Licence Committee - minutes

Centre 0316 Centre for Reproduction and Gynaecology Wales (CRGW)

HFEA Level 2, 10 Spring Gardens, London SW1A 2BU
12 July 2018 at 10.00 am

Committee members	Andy Greenfield (Chair) Ruth Wilde Kate Brian	
Members of the Executive	Richard Chamberlain	Temporary Committee Clerk
Legal Adviser	Graham Miles	Blake Morgan LLP
Specialist Adviser		
Observers	Catherine Burwood	Senior Governance Manager

Declarations of interest:

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

The committee had before it:

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

The following papers were considered by the committee:

- Report of an investigation into a serious incident
- Report of a targeted interim inspection
- Licensing minutes from the last three years including:
  14 July 2016 – Executive update,
  5 May 2016 – Executive update, consent to legal parenthood audit,
  and 17 March 2016 – Renewal inspection report

1. Consideration of Report of an investigation into a serious incident and a Targeted Interim Inspection Report

1.1. The Centre for Reproduction and Gynaecology Wales had a serious incident in December 2017 when a surrogate infant died soon after birth and the surrogate mother remained in hospital for further treatment due to serious post-birth complications.

1.2. The committee was concerned that the centre had approved a surrogate mother of 43, with a BMI of 33 (in the obese range) and a history of previous complex pregnancies, without due diligence having been undertaken by the centre, including checking with the surrogate's GP.

1.3. The committee noted, following an inspection undertaken on 5 and 6 March 2018, that the Executive was minded to recommend revocation of the centre's licence. The Executive had significant concerns about the safety of patients, gametes and embryos due to the nature and extent of non-compliances. The Executive was of the view, at that time, that the PR had failed in his duty under section 17 of the Act.

1.4. However, following consideration of submissions from the PR and his legal advisers, undertaking to make the improvements recommended by the inspectors, the Executive decided not to recommend revocation to the Licence Committee.

1.5. The committee noted from the Executive's recommendation the considerable efforts the PR had made to address non-compliances in both reports and that he had provided evidence of the remedial steps he had taken, many of them concerning staff training.

1.6. The committee noted and welcomed the Executive's intention of intensive monitoring in the next months up to December 2018. This could include site visits, providing workshop-based support and teleconference updates.

1.7. The committee expressed concern about the PR's ability to communicate actions to the centre's staff given that the centre had been in a cycle of repeated non-compliance. It was agreed that the lack of a functioning QMS had been most concerning and the lack of communication between the PR and the lead consultant was noted from the major incident report.

1.8. The committee noted that the centre's current licence will expire in July 2019. Assuming an application for renewal of the licence is made, a licence renewal inspection will need to take place in early 2019. Such an inspection, following a period of intensive monitoring, will enable the Executive to make an appropriate informed recommendation at that time as to whether the licence should be renewed.

2. Decision

2.1. The committee decided to accept the Executive's recommendation that the licence should continue with no additional conditions at this stage on the basis that the Executive will conduct the closest possible monitoring of the centre's performance over the next six months. The committee considered that this will provide an opportunity to assess whether corrective actions can be embedded in practice and whether recent improvements in quality can be sustained.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Andy Greenfield

Date

12 July 2018

Report of an investigation into a serious incident

Centre for Reproduction and Gynaecology Wales - 0316

Date of investigation visit: **21 December 2017**

Investigation team: **Polly Todd, Clinic Inspector**

Sharon Fensome-Rimmer, Chief Inspector.

Present		
HFEA	Polly Todd Sharon Fensome-Rimmer	Clinic Inspector Chief Inspector
CRGW	Dr Lyndon Miles Amanda O'Leary	Person Responsible (PR) Lead Consultant

1. Background

1.1 On 18 October 2017, the Human Fertilisation and Embryology Authority (HFEA) received a letter from West Hampshire Clinical Commissioning Group (CCG) regarding a serious incident investigation (SII) carried out by Hampshire Hospitals NHS Trust that had taken place following the death of a baby and serious complications for the surrogate mother. The letter (Annex 1) expressed concerns about the assessment by a fertility clinic of the surrogate woman's suitability to undergo assisted conception, and the lack of information provided by the clinic relating to the surrogate woman's ongoing obstetric care. The concerns identified by the CCG were:

i. That surrogate mothers self-select and provide only a self-assessment of their current and previous medical and psychological history.

ii. There appears to be no requirement to involve the General Practitioner (GP) in verifying that the information provided is accurate or complete.

iii. That the choice of the surrogate woman fell significantly short of expected practice resulting in the child being' put in harm's way'.

iv. Whether the basic standards for selection of the surrogate woman were met by the clinic.

v. That none of the critical information regarding the surrogate woman's medical and psychological history was shared with the obstetric unit managing her care.

vi. That her care (at the earliest stage) was compromised without access to this history, and the subsequent potential for inequity of care of surrogate mothers compared to natural mothers.

1.2 Further to the letter from the CCG, we sought information relating to the identity of the treating clinic and were provided with this on 8 November 2017. We wrote to the CRGW clinic on 17 November 2017 seeking confirmation that it was aware of the incident and additional observations. The clinic responded on 21 November 2017 (Annex 2). An HFEA management review meeting was held on 22 November 2017 which agreed that further information be sought from the Person Responsible (PR); a copy of the report of the SII be obtained from the CCG and that following receipt of the report a visit would be undertaken to the clinic to investigate. The report of the SII was received on 30 November 2017 (Annex 3).

1.3 In reviewing the Hampshire Hospital's SII we noted that it identified that the HFEA relies on the surrogate woman's self-assessment for suitability as a surrogate as a 'root cause' of this incident. It identified two other root causes: the need to undertake a difficult induction in a preterm baby; and care being led by the patient's wishes with a lack of multi-disciplinary decision-making. Our requirements of clinics undertaking an assessment of suitability for surrogacy are set out in Section 6 of this report.

1.4 A scheduled site visit to the clinic was undertaken on 21 December 2017 by the HFEA Inspector for the clinic and HFEA Chief Inspector. Areas for review were prepared in advance which formed the basis of questions put to the PR and relevant staff at the time of the visit. The findings of this visit raised further concerns and suggested that many issues raised by the CCG were valid.

1.5 A second management review meeting was held on 22 December 2017. It was agreed that the PR be informed that a further management review meeting would be held on 11 January 2018, to allow for sufficient time to review the relevant evidence and to reflect on the findings of the investigation. It was also agreed the PR be invited to offer any further information he wished to be considered at that meeting, which he did (Annex 2a).

1.6 This report documents our findings and has been prepared following the management review meeting conducted over several days.

2. The Report

Section 3 of the report sets out the aim of the investigation.

Section 4 sets out the documentation reviewed or referenced during the investigation.

Section 5 provides the background to the incident.

Section 6 sets out the relevant HFEA requirements placed on clinics.

Section 7 describes our findings.

Section 8 is our assessment of those findings as to the extent the clinic has met HFEA requirements.

Section 9 is our review of professional body requirements, together with our observations of practise in relation to those requirements.

Section 10 is our conclusions.

3. Aim of the investigation:

3.1 To explore the concerns set out by West Hampshire CCG. In doing so we also:

3.1.1 Sought to understand the background and review events.

3.1.2 Undertook a review of the clinic's policies, procedures and practices relating to treatments involving surrogacy to assess compliance with HFEA regulatory requirements relating to surrogacy and associated aspects of provision – in particular:

i. The clinic's policies and procedures directing their activities relating to surrogacy.
ii. The clinic's assessment of the surrogate woman and commissioning couple's (intended parents) history.
iii. The records held by the clinic relating to the intended parents and surrogate woman.
iv. Whether the intended parents and surrogate woman received a proper offer of counselling.
v. The 'Welfare of the Child' assessment of the surrogate woman, her partner and the intended parents.
vi. The information given to the intended parents and the surrogate woman.
vii. The clinic's handling of incidents and the arrangements for clinical governance.

3.2 Considered professional body requirements relating to aspects of care provision, and if necessary make observations in relation to those requirements.

