature infertility and the gamete provider has to consent to the added storage period. This information should be included in the written patient information to ensure full compliance with CoP Guidance 17.13b.

Information is also provided to prospective patients seeking egg freezing services via the CRGH website. CoP Guidance 4.5a requires centre's websites to contain treatment data from within the last three years. The CRGH website contains treatment and success rate data for 2014 and the same data was also used to inform the prospective patient in December 2016. This information would currently be considered compliant but this will not be the case by the end of 2017. The website information regarding egg freeze/thaw success rate is also not compliant with other aspects of CoP Guidance 4.5:

- b) The website should provide the live birth rate per treatment cycle....
- c) The data should show split by maternal age.....
- d) The website should provide raw numbers rather than just percentages.

It is noted that the HFEA Fertility Treatment 2014: Trends and figures is referenced as a source of national data on the CRGH website, and national average data for most treatments is available.

The centre's website also states: 'The HFEA has also recognised CRGH as having the highest number of live births using [frozen eggs](#) in the UK.' This website link used to connect to the HFEA response to 'Freedom of Information' request F-2013-03311: Questions regarding egg freezing and egg thawing in UK clinics, until recently available on the HFEA website and still available at:

<http://hfeaarchive.uksouth.cloudapp.azure.com/www.hfea.gov.uk/8597.html>.

This HFEA data is more than three years old and should not be referenced on the centre's website to justify this statement (CoP Guidance 4.5c). Unless the centre has further evidence in support of the statement, it should be removed.

3.5. Treatment advice provided

The PR described that VA was very experienced and had recently had her competencies signed off by another senior consultant at the centre. VA is a GMC registered doctor. VA has led the centre's egg freezing programme for some years. The inspectors had no concerns that VA was not qualified or competent to undertake her clinical duties at the centre.

VA recalls that during the mini-consultation with the reporter/prospective patient she asked a clear question regarding when the prospective patient wanted children. The patient replied that she wanted definitely to delay for 10 years, did not have a current partner and that she wanted to freeze eggs. VA confirmed with the reporter that she was 30 years old and did not want children for 10 years. The reporter was clear on these facts. VA considers advising egg freezing in the situation described was not incorrect and was logical and reasonable advice to provide given the prospective patients opinions and life situation. The PR was supportive of VA's opinion given the facts of the consultation.

The inspectors found no regulatory concerns related to this allegation

3.6. The use of 'free' mini-consultations

The Daily Mail article appeared concerned that the clinic 'even offers free consultations for those considering egg freezing. They last around 15 minutes – perfect for a busy

career woman on her lunch break.'

The PR advised the inspectors that 15 minute mini-consultations were provided to many prospective patients, not just those considering egg freezing, and had been on-going for 12-18 months. The PR and VA indicated that the egg freezing programme is well used and that, in their opinion, prospective patients appreciate the opportunity to visit the clinic and discuss with a clinician the possibility of egg freezing.

Both the PR and VA considered it difficult to have a detailed conversation with a prospective patient in a mini-consultation because of time constraints. Neither would consider any information provided in one as part of a patient's preparation for licensed activity or to fulfil any statutory requirements regarding information provision to patients. Indeed as discussed above, the time pressures of the mini-consultation contributed to the misunderstandings regarding success rates. The PR and VA considered the mini-consultations to be more about introducing prospective patients to the clinic and a clinical staff member, and providing an opportunity for a brief discussion about a potential treatment, including how it is done, the risks and benefits, and success rates. This provides the prospective patient with some information and first-hand experience on which to base their decision as to whether to investigate further whether to have treatment at the centre.

The PR feels that the mini-consultation programme has advantages and disadvantages, and that they work for many patients, but noted that some consultants at the centre had concerns about them. He advised that the centre management team were to discuss at a meeting in mid-June 2017, whether to lengthen them to 30 minutes to reduce risks or to stop doing them altogether.

The HFEA's powers are limited with regards to costs of treatments as well as consultations and other services provided in support of the provision of treatment. The inspectors found no regulatory concerns related to this allegation, considering it unlikely that a free mini-consultation would unfairly influence a patient to commit to having egg freezing treatment; especially as the not insignificant cost of this treatment pathway is advised to the patient if they investigate the treatment further.