4. Documentation reviewed or referred to during the investigation:

4.1 Letter from West Hampshire CCG (Annex 1).

4.2 Email exchange with PR 22 December 2017 and January 2018 (Annex 2 and 2a)

4.3 Serious incident investigation report of Hampshire Hospital NHS Foundation Trust (Annex 3)

4.4 Medical records documentation (patient history sheet) for intended parents and surrogate woman obtained from CRGW. (Annex 4)

4.5 Human Fertilisation & Embryology Act 1990 (as amended).

4.6 HFEA Code of Practice (CoP) 8th Edition, revised May 2017.

4.7 HFEA Standard Licence Conditions (SLC)

4.8 CRGW's surrogacy and 'Welfare of the Child' processes (Annex 2b and 2c).

4.9 The surrogate woman's 'Welfare of the Child' assessment and 'Consent to Disclosure' forms.

4.10 General Medical Council (GMC) 'Good Medical Practice 2013'

4.11 GMC and Nursing and Midwifery Council (NMC) 'Openness and honesty when things go wrong: the professional duty of candour' guidance. 2015

5. Background to the incident

5.1 The consultation record (Annex 4) shows that the surrogate woman and the intended parents had a consultation on '17/10'. Our assumption is this consultation took place on 17 October 2015 (as the baby was born in December 2016). We conclude the surrogate woman entered into an agreement with a commissioning couple (the 'intended parents') to carry a pregnancy then. For the intended parents to apply for a parental order to become the legal parents of any child born from a surrogacy arrangement, the embryo must be created using gametes from one or both commissioning parents. The consultation record (Annex 4) states that donor eggs were used, therefore, the intended father's gametes must have been used, otherwise neither of the intended parents would be able to apply for a parental order. The couple are believed to be friends with the surrogate woman, and had treatment to facilitate the arrangement at the Clinic for Reproduction and Gynaecology Wales (CRGW). The surrogate woman had four previous pregnancies between 1991 and 2008 and all resultant babies were born by normal delivery. She was 42 years old (according to the clinic's documentation) and when she booked at Hampshire Hospital (Basingstoke site) for her obstetric care on 1 July 2016, was found to have a body mass index (BMI) of 33 (weight 81.7kgs; height 159cms,) in the 'obese' range in line with BMI calculations.

5.2 The surrogate woman requested that her obstetric care be provided in a different area to that in which she lived, the reason for this is not known. She had previous complex

pregnancies due to the presence of three atypical red cell antibodies which required surveillance within foetal medicine units and early delivery of her children born in 1997 and 2008. The surrogate woman also had a severe obsessive-compulsive disorder (OCD) which impacted on her daily life and related to anxiety and concerns around infection and cleanliness.

5.3 Her obstetric care for this pregnancy was provided by the foetal medicine consultant. Her OCD symptoms worsened during pregnancy, and, due to a rise in the level of her red cell antibodies, labour was induced at 36 weeks gestation. Her mental health (OCD) significantly impacted on the care she received in labour. After a failed induction of labour, the baby was born by caesarean section on 9 December 2016 in very poor condition and sadly died in the arms of the intended parents 40 hours later.

5.4 The surrogate woman required a blood transfusion following delivery and suffered complications resulting in her re-admission to hospital and an emergency laparotomy to drain a pelvic abscess.

5.5 The lead consultant told us during our discussions with her on 21 December 2017 that the surrogate woman had previously attended CRGW with another commissioning couple that lived in the local area. That treatment did not take place, so when she (the surrogate woman) was approached by these intended parents, she recommended CRGW to them, as the couple were apparently not happy with the care received by another licenced clinic. The PR also told us that he had no knowledge of the serious incident that had taken place, leading to the baby's death, until he had been contacted by the HFEA Chief Inspector to provide information to the HFEA, when we became aware of the CCG's concerns on 17 November 2017.

6. Requirements placed on clinics

6.1 The Human Fertilisation and Embryology Act 1990 (as amended) referred to hereafter as 'the Act' and the HFEA Code of Practice (CoP) set out several requirements relating to the screening of intended parents providing gametes in surrogacy arrangements. The CoP Guidance (Note 14) on Surrogacy requirements sets out our expectations of clinics including:

- Intended parents (who are providing gametes) in a surrogacy arrangement must be screened in line with requirements for gamete donors.
- Assessing those involved in surrogacy arrangements before providing treatment, in line with the welfare of the child assessment process (CoP guidance note 8).
- Ensuring those involved in surrogacy arrangements receive information about the effect of the parenthood provisions and Parental Orders (CoP guidance note 14.3).
- Ensuring that those involved in a surrogacy arrangement understand that the arrangement is unenforceable (CoP guidance note 14.4).

- Giving all those involved in a surrogacy arrangement a suitable opportunity to receive proper counselling about the implications of the steps they are considering (CoP guidance notes 3 and 14.7).
- That the clinic must satisfy itself that all those involved in a surrogacy arrangement receive enough information and understand the legal implications of these arrangements well enough to give informed consent (CoP 14.5). Allowing time for those involved to reflect on their decisions before obtaining their consent. Clinics should give those involved an opportunity to ask questions and receive further information, advice and guidance (CoP 14.8).

Our requirements in relation to the welfare of the child assessment process and counselling are key components of requirements in relation to surrogacy.

6.2 Welfare of the child

6.2.1 Section 13 of the Act sets out several conditions which attach to all treatment licences issued by the HFEA, including this clinic's licence. The condition relating to welfare of the child considerations is at Section 13 (5) of the Act and in HFEA licence condition T56.

T56: 'A woman must not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.'

6.2.2 Paragraph 1.3 of this report refers to the (Hampshire Hospitals NHS Trust) serious incident investigation report reference to the HFEA relying on a surrogate's self-assessment for suitability as a surrogate. A surrogate woman's *self-assessment* of her own suitability as a surrogate is not a requirement, nor sufficient, to meet the obligations of a clinic in undertaking an assessment of the welfare of the child. The CoP guidance (guidance note 8) sets out our expectations of licensed clinics in meeting this mandatory requirement, including:

- The need for documented procedures to ensure that proper account is taken of the welfare of any child who may be born as a result of treatment, and any other child who may be affected by the birth (guidance note 8.2)
- In a surrogacy arrangement, clinics should assess both those commissioning the surrogacy arrangement and the surrogate (and the surrogate's partner, if she has one) in case there is a breakdown in the surrogacy arrangement (guidance note 8.4).
- Taking a medical and social history from each patient and their partner (if they have one). Where appropriate, the patient and their partner may be interviewed separately (guidance note 8.9).
- Considering many factors likely to cause a risk of significant harm or neglect to any child who may be born or to any existing child of the family (guidance note 8.3 and 8.10)

- Obtaining consent to approach any individuals, agencies or authorities for any information required for further investigation of several possible circumstances. Where consent is refused this should be taken into account when deciding whether to provide treatment (guidance note 8.13).
- Refusing treatment if the clinic concludes that any child who may be born or any existing child of the family is likely to be at risk of significant harm or neglect, or the clinic cannot obtain enough information to conclude that there is no significant risk. In doing so, taking account of the views of staff involved (guidance note 8.15 and 8.16).
- And in all cases, recording in the patient's medical records the information it has considered during the assessment. If further information has been sought or discussion has taken place, the record should reflect the views of those consulted in reaching the decision and the views of the patient (and their partner if they have one) (guidance note 8.18).

6.3 Counselling

6.3.1 Section 13(6) and (6A) of the Act make it a mandatory requirement of all licensed clinics that an offer of counselling must be made before treatment, and consent to treatment, commences. The CoP guidance (guidance note 3) sets out our expectations of licensed clinics in meeting this mandatory requirement, including:

- Offering counselling after information about the services to be provided has been given to the patients and before patients consent to treatment, or to the storage or use of gametes or embryos (guidance note 3.1).
- Making patients aware that the offer of counselling is routine and should include written information about the service and when it can be taken up (guidance note 3.2).
- In cases involving treatment with donated gametes, the centre should offer counselling about the implications of treatment with donated material separately from counselling about the implications of treatment in general, and before treatment commences (guidance note 3.3).
- Distinguishing the provision of counselling from assessing a person's suitability to receive treatment, the consent process and the normal relationship between clinical staff and patients or donors (guidance note 3.7).
- Keeping a record that it has offered patients counselling, even if they choose not to accept this offer (guidance note 3.13).

6.4

In addition to these requirements, the Act and CoP sets out several other requirements that apply to clinics carrying out licensed activities generally and were applicable in this matter. These include, but are not limited to:

1. Information to be provided prior to the patient consenting to treatment (guidance note 4)
2. Confidentiality and privacy (guidance note 30)
3. The reporting of adverse events and incidents (guidance note 27)

4. Record keeping (guidance note 31)
5. Maintaining policies and procedures as part of a management system to ensure quality (guidance note 23)
6. The suitability of practices (standard licence condition T2)

7. Our findings

7.1 The clinic's policies and procedures in place directing their activities relating to surrogacy

7.1.1 We place a requirement on clinics to have standard operating procedures (SOPs) for all activities authorised by this licence and other activities carried out when providing treatment services (standard licence condition T33(b)). At the investigation visit we asked for a copy of the clinic's SOP or such like relating to its surrogacy treatment service. The clinic could not provide an SOP or equivalent that detailed its criteria for treatment, including consideration of the patient's age, BMI or medical history. The PR told us that the clinic would not treat someone with a BMI over 40, but was unsure if there was an SOP to support this.

7.1.2 The PR told us the decision to treat was taken by the lead consultant based on the consultation with the surrogate woman and intended parents. The clinic did not provide evidence of a written protocol or procedure which would inform the lead consultant's actions or decisions here, for example a document or SOP outlining the range of factors that the treating clinician should have regard to when deciding whether to offer treatment, or any document setting out the requirement to contact the patient's GP for example.

7.1.3 In the absence of any such protocol or procedure, the lead consultant told us she had not referred to any professional body guidance in consideration of the suitability of the surrogate woman to undergo assisted reproductive treatment.

7.1.4 The clinic provided a copy of an audit of its surrogacy practice. (Clinical audit is a process that seeks to improve patient care and outcomes through systematic reviews against specified criteria). One of the objectives of the clinic's surrogacy audit related to checking the completion of medical records within treatment files of patients. The findings of the audit indicated that the objective of checking the completion of medical records had not in fact been reviewed or included in the audit.

7.2 The clinic's assessment of the surrogate woman and commissioning couple's history

7.2.1 We saw no evidence to indicate that the surrogate woman had given consent for her information, including the sort of sensitive personal data that one would expect the clinic to discuss with the surrogate in such a consultation, to be shared with the intended parents.

7.2.2 The lead consultant reported that she undertook a joint consultation, that is with the intended parents and the surrogate woman present at the same time, to gather medical

history information. The record of the consultation is at Annex 4. The clinic was unable to provide a rationale for the consultation being undertaken jointly, other than stating that is 'what they did.' We saw no documented evidence to show this practice had been discussed with the surrogate woman, or that she had been given an opportunity to have a separate, individual consultation for this information to be gathered.

7.2.3 The clinic treated the parties involved in this surrogacy arrangement, as a group, rather than individuals, and we did not see evidence that documented why the privacy of each of the parties involved was not maintained.

7.2.4 We did not see evidence of a record for each individual in the arrangement, instead the clinic chose to document confidential information on a single 'patient history sheet' (Annex 4).

7.2.5 The lead consultant confirmed that her usual practice is to seek further information from GPs about the intended parents and the surrogate, and, on confirmation of a viable pregnancy, she would inform the GP via a letter given to the patient. The lead consultant reported that she had contacted the intended parents' GP for further information but had not done so for the surrogate woman. Moreover, she was unable to provide evidence to confirm that on confirmation of a viable pregnancy she had communicated with the surrogate woman's GP in line with her 'usual practice'. She told us that the clinic does not keep a copy of the letter provided to the patient. The lead consultant could not provide a rationale for these acts and omissions of her practice.

7.2.6 In relation to the surrogate woman's age at treatment (42), the HFEA does not place restrictions on the age of patients or surrogates seeking treatment, but does for people wishing to donate their gametes (guidance note 11.2). However, we do expect that the age of the patient is considered when making a holistic assessment of an individual's suitability for treatment. We did not see any evidence of any assessment made by the lead consultant as to whether the patient's age was considered in deciding whether to proceed with treatment.

7.3 Review of the treatment records of the intended parents and surrogate woman

7.3.1 Good record keeping is an integral part of healthcare provision and essential to the provision of safe and effective care and a mandatory requirement for all licensed fertility clinics including this one. The records available for the investigation team to review are the patient record sheet at Annex 4. The clinic reported to us that it maintains a combination of electronic records (which contain information relating to the demographics of patients) and paper records, in that they take paper notes then scan these onto an electronic record. In preparing for the investigation visit the clinic printed off all the records it held relating to the intended parents and the surrogate woman.

7.3.2 The patient record sheet of the consultation with the intended parents and surrogate woman has been recorded on a single sheet of paper (Annex 4). The clinic could not

provide a completed record for each party involved in the surrogacy arrangement. The patient history sheet has some evidence of discussion as to the surrogate woman's history: however, this is limited, illegible in places and incomplete in parts on the scanned copy.

7.3.3 Given the fact that a woman's medical or surgical history, and particularly, her obstetric history, may be relevant to decisions relating to any future fertility treatment especially where the woman would be carrying a child for another couple, the absence of any records in the surrogate woman's notes, reflecting a full exploration of her obstetric history is noteworthy.

7.3.4 We also expected to see evidence of exploration as to the circumstances of the surrogate woman having an IVF pregnancy for her fourth child and the relevance of this in relation to future conception and pregnancy. Furthermore, we would expect to see a record of a wider consideration of risk factors, for example relating to the surrogate woman's age; parity; BMI; mental health issues and a rationale for accepting her for treatment. In the light of these factors we would expect to see a discussion recorded of risks and benefits (if any) of treatment. It is reasonable to expect a record of this discussion, or reason why this had not been carried out, to form part of further liaison with the surrogate woman's GP – with evidence of such liaison being recorded. We saw no evidence of these considerations.

7.3.5 The lead consultant could not explain to the investigation team why an assessment of these issues did not take place, and was unable to provide any further documentation to evidence that a thorough assessment of the surrogate's suitability had been undertaken. Moreover, the practitioner conceded her failure to consider and document any risk factors relating to the treatment of the surrogate.

7.4 Ensuring the offer of proper counselling

7.4.1 Treatment should not take place unless the woman and the intended second parent have had the opportunity to receive proper counselling (see paragraph 3(1)(a) and (b) of Schedule 3 of the HFE Act 1990). In the records of the intended parents and the surrogate woman we would expect to see evidence that discussions had taken place regarding the implications of the proposed treatment; that an offer of counselling had been made; and a record of the patient's decision relating to that offer of counselling. We did not see any evidence of this in the medical record and there was no indication that the surrogate woman's partner had received an offer of proper counselling.

7.4.2 The clinic's 'Surrogacy' protocol (Annex 2b and 2c) indicates that parties will be offered counselling and that once *'all involved have seen the counsellor then all individuals must attend to complete the consents'*. In not insisting that the intended parents and surrogate woman see the counsellor, the lead consultant failed to follow the clinic's own protocol.

7.4.3 We saw an 'in house' consent form, signed by the surrogate woman, which listed that counselling had been offered. It does not record when the offer of counselling had been made or that any discussion about counselling with the surrogate woman took place.

7.5 Review of the 'Welfare of the child' assessment

7.5.1 No treatment services regulated by the HFEA may be provided unless account has been taken of the welfare of any child who may be born as a result (including the need of that child for supportive parenting) and of any other child who may be affected by the birth (Section 13(5) of the Act). This assessment should include taking the medical and social history from each patient and their partner (if applicable) and in the case of surrogacy arrangements, where the child is not to be raised by the carrying mother, the surrogate's partner (if she has one) should also be assessed.

7.5.2 We saw a 'Welfare of the Child' (self) assessment form completed by the surrogate woman in which she declared she had no mental or physical conditions, or other conditions that may pose a risk to the child. It is important to note here, given the conclusions of the Serious Incident Investigation, that a surrogate woman's *self-assessment* for suitability as a surrogate is not a requirement, nor sufficient, to meet the obligations of a clinic in undertaking an assessment of the welfare of the child.