The PR advised the HFEA subsequent to the inspector's visiting CRGH:

'CRGH offer free 15 minute mini-consultations for potential patients who would like to get to know the team and premises before making the decision as to whether to book a full consultation. We have calculated that between January 16 to December 16, we had 439 mini-consultations of which 209 patients subsequently booked for a full consultation. As discussed at our meeting, a patient cannot start treatment at CRGH without a full consultation. There is clearly an appetite for patients to view clinics before committing to a full consultation. However, the 15 minute slot may be too restrictive for both patient and consultant and therefore we think the best course of action is to extend the mini-consultations to 30 minutes, and this will be discussed at the next MDT meeting on 19 June.'

The inspectors note the PR's commitment to consider extending the mini-consultations to 30 minutes, which they consider will limit the potential for misunderstandings which seem to have occurred in this case. The centre's inspector will follow up with the PR to find the outcome of the MDT's consideration.

4. Conclusion:

From our investigation, performed as per section 2, we have concluded that:

- 4.1. The request for information by the prospective patient at the mini-consultation, regarding her actual chance of achieving a live birth if she froze eggs in the near future then used them in treatment 10 years later, was not satisfied with accurate information (SLC T58). This is because a statistic was used to inform the patient – a 65% clinical pregnancy rate per cycle started for treatments in 2014 using thawed donor eggs – which was an approximation as it did not precisely fit the prospective patient's clinical situation (freezing eggs for her own use) or the question asked, for reasons discussed in Section 3.1.
- 4.2. Information provided to the prospective patient regarding egg storage periods may have given an impression that storage beyond 10 years was possible in all cases, as there was no discussion regarding the conditions which need to be satisfied to allow egg storage beyond 10 years (CoP Guidance 17.13b). This is important information which should be provided at the earliest opportunity to those considering egg storage. It also does not require lengthy discussion.
- 4.3. The inspectors recognise that the 15 minute mini-consultation is useful for many patients but also that time pressures limit explanation and clarification when misunderstandings occur. Because of this clear and accurate information should have been available so that the prospective patient could be provided with the live birth rate per cycle started for a recent set of treatment cycles where egg freezers have subsequently been treated with their own thawed eggs. A brief discussion of the requirements for extension of the 10 year statutory storage period for eggs should also have occurred.
- 4.4. The centre states that it has 'the highest number of live births using frozen eggs in the UK' on its website and in advertising media, e.g. a poster. This was true when the HFEA response to 'Freedom of Information' request F-2013-03311: Questions regarding egg freezing and egg thawing in UK clinics, was published in January 2014. There is no more recent data to support it.
- 4.5. Written patient information regarding egg thaw treatments is potentially non-compliant with CoP Guidance 17.3b and c, because it does not include the live birth rate per cycle for a recent treatment data set, or information regarding the conditions which need to be satisfied to allow egg storage beyond the 10 year initial statutory storage period. It is possible that this information is provided to egg freezing patients verbally or in another document, but it should be included in the information sheet specific to egg freezing.
- 4.6. The information regarding egg thaw treatments and their success rates provided on the centre's website is non-compliant with CoP Guidance 4.5b,c,d for reasons discussed in Section 3.4.

- 4.7.** The inspectors conclude that the use of 15 minute mini-consultations exerts time pressures which can compromise effective information provision to patients. The inspectors were therefore reassured by the PR's communication that their use was to be reviewed.
- 4.8.** While noting the failings in information provision during the mini-consultation which led to the Daily Mail allegations, the inspectors consider that their impact was likely to be minimal. Once prospective patients agree to treatment at the centre, 'proper' information is provided to them verbally and in writing, prior to them giving any consent for treatment. They are also provided with opportunities for counselling and to ask questions about their treatment. The inspectors are mindful that written information about egg freezing is currently potentially non-compliant but also that information is provided verbally or in other documents. The PR should ensure that information about success rates for egg freezers and the requirements for the extension of the statutory storage period is provided to prospective patients verbally or in other written information until the egg freezing information sheet is reviewed.
- 4.9.** The inspectors also note the good practices shown by CRGH. They have engaged effectively with this investigation and provided information promptly at the request of the centre's inspector. They are committed to treating patients fairly and in a manner compliant with HFEA requirements.