7.5.3 The clinic did not contact the surrogate woman's GP for further information, but told us that they would usually do so. At the time of the investigation visit, they could give no reason for not doing so. As such the clinic placed reliance on the information provided by the surrogate woman about herself and missed the opportunity to obtain information from the surrogate's GP which may have informed decisions as to the surrogate's future treatment and suitability.

7.5.4 We saw no record or evidence of what, if any, information had been considered during the assessment of the surrogate woman.

7.5.5 The clinic confirmed to us it did not complete a 'welfare of the child' assessment in relation to the surrogate woman's partner and, following the investigation visit, confirmed to us that at the time of the incident, it *'wasn't routine practice to seek WOC on the surrogate's partner'* (Annex 2a).

7.5.6 Also following the investigation visit, we asked the PR to provide a copy of the clinic's 'Welfare of the Child' protocol. The PR submitted the clinic's 'Surrogacy' protocol (Annex 2b and 2c), which gives a brief description of HFEA requirements relating to 'welfare of the child' assessment*, 'that the commissioning couple and the surrogate mother (and her partner if she has one) should complete the welfare of the child form.'* The protocol does not reference the completion of a 'welfare of the child' assessment. and does not direct practice to comply with this requirement.

7.5.7 We did not see evidence of a 'welfare of the child' assessment undertaken by the clinic or any evidence to suggest that the clinic took steps to test the veracity of the information that the surrogate woman provided in the 'welfare of the child' assessment she completed herself.

7.6 Review of information provided to the intended parents and surrogate woman

7.6.1 Our requirements and GMC professional body guidance place a responsibility on clinics and clinicians to provide relevant information to patients which will enable them to make informed decisions about their care.

7.6.2 We saw an in-house 'surrogacy agreement' which outlined the terms and conditions of the surrogacy arrangement between the surrogate woman and the intended parents. This appeared to be a comprehensive document of a contractual nature. The clinic was unable to tell, or demonstrate to, the investigation team what information had been provided to the intended parents, the surrogate woman or her partner, other than that outlined in the surrogacy agreement.

7.7 Review of the clinic's handling of incidents and arrangements for clinical governance

7.7.1 Clinics must report all adverse incidents and near misses to the HFEA within 24 hours of their identification. This includes information about any 'suspected serious adverse events' that, (not exclusively) 'lead to death or life-threatening conditions' or 'might result in, or prolong hospitalisation or illness.'

7.7.2 The Hampshire Hospital NHS trust's serious incident investigation report, at the action plan, states that the clinic and the HFEA were contacted in February 2017 and April 2017 respectively. Following our visit to the clinic on 21 December 2017 we confirmed that the hospital's clinical director had contacted the clinic's lead consultant in February 2017 and had discussions with her then about the incident.

7.7.3 The lead consultant told us that she knew of this incident prior to our contacting the clinic in November 2017, and had discussed it with her 'clinical colleagues.' She also told us she had not informed the PR or taken steps to inform the HFEA. She did not provide her reasoning for not speaking to the PR, but told us she was aware of the PR's responsibilities, liabilities and duties under the terms of the Act.

7.7.4 The PR told us that he was not aware of the incident until we contacted him. He also told us that had he been made aware of this incident at the time the lead consultant became aware of it, he would not have reported it to the HFEA. He explained he would not normally report to us other instances where, for example, a baby had been born prematurely or subsequently died.

8. Our assessment of the findings as to the extent the clinic has met HFEA requirements

From the findings of our investigation set out in Section 7 further to our meeting with the lead consultant and the Person Responsible at the investigation visit, a review of

documentation provided at, and since, the investigation visit the investigation team make the following assessment in relation to HFEA requirements:

8.1 The clinic's policies and procedures in place directing their activities relating to surrogacy

8.1.1 Schedule 3ZA of the Act sets out the circumstances in which an offer of counselling is required as a condition of a licence for treatment. Licence Conditions T32, T33, T35 and T36 include requirements on clinics to:

- Put in place a quality management system and implement this system to continually improve the quality and effectiveness of the service provided (T32);
- Hold documentation, for example, standard operating procedures (SOPs) for all activities authorised by the licence and in carrying out treatment services that do not require a licence (T33(b));
- Have standards in place by which quality can be assessed (T35);
- Audit their activities, at least every two years, undertaken by trained staff, and record and implement corrective actions necessary to meet the indicated standards (T36).

8.1.2 At the time of the investigation visit the clinic provided no evidence of procedures, protocols or any other guidance to inform the actions to be taken by staff treating patients in a surrogacy arrangement. The clinic subsequently provided two protocols to the investigation team on 31 January 2018 (Annex 2b and 2c). The clinic also failed to audit its own surrogacy practices properly by omitting to audit an objective (about the completeness of medical records). These are significant failings and are breaches of the requirements set out above.

8.1.3 In the absence of procedures, protocols or guidance the lead consultant did not have regard to GMC professional body requirements (see section 9), nor could she evidence any criteria she applied in any consideration by her of the suitability of the surrogate woman to undergo assisted reproductive treatment.

8.2 The clinic's assessment of the surrogate woman and intended parent's history

8.2.1 A condition of the licence (T58) is that prior to giving consent gamete providers must be provided with information about the nature of the treatment, the consequences and risks, any tests, the recording and protection of personal data and confidentiality, the right to vary or withdraw their consent, and the availability of counselling.

8.2.2 A condition of the licence (T46) is for each patient/donor the centre must maintain a record containing:

a. patient/donor identification: first name, surname, date of birth, age and sex
b. how, and by whom, the patient/donor has been reliably identified
c. the services provided to them
d. medical history
e. welfare of the child assessment

f. consent, including the purpose or purposes for which their gametes or embryos created using their gametes may be used, and any specific instructions for use and/or disposal, and
g. clinical and laboratory data and the results of any test carried out.

The clinic conducted a joint consultation with the intended parents and surrogate woman. It failed to maintain a record for each of the individuals involved in this surrogacy arrangement, and it failed to document comprehensive medical histories for each.

8.2.3 A condition of the licence (T56) is that a woman must not be provided with treatment services unless account has been taken of the welfare of any child who may be born from the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth. The clinic failed to demonstrate it had undertaken a thorough 'welfare of the child' assessment, choosing to rely solely on the information provided by the surrogate woman. Additionally, the CoP at 8.4 states if the child is not to be raised by the carrying mother (that is, in a surrogacy arrangement) the centre should assess both those commissioning the surrogacy arrangement and the surrogate (and the surrogate's partner, if she has one) in case there is a breakdown in the surrogacy arrangement). The centre, by their own admission, do not routinely conduct 'welfare of the child' assessments of the partners of surrogate women.

8.2.4 A condition of the licence (T47) is that all records must be clear and readable, retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation. The consultation sheet (Annex 4) is illegible in parts and has missing information on the scanned copy.

8.2.5 A condition of the licence (T58) is that 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

We saw no evidence to demonstrate that the intended parents had been provided with information in line with this licence condition. The clinic could not provide a comprehensive record for any of the individuals involved in this arrangement and in our view, the record is insufficient to meet the requirements of conditions of the licence T46, T56 and T58.

8.2.6 As such we must conclude the clinic failed to provide information about the nature of the proposed treatment (and risks) and that it failed to conduct a thorough assessment of the surrogate woman to determine her suitability for treatment (for example by not taking account of her age, BMI, her physical and mental health history) and, in failing to do so, an opportunity was missed to gather information that would have informed the decision as to

the surrogate woman's suitability to undergo treatment. Therefore, the clinic is in breach of the licence conditions T46, T47, T56 and T58.

8.2.7 We are of the view that the absence of a comprehensive history for the surrogate woman contributed to the events leading to the incident. Missing information relevant to a decision about the surrogate woman's suitability for treatment would have alerted practitioners to increased obstetric risks for this woman, and any pregnancy she carried. This, in turn, might have altered the lead consultant's decision to proceed with treatment.

8.2.8 The clinic did not follow what it said was its usual practice of liaising with other healthcare professionals to seek information that would inform a decision as to the suitability of the surrogate woman to undergo treatment. Therefore, a second opportunity was missed to gather information that may have informed the decision as to proceeding with the treatment.

8.2.9 Section 33A of the Act sets out confidentiality and disclosure obligations. A condition of the licence (T43) sets out that the clinic must ensure all information is kept confidential and only disclosed in circumstances permitted by law. In assessing the surrogate woman and intended parents the lead consultant undertook the consultation with all parties present. The clinic's actions did not maintain patient confidentiality. The possibility cannot be ruled out that had the surrogate had a private consultation rather than having to provide her medical history during a joint consultation with the intended parents, she may have disclosed more information. However, whilst there is no evidence to suggest that this would have been the case, she may have felt more comfortable providing detail about her medical history and personal circumstances which in turn may have informed subsequent discussions and decisions about her treatment and care, or at least possibly prompted the consultant to contact the surrogate woman's GP to seek further information about her medical history. In addition to this being evidence of a limited regard to the privacy and dignity of all the individuals in this arrangement, it is also a breach of the Act and licence condition T43, and each party's expectations of confidentiality.

8.3 Review of the treatment records of the intended parents and surrogate woman

8.3.1. It is a condition of all licences, by section 12(1)(d) of the Act read with General Directions 0012 that proper records shall be maintained in the form set out by the Authority. Our requirements detailed in guidance notes 3,4, and 31 of the CoP include obligations to:

i. Hold prescribed information relating to the people receiving licensed treatment and the services provided to them, including, but not limited to, their medical history and 'welfare of the child' assessment - licence condition T39 read with general Direction 0012 and licence condition T46.
ii. Maintain records which are legible, clear and indelible licence condition T38 and T47.

8.3.2 We did not see evidence of good record keeping. We found the clinic did not:

1. maintain clear, legible and accurate records (T47)
2. document a thorough assessment of the surrogate woman's social, medical, surgical, obstetric history (T46(d))
3. document decisions made and actions agreed with the surrogate woman and the intended parents (CoP 4.2)
4. document the 'welfare of the child' assessment (T46(e); CoP 8.18)
5. document the information provided to the surrogate woman and intended parents (CoP 4.4).
6. record who was making the record and when it was made.
7. maintain individual records for the parties involved in this surrogacy treatment (T46).
8. document the offer of counselling for the intended parents and the surrogate woman's partner (CoP 3.13).
9. maintain complete records, in that, part of the notes recorded for the surrogate woman are missing from the scanned document (T39).

8.3.3 The clinic is therefore in breach of licence conditions T38, T39 (read with General Direction 0012), T46 and T47.

8.4 Ensuring the offer of proper counselling

8.4.1 Schedule 3 of the Act at paragraph 3(1)(a) and (b), set out in licence condition T60, states that a woman must not be provided with treatment services using embryos or donated gametes unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

8.4.2 We only saw evidence on the clinic's in-house consent form, signed by the surrogate woman, that an offer of counselling (to her) had been made. The CoP at 3.13 states that clinics should keep a record that it has offered patients' counselling. We saw no evidence that any information had been provided to the surrogate woman, prior to this 'offer', and there was no record of when the offer of counselling had been made or that any discussion about counselling with the surrogate woman took place.

8.4.2 The clinic could not show that the intended parents or the surrogate woman's partner were given an opportunity to receive proper counselling or have received information in line with the requirements set out in section 13(6) and (6A) of the HFE Act 1990.

8.5 Review of the 'welfare of the child' assessment

8.5.1 It is a condition of the licence at T33(b) and (c) that a clinic has adequate policies and procedures to direct its practice in relation to its licensed activities. Paragraph 8.1 above

references the inadequacy of policies and procedures in relation to the clinic's surrogacy service. When we visited, the clinic did not have a documented procedure in place that ensured proper account was taken of the welfare of the child born as a result of surrogacy treatment or any child affected by the birth.

8.5.2 The clinic's 'Surrogacy protocol', provided to us subsequently at Annex 2b and 2c briefly describes HFEA requirements relating to 'welfare of the child' assessment*, 'that the commissioning couple and the surrogate mother (and her partner if she has one) should complete the welfare of the child form.'* The protocol does not reference a 'welfare of the child' assessment. and does not direct practice to comply with this requirement. As 'welfare of the child' assessment is central to the provision of licenced activity, we expected to see a robust protocol detailing the requirements of the assessment and actions to be taken if further investigation or information is required. We did not see this. The clinic does not have adequate policies and procedures to direct its practice in relation to a 'welfare of the child' assessments and is in breach of licence conditions T33(b) and (c). Nor does it have suitable arrangements for establishing standards of quality and safety and auditing those activities. As such the clinic is in breach of paragraph 3(1)(a) and (b) of Schedule 3 of the Act and the conditions of a licence T32, T35 and T36.

8.5.3 It is a condition of the licence at T56 that a woman must not be provided with treatment services unless account has been taken of any welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth. A 'welfare of the child' (self) assessment form was completed by the surrogate woman. In it she declared she had no mental or physical conditions, or other conditions that may pose a risk to the child. The clinic relied on the self-assessment declaration made by the surrogate woman. It did not undertake an assessment. It did not seek information from the surrogate woman's GP in line with their 'usual practice'. Furthermore, it did not complete a 'welfare of the child' assessment in relation to the surrogate woman's partner. The clinic has failed to demonstrate that a proper 'welfare of the child' assessment was undertaken in relation to the surrogate woman and the intended parents. The clinic told us it did not conduct a 'welfare of the child' assessment for the surrogate woman's partner. The clinic is therefore in breach of Section 13(5) of the Act and is in breach of licence condition T56 and CoP guidance note 8.4).

8.6 Review of information provided to the intended parents and surrogate woman

8.6.1 It is a condition of the licence at T58 that prior to giving consent, gamete providers must be provided with information about the nature of the treatment, the consequences and risks, any tests, the recording and protection of personal data and confidentiality, the right to vary or withdraw their consent, and the availability of counselling. This is so patients can make informed decisions about their care.

8.6.2 We did not see any records or evidence of information having been provided to or received by the intended parents, the surrogate woman or her partner – other than that outlined in the surrogacy agreement, which provided some information about the terms and conditions of the surrogacy arrangement, but did not meet the requirements of the licence condition or CoP requirements.

8.6.3 The clinic has therefore failed to meet the requirements of licence condition T58 and therefore the individuals involved in this arrangement have not been given the information necessary for them to provide fully informed consent. The clinic has failed to demonstrate how it meets the standards set out in the CoP guidance notes 3.1; 3.2; 4.2; and 4.4.

8.7 Review of the clinic's handling of incidents and arrangements for clinical governance

8.7.1 By Section 17(1)(g) of the Act it is a requirement that the Person Responsible notifies the Authority of any serious adverse events or serious adverse reactions and provides a report analysing the cause and ensuing outcome. Licence conditions T118, T119, T120, T121 and General Directions 0011 set out our requirements.

- The centre must establish, implement and comply with documented procedures to report, investigate, register and transmit information about serious adverse events and serious adverse reactions that occur on any premises to which a licence relates and any relevant third-party premises (T118).

- The documented procedures referred to in T118 must enable the centre to communicate to the Authority, without delay:
    a. all relevant available information about suspected serious adverse events and reactions, and
    b. the conclusion of the investigation to analyse the cause and ensuing outcome in relation to serious adverse events and reactions (T119)

- The PR must notify the Authority of any suspected serious adverse events and serious adverse reactions by providing the information set out below and such other information as the Authority may specify in Directions:
    a. identification of the centre
    b. identification of the premises concerned
    c. report identification
    d. date of notification, and
    e. date of serious adverse event/serious adverse reaction

    In relation to serious adverse events the following information is also required:

    f. an evaluation of the event by activity, (procurement, testing, transport, processing, storage, distribution or other) and specification of the source of error, (defect in gametes or embryos, equipment or material failure or defect),

human error or other (to identify preventable causes), to be followed by a conclusion report including items (a) to (e) above. (T120).