5. Recommendations

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
<p>Information provided during the mini-consultation Verbal information provided to a prospective patient regarding her chance of a live birth if she froze her eggs now then used them in her treatment in 10 years, was potentially inaccurate. The verbal information provided about egg storage did not mention the conditions under which an extension of the 10 year statutory storage period can be provided, so indirectly inferred that the storage of all eggs could be extended beyond 10 years (SLC T58; CoP Guidance 17.13b,c).</p>	<p>The PR should ensure that verbal information provided to egg freezing patients includes appropriate success rate data, ideally live birth rates per thaw cycle started for egg freezing patients, for a recent treatment cohort.</p> <p>The PR should also ensure that any discussion about egg storage includes the statutory 10 year storage period and the conditions necessary for any extension of storage beyond 10 years</p> <p>This recommendation should be implemented by 30 September 2017 and the centre's inspector informed of the actions taken.</p>	<p>The PR will ensure that this information is provided during mini consultations.</p>	<p>The inspectors are satisfied with the PR's response. The centre's inspector will follow up regarding the actions taken with the PR.</p>

<p>Written information Written information provided to patients regarding egg thaw treatments is potentially non-compliant with CoP Guidance 17.3b and c, because it does not include the live birth rate per cycle for a recent treatment data set, or information regarding the conditions which need to be satisfied to allow egg storage beyond the 10 year initial statutory storage period.</p>	<p>The PR should ensure that written information provided to egg freezing patients includes appropriate success rate data, ideally live birth rates per thaw cycle started for egg freezing patients, for a recent treatment cohort. The information should also discuss the conditions necessary for any extension of storage beyond 10 years.</p> <p>This recommendation should be implemented by 30 September 2017 and the centre's inspector informed of the actions taken.</p>	<p>The PR will ensure that in addition to the information currently available, recent CRGH live birth data per thaw cycle started (for donor and own eggs) will also be made available in the patient information sheet and all relevant literature.</p> <p>Information regarding the conditions which need to be satisfied to extend the storage period which are detailed in our consent form, will also be included in the patient information sheet and all relevant literature.</p>	<p>The inspectors are satisfied with the PR's response and will request the updated written patient information when it is completed so it can be reviewed for compliance.</p>
<p>Information on the website and in advertising material Information on the CRGH website regarding egg thaw treatments and their success rates is non-compliant with CoP Guidance 4.5b,c,d. The website and advertising materials also uses a HFEA publication containing treatment data which is more than five years old, to justify the statement that CRGH has 'the highest number of live births using frozen eggs in the UK'.</p>	<p>The PR should ensure that information on the CRGH website and in advertising materials is accurate and justified by treatment data which is less than three years old.</p> <p>This recommendation should be implemented by 30 September 2017 and the centre's inspector informed of the actions taken.</p>	<p>The PR will ensure that any data regarding egg thaw treatment on the website complies with CoP Guidance 4.5. The current egg thaw treatment data is within the three year period.</p> <p>The HFEA 2014 FOI request is no longer referred to on the website and will no longer be referred to in any leaflets.</p>	<p>The inspectors are satisfied with the PR's response and will request the PR to advise when the website is updated so it can be reviewed for compliance.</p>

This data is more than three years old and should not be used to support this statement on the centre's website or in advertising material (CoP Guidance 4.5a).			
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Annex 1: The Daily Mail allegations (black script) and the centre's response to them (red script), provided to the HFEA 26 April 2017

1. Egg freezing is sold to women in their 30s and 40s as a means to delay having a baby.

Official statistics from the HFEA show just 13 per cent of cycles lead to a live baby and only one in every 57 eggs defrosted results in a live baby.

However, the Centre for Reproductive and Genetic Health is presenting statistics in a very misleading way to encourage women to pay for expensive treatment.

This is risking women freezing their eggs under false pretences and failing to fall pregnant when they are older.

An undercover reporter from the Mail had an appointment with Dr Vidya Atluri on [Friday December 2, 2016](#).