- The centre must thereafter notify the Authority of the conclusion of the investigation into the serious adverse event/serious adverse reaction by providing at least the information set out below and any such other information as the Authority may specify in Directions:
    a. identification of the centre
    b. identification of the premises concerned
    c. report identification
    d. date when the serious adverse event/serious adverse reaction was confirmed
    e. date of the serious adverse event/serious adverse reaction, and
    f. corrective measures taken.

    In relation to serious adverse reaction(s) the following additional information is also required:

    g. date when the serious adverse reaction was confirmed
    h. unique donation identification number
    i. confirmation of the type of reaction(s) or a change in the type of reaction(s),
    j. clinical outcome, if known:
        i. complete recovery
        ii. minor sequelae
        iii. serious sequelae, or
        iv. death
    k. root cause analysis
    l. outcome of investigation and final conclusions, and
    m. recommendations for preventive and corrective actions (T121).

General Directions 0011 defines an adverse incident and serious adverse event as:

- Adverse Incident: 'Any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre. This includes serious adverse events, serious adverse reactions, breaches of confidentiality and ovarian hyperstimulation syndrome (OHSS) which requires a hospital admission and has a severity grading of severe or critical.'
- Serious adverse event: Any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of gametes or embryos intended for human application and which, in relation to a donor of gametes or a person who receives treatment services or non-medical fertility services, and

  a. might lead to the transmission of a communicable disease, to death, or life-threatening, disabling or incapacitating conditions, or

  b. might result in, or prolong, hospitalisation or illness.

8.7.2 By paragraph 2 and 3 of General Direction 0011, such incidents and adverse events must be notified to the Authority within 12 working hours of their identification and must be reported to the HFEA within 24 hours of discovery of the incident or event.

8.7.3 The clinic decided to treat a surrogate woman with the intended parents. Because of that treatment the surrogate woman became pregnant and gave birth, and as we know the baby sadly died soon afterwards. The hospital trust where the birth took place instituted a serious incident review, and within two months contacted the lead consultant at the clinic seeking further information regarding the selection of patients who wish to become surrogates. As we show in this report, we believe there were significant failings in the clinic's practices and significant breaches of regulatory and statutory requirements. In any event, the lead consultant said she did not inform the PR, whilst also telling us she understood the responsibilities of the PR set out in the Act.

8.7.4 The death of the baby born following treatment provided to the surrogate mother meets the criteria of both a serious adverse incident and serious adverse event set out above. We are told the PR did not know about the incident. As such he could not have reported it as an incident. He told us that had he known about the incident, he would not have considered it reportable to the HFEA in line with his obligations under S17 of the Act. As such the PR has failed, or is unable, to distinguish between the actions of the clinic that may have had a direct contributory effect on an adverse outcome, and those where such actions (for example routine assisted reproduction treatment) could not reasonably be seen to have contributed to an adverse outcome (for example, miscarriage or premature birth). In any case, the PR failed to meet his duties under section 17(1)(g) and schedule 3A of the Act.

8.7.5 The lead consultant's failure to discuss this incident with the PR calls into question, amongst other things, her ability to recognise her own role in this matter and the clinic's governance arrangements and processes for managing and reporting incidents.

9. Review of professional body requirements

9.1 Given the central role played by the lead consultant in this surrogacy treatment, we had regard to the General Medical Council's (GMC) professional body requirements. '*Good medical practice'* (April 2014*)* is professional body guidance published by the GMC on the standards expected of all GMC registered doctors. The GMC says that all doctors must be familiar with, and follow, *Good medical practice* and the explanatory guidance (page 4, section 3). This includes (but not exclusively) treating patients as individuals (Domain 3, section 47); maintaining knowledge and skills (Domain 1, section 8); working collaboratively (Domain 1, section 16(d) and Domain 3, section 35 and 44(a) and (b)); maintaining proper records (Domain 1, section 19 – 21) and contributing to adverse event recognition (Domain 2, section 23(b)).

9.2 The lead consultant, by her own admission has stated that she did not share her knowledge of this incident with the PR or regulator, despite knowledge that the care she

had provided was being investigated. It is unknown, whether she has held discussions with the intended parents or surrogate woman relating to her care and the impact (if any) on the outcome.

9.3 We did not see evidence that the intended parents or the surrogate woman were treated as individuals during this process. The clinic reported that the intended parents and the surrogate woman had a joint consultation where their medical histories were taken and confidential information shared. The clinic provided us with its protocol after the investigation visit (Annex 2b) which details that if the parties are seen together '*it would be prudent to see the surrogate alone at some point of the consultation to ensure that they are fully aware of the process'.*

9.4 We saw no record or evidence that indicated the surrogate woman was given an opportunity to been seen alone during her consultation and the lead consultant did not follow the clinic's own protocol.

9.5 GMC 'Good medical practice', Domain 1, section 19 requires that 'documents you make (including clinical records) to formally record your work must be clear, accurate and legible. You should make records at the same time as the events you are recording (or as soon as possible afterwards). Clinical records should include, the relevant clinical findings; the decisions made and actions agreed, and who is making the decisions and agreeing the actions; the information given to patients; any drugs prescribed or other investigations or treatment and who is making the record, and when' (GMC 'Good medical practice' Domain 1, section 21). We did not see evidence of individual records in place relating to the surrogate or the intended parents. The single record available for review by the investigation team (Annex 4) has very limited information and is illegible in parts, with some information missing from the scanned copy. The date when the consultation took place is incomplete and the time which the consultation took place is missing. The record does not appear to have been signed by the lead consultant and there is no record of the information provided to the patients or of discussions and decisions made and agreed.

9.6 GMC standards (Good medical practice' Domain 1, section 15) require doctors to provide a good standard of practice and care. 'If you assess, diagnose or treat patients, you must: adequately assess the patient's conditions, taking account of their history (including the symptoms and psychological, spiritual, social and cultural factors), their views and values; where necessary, examine the patient; promptly provide or arrange suitable advice, investigations or treatment where necessary and refer a patient to another practitioner when this serves the patient's needs'. The lead consultant told us she did not refer to any professional body guidance when making her assessment of the suitability of the surrogate woman to undergo another pregnancy. She also told us she did not record evidence in any records of her considerations of the surrogate woman's risk factors when deciding to provide treatment. She also told us she did not assess the surrogate woman's condition, considering psychological and social factors and there is no evidence of a referral to the GP once the woman became pregnant.

9.7 The GMC has also published guidance 'Openness and honesty when things go wrong: the professional duty of candour' (2015) which sets an expectation that all healthcare professionals have a *duty of candour*, that is to be open and honest with patients when things go wrong, as set out in guidelines by their professional bodies. They must also be open and honest with their colleagues, employers, relevant professional body and regulators. They should share all they know about what went wrong, why and what they plan to do to ensure it doesn't happen again.

9.8 The HFEA has no powers to make an assessment about a professional's compliance with their professional body requirements. Nevertheless, the investigation team can make observations. We observe that in many aspects of her care the lead consultant's actions do not meet expected GMC professional standards, as follows:

1. Significant aspects of the lead consultant's practice do not meet HFEA requirements, as set out in this report. Observation of the regulatory requirements of other regulatory bodies is an expectation of doctors registered with the GMC (Good medical practice Domain 1 section 12).
2. Failure to recognise the patients' rights to privacy, by conducting joint consultations with the intended parents and the surrogate woman (Good medical practice, professionalism in action; section 2).
3. Insufficiency of any explanation or justification for actions, or decision making (GMC 2014 'Good medical practice; keeping records').
4. Insufficient or inadequate assessment of the surrogate woman's medical and obstetric history, with insufficient consideration of her associated risk factors, such as BMI, age, parity. (Good medical practice, Domain 1, section 15(a))
5. Failure to liaise at a sufficient level with other healthcare professionals, by not seeking further information from the surrogate woman's GP; and insufficient handover of care to the surrogate woman's GP when a viable pregnancy was confirmed. (Good medical practice; Domain 1 section 16(d)).
6. Poor record keeping for all individuals involved in the surrogacy arrangement. The record was scant, incomplete and illegible in parts and the date of when the record was written is incomplete. In addition, the clinical findings and decisions made or actions agreed with the patients were not recorded (Good medical practice; Domain 1, sections 19 and 21(a -e)).
7. We observed no good reason why the incident was not recognised as an adverse event, nor reported to the PR or HFEA (Good medical practice; Domain 2, sections 23(b) and 24).
8. We see little evidence of openness or candour in the lead consultant's actions, once she became aware of the incident, in dealing with the surrogate woman, intended parents or colleagues (GMC 2015 'Openness and honesty when things go wrong; the professional duty of candour').

10. Our conclusions

10.1 The letter from West Hampshire CCG to the HFEA of 18 October 2017 identified several concerns about the standards of care provided by CRGW, a licensed clinic. Their concerns with our conclusions (shown in **bold**) follow:

i. The reliance on the self-assessment of the surrogate woman regarding her current and previous medical and psychological history: **We conclude that the clinic placed too much reliance on the self-assessment undertaken by the surrogate woman and insufficient regard was given to her medical and psychological history.**

ii. The lack of involvement of the General Practitioner (GP) in verifying the accuracy and completeness of that assessment: **We conclude that there was no involvement of the surrogate woman's GP in informing the clinic's assessment of her suitability for surrogacy.**

iii. The surrogate woman's obstetric history; her Body Mass Index (BMI); age and other underlying conditions of her medical history, were not considered: **We conclude that there is no evidence to indicate that they were considered.**

iv. The acceptance of her as a surrogate woman failed to take account the 'Welfare of the Child' considerations: **We conclude that there were no 'welfare of the child' considerations.**

v. The surrogate woman's consent to proceed with treatment was compromised without assurance of her full medical and obstetric history: **We conclude that because insufficient information was provided to the surrogate woman, and intended parents, their ability to make a fully informed consent to proceed with treatment was compromised.**

vi. That her care (at the earliest stage) was compromised without access to this history, and the subsequent potential for inequity of care of surrogate mothers compared to natural mothers: **We conclude that, as above, insufficient consideration was given to the surrogate woman's medical history. However, once the clinic had transferred the pregnant surrogate woman to the care of her GP, the responsibility for providing information to the obstetric team fell to the GP when the obstetric referral was made.**

vii. Whether basic standards of the selection of women as potential surrogate mothers were met by the clinic in question: **We conclude that the clinic did not meet expected requirements in ensuring the suitability of the surrogate woman in proceeding to treatment.**

10.2 We make a further comment in relation to the report of the Serious Incident Investigation undertaken by Hampshire Hospitals Trust. It identified one of three root causes of the incident, as the HFEA's reliance on the surrogate woman's self-assessment for suitability

as a surrogate. As the report clarifies in paragraphs 6.2.2 and 7.5.2 the HFEA do not require licensed clinics to place a reliance on a surrogate woman's self-assessment for suitability as a surrogate.

10.3 Section 8 of this report identifies the clinic's significant and critical failures to meet HFEA requirements, and referencing those requirements. In summary:

The clinic's policies and procedures in place directing their activities relating to surrogacy

We conclude, that at the time of the investigation visit, there was limited evidence of procedures, protocols or any other guidance to inform the actions to be taken by staff treating patients in a surrogacy arrangement. A protocol was subsequently provided to the investigation team. The clinic also failed to audit its surrogacy practices properly by omitting to audit an objective (relating to the completeness of medical records).

The clinic's assessment of the surrogate woman and commissioning couple's history

We conclude that the clinic failed to provide information about the nature of the proposed treatment (and risks) and failed to conduct a thorough assessment of the surrogate woman to determine her suitability for treatment. An opportunity was missed to gather information from her GP that would have informed the decision as to the surrogate woman's suitability to undergo treatment. There was also no regard to the privacy and dignity of all the individuals involved in this arrangement and their expectations (and our requirements) as to confidentiality.

Review of the treatment records of the intended parents and surrogate woman

We saw evidence of extremely poor record keeping. We found there was a failure to maintain proper records at key stages of the process.

Ensuring the offer of proper counselling

We saw no evidence that any discussion about counselling with the surrogate woman took place. The clinic has failed to demonstrate that the intended parents or the surrogate woman's partner were given an opportunity to receive proper counselling or have received information in line with the requirements set out in Schedule 3 of the Act.

The 'Welfare of the child' assessment

The clinic failed to demonstrate that a proper 'welfare of the child' assessment was undertaken in relation to the surrogate woman, and the intended parents. They also failed to complete any 'welfare of the child' assessment of the surrogate woman's partner.

Review of information provided to the intended parents and surrogate woman

We did not see any records or evidence of information having been provided to or received by the intended parents, the surrogate woman or her partner – other than that outlined in the surrogacy agreement, which we assess as inadequate for this purpose.

Review of the clinic's handling of incidents and arrangements for clinical governance

The incident meets the criteria of both a serious adverse incident and serious adverse event set out above. We are told the PR did not know. As such he could not have reported it as an incident. He told us that had he known about the incident he would not have considered it reportable to the HFEA in line with his obligations under S17 of the Act. The lead consultant's failure to discuss this incident with the PR calls into question, amongst other things, the clinic's governance arrangements. Whether the management arrangements within the clinic (the lead consultant is the clinic's licence holder) are contributory factors in any considerations or processes for managing and reporting incidents, is unknown at this stage and may require further exploration.

10.4 We conclude that the concerns identified in the investigation of this incident may be indicative of wider failings within the clinic, requiring further investigation. Before considering further action necessary under the terms of the HFEA 'Compliance and enforcement policy' (including any recommendations to a Licence Committee of the HFEA) we must seek the views of the clinic in providing us with comments on this report and we invite the PR now to do so.

10.5 This report also identifies concerns relating to the standards of care provided by the lead consultant. We note the lead consultant is registered with the General Medical Council. The HFEA will consider a referral to the GMC when it has received comment from the PR and during the next management review under the terms of the HFEA 'Compliance and enforcement Policy.'

10.6 The clinic is registered with Health Improvement Wales (HIW). A copy of this investigation report and summary will be forwarded to HIW following any determination made by a HFEA Licence Committee.

Date: 19 February 2018

References:

1. GMC 'Duties of a registered doctor with the GMC' (accessed 22 December 2017).
2. GMC 2014 'Good medical practice; keeping records' GMC, Manchester.
3. GMC 2015 'Openness and honesty when things go wrong: the professional duty of candour' GMC, Manchester.
4. Human Fertilisation and Embryology Act 1990 (as amended).
5. Human Fertilisation and Embryology Authority (HFEA) Code of Practice (2017). sections 4; 8; 14; 27,30,31. 8th edition.
6. Human Fertilisation and Embryology Authority (HFEA). General Directions 0012 Retention of records, Version 4; October 2015.
7. HFEA Standard Licence Conditions.
8. NHS Choices 'What is Body Mass Index' https://www.nhs.uk/chq/Pages/3215.aspx accessed 19 January 2018.

Targeted Interim Licensing Report

Centre name: Centre for Reproduction & Gynaecology Wales (CRGW)
Centre number: 0316
Date licence issued: 9 July 2016
Licence expiry date: 8 July 2019
Additional conditions applied to this licence:
Date of inspection: 6 and 7 March 2018
Inspectors: Polly Todd (lead); Grace Lyndon; Vicki Lamb
Date of Licence Committee: 12 July 2018

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

On 18 October 2017, the HFEA received a letter from West Hampshire Clinical Commissioning Group (CCG) regarding a serious incident investigation (SII) carried out by Hampshire Hospitals NHS Trust that had taken place following the death of a baby and serious complications for the surrogate mother. The letter expressed concerns about the assessment by the fertility clinic of the surrogate woman's suitability to undergo assisted conception, and the lack of information provided by the clinic relating to the surrogate woman's ongoing obstetric care. The SII conducted by Hampshire Hospitals NHS Trust cited the HFEA's reliance on the surrogate's self-assessment for suitability as a surrogate, as one of three root causes of the incident.

As a result of this, the HFEA conducted an investigation visit to the centre on 21 December 2017 to explore the concerns expressed by the CCG and assess compliance with the HF& E Act 1990 (as amended) (the Act), SLC, and CoP requirements. That investigation highlighted a number of significant concerns and extensive non-compliance with SLC, the Act and CoP.