Dr Atluri told her the clinic has a 65 per cent success rate with egg freezing. Asked what this figure represented, Dr Atluri said: 'From the frozen eggs, you thaw them out and then when you get a partner you fertilise and then put it back in.'

The reporter said: 'So if I had my eggs frozen, the chances of me having a baby from them is...'

Dr Atluri answered: '65 per cent. It is good.'

The reporter said: 'If I came back to you when I was 40 and I wanted to have a baby from my frozen eggs, it's even then about a 65 per cent success rate?'

Dr Atluri agreed, adding: 'Because the eggs are frozen when you're 30.'

On what basis does the Centre for Reproductive and Genetic Health tell patients its live birth rate from thawing frozen eggs is 65 per cent?

Our pregnancy rate based on 2014 data is 64.3% for patients using frozen donor eggs. Donors are 35 and under so this would be representative of a 30 year old woman seeking treatment with her own frozen eggs. We have in the last few weeks submitted a scientific paper to the medical journal *Reproductive Biomedicine Online* (under peer review), reporting CRGH's experience with regards to all the amalgamated data regarding clinical outcomes using donor frozen eggs so far at CRGH. We are enclosing a copy for your perusal. Statistics for clinical pregnancies per patient (per embryo transfer) and live birth rate per patient are included in the attached, see table 2: "Clinical outcomes of the donor oocyte and the control groups".

How big is the sample of patients that this is based on?

The paper refers to the outcomes of treatment using 1,127 frozen eggs (110 cycles). The 2014 data had 28 patients in that cohort.

We are also in the process of starting the first pediatric assessment of babies born in the UK from frozen eggs, in collaboration with Professor Alastair Sutcliffe at the Portland Hospital.

What are your comments?

Egg freezing is offered as an option to give a patient a chance of preserving her fertility if that patient deems it is not possible for her to have a child at that particular time. We cannot guarantee a child will result but it can offer a chance. We are not promoting delaying motherhood. Please refer to our website where we state: "Although egg freezing may assist you in having a baby in the future, it is not a guarantee and parenthood should not be delayed if possible in reliance on this." All of the above would have been discussed in detail should the

reporter have chosen to attend a full consultation rather than a 15 minute informal mini-consultation where time is restricted.

The HFEA present statistics from all clinics across the UK and the data you quote appears to be from 2013. Every IVF clinic is different, and has their own success rates based on their expertise. We present in house statistics which represent success rates for patients who have attended our clinic.

Success of IVF treatment is largely dependent on the age the woman is/was when her eggs are collected. Frozen eggs remain the same biological age that they were frozen at. For example, a woman who freezes her eggs at 30 and uses them for treatment at 40 is using the eggs of a 30-year-old. This means that she has a higher chance of pregnancy, and a lower chance of miscarriage and genetic abnormalities than if she were to use her 'fresh' 40-year-old eggs.

2.

The reporter said she was 30, married and wanting to wait ten years before having children. Dr Atluri said it would be a 'very good idea' for her to freeze her eggs.

She made no attempt to discuss other options, such as the fact that the reporter is much more likely to get pregnant if she simply tries naturally in the next few years.

Delaying having children for ten years at the age of 30 is clearly inadvisable for someone who definitely wants children.

When the reporter said: 'The thing is I don't think I want children for another, maybe, ten years,' Dr Atluri replied: 'Then it's a good idea to freeze the eggs. It is a very good idea to freeze the eggs.'

What are your comments?

15 minute mini-consultations are designed to give a snapshot of the services we provide and any potential treatment that the patient may be enquiring about. Doctors do their best to be as informative as possible given the time constraints. A full discussion regarding treatment takes place during the 1 hour consultation where all the patient's options are discussed. It is unjustified to make a judgement based on a 15 minute conversation.

3.

Legally, women can only freeze their eggs for ten years. But Dr Atluri indicated that the reporter could freeze eggs at 30 for 20 years. She said she could freeze them until she is 40 and then 'you can extend it again another ten years'.

What are your comments?

HFEA regulations state that it is possible to extend storage of eggs beyond 10 years, by further 10 year periods up to a maximum of 55 years if a patient or their partner is prematurely infertile or likely to become prematurely infertile and a medical practitioner certifies this.