This is a report of a scheduled (rather than unannounced) interim inspection and provides information on the centre's performance and level of compliance since the renewal inspection in 2016. Alongside this, the inspection team reviewed aspects of the centre's service and performance relating to the SII and their impact in relation to other treatments or aspects of care.

The inspection focussed on key areas of risk and ongoing areas of concern as follows:

- non-compliances identified at the renewal inspection in 2016 to ensure full compliance with the recommendations made at that time;
- surrogacy treatments, including documentation, screening and standard operating procedures;
- welfare of the child assessment;
- donor treatments;
- incident reporting;
- the quality management system;
- record keeping and document control.

As part of the HFEA's ongoing activities relating to 'legal parenthood' this area of practice is currently a focus for all inspections.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Licence Committee (LC) with information on which to make a decision about the continuation of the licence in conjunction with the findings of the report of an investigation into a serious incident (December 2017). The recommendation of the Executive with regards to the centre's licence is recorded in the Executive summary accompanying this report.

Summary for the Executive Licensing Panel

Summary for licensing decision

Further information and the Executive's recommendation is contained on the Executive summary report to LC.

The inspection team notes the centre's reduction of their multiple pregnancy rate from 27% to 12% since the last inspection, which is to be commended, and the good feedback from patients.

The LC is asked to note that this report makes recommendations for improvement in relation to four critical, six major and two 'other' areas of non-compliance or poor practice.

The PR has provided evidence that the following recommendations have been implemented. Where required and by the dates specified, the PR will provide an update or summary of audits conducted to ensure that corrective actions taken are effective.

Critical areas of non-compliance:

- **The PR must ensure that there is effective written consent for all stored gametes and embryos.**
- **The PR must ensure that medicines management practices at the centre are compliant with regulatory requirements.**
- **The PR must ensure that the processes for prescribing, administering and monitoring intralipid infusions 'off label' is compliant with professional body guidance.**

Major areas of non-compliance:

- The PR should ensure that infection control measures and practices are compliant with regulatory and best practice guidance.
- The PR should ensure that donor screening practices are compliant with standard licence conditions, regulatory and professional body requirements.
- The PR should ensure that the premises are safe and fit for purpose.
- The PR should ensure that the emergency resuscitation equipment is complete, fit for purpose and compliant with best practice guidance.
- The PR should ensure that a suitably competent and knowledgeable safeguarding lead is appointed.
- The PR should ensure that proper records are maintained as specified the Authority and professional body guidance.

'Other' areas of practice that require improvement:

- The PR should ensure that the centre's procedures for managing surrogacy treatments are compliant with Code of Practice requirements.
- The PR should ensure that guidance from the HFEA is incorporated into practice.

The PR has provided a commitment to implementing the following recommendations:

Critical areas of non-compliance:

- **The PR must ensure that there is an effective and robust QMS in place to improve the quality and effectiveness of the service provided in accordance with standard licence conditions and HFEA practice guidance.**

Information about the centre

The Centre for Reproduction & Gynaecology Wales (CRGW) has held a licence with the HFEA since July 2010 and provides a full range of fertility services.

The centre is registered with Health Inspectorate Wales (HIW) which did a joint inspection with the HFEA at the renewal inspection in January 2016.

The centre provided 882 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 November 2017. In relation to activity levels this is a medium sized centre.

Other licenced activities at the centre include the storage of gametes and embryos.

On 17 March 2016, following the renewal inspection, a licence committee issued a three-year licence (rather than the usual four) because of the following concerns:

- The number and seriousness of non-compliances found at the renewal inspection (one critical; three major and ten other areas of non-compliance).
- The centre's multiple pregnancy rate (26% at the interim inspection in 2014 and 27% at the renewal inspection in 2016).
- The centre not having completed a full legal parenthood audit.
- That no-one at the centre, including the person providing conscious sedation, was trained in life support to a higher level than basic.
- That intralipids continue to be prescribed by the centre off-label in cases of patient request, despite concerns being raised by the Royal College of Obstetricians and Gynaecologists over a lack of evidence of safety and efficacy.

The centre's current licence is due to expire on 8 July 2019.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period November 2016 to October 2017 show the centre's success rates are in line with national averages.

In 2017 the centre reported 114 cycles of partner insemination with 17 pregnancies. This represents a clinical pregnancy rate of 15% which is in line with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

[1] The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Between November 2016 and October 2017, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 12%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: fertilisation checks and thawing of embryos. All of the procedures observed were witnessed using a manual witnessing system in accordance with HFEA requirements.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

On inspection, the 'bring-forward' system was discussed with staff and storage records were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are not effective because one sample for which the period of consent had expired on 9 January 2018, was not discarded until 6 March 2018 (the day of the inspection). The PR reported that he did not wish to be hasty in discarding samples.

In addition, on review of an extended storage consent, a medical practitioner statement (MPS) had been signed, but not dated by the medical practitioner. Staff reported that the consultant had signed the consent on the 19th of the month but could not provide the inspection team with evidence to substantiate this assumption. The centre's records indicated that the patient's storage consent period expired on the 18th of the month, which would suggest that, if the MPS was signed on the 19th, the extended storage consent may not have met the requirements of the HFEA's statutory storage regulations. Further information was requested from the PR after the inspection to determine if the patient's consent to extended storage is lawful. The PR has not responded to this request.

Additionally, staff place reliance on an electronic data system that calculates storage expiry dates incorrectly. The inspection team are concerned that this may have an impact on other storage consents.

See recommendation 1.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out: patients attending for consultations were seen promptly on arrival; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were

able to carry out their activities without distraction and were available to carry out witnessing activities when required.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: the quality management system; consent to treatment and storage; legal parenthood; storage of gametes; witnessing; welfare of the child assessment (WoC); controlled drugs and the provision of information.

The effectiveness of the centre's QMS was also assessed by reviewing the following SOPs: non-clinical emergencies; WoC; sperm donor recruitment; oocyte donation; provision of information; legal parenthood; 'deviation from legal parenthood' and safeguarding.

The centre's QMS and procedures for auditing and acting on the findings of audits are not compliant with requirements because:

- Audits lacked detail and there were no measurable corrective actions (legal parenthood; consent; controlled drugs). For example, on the legal parenthood audit the auditor documented an action as *'there could be a learning need'* and the controlled drugs audit recorded *'need to do better, re-audit in 6 months'*. There was no date on the audit to indicate when it had been undertaken or when the re-audit date was scheduled.
- The achieved practice standard was not documented in all audits (welfare of the child) and was incorrect in one audit reviewed (controlled drugs). This raises concerns that there are no mechanisms for ensuring accurate auditing or data collection and that this could impact on the implementation of corrective or preventative actions.
- One audit reported 100% compliance when non-conformities had been identified (see legal parenthood section).
- Timeframes for the completion of corrective actions (where documented) were not given (consent; legal parenthood; controlled drugs).
- There was no indication on audits as to whether corrective actions had been implemented (consent; legal parenthood; welfare of the child; controlled drugs; provision of information).
- Two of the audits reviewed had not been performed in the previous two years (provision of information audit last conducted 24/7/15 and consent audit last conducted 27/7/15).
- The centre has not completed a record keeping audit.
- The controlled drugs audit lacked scope in that it only audited against the non-compliances found at the renewal inspection in 2016, and did not identify the non-compliances found at this inspection (see medicines management section for further detail).
- The centre could not provide an SOP for record keeping.

- The WoC SOP makes no reference to completion of an assessment if more than two years have elapsed since the last one. It only instructs updating of the form, *'where the form is over two years old, it is updated'.*
- The WoC SOP does not mention the requirement to repeat an assessment if a child has been born since the previous assessment.
- The centre could not provide a current legal parenthood SOP and the archived version provided to the inspection team appeared to be an information sheet for patients in that it did not direct clinical procedure.
- The centre's 'deviation from legal parenthood' version is dated 2012 and there is no indication to confirm that this document has been reviewed or updated since that time.
- Given the extent of the issues identified with the QMS, the inspection team conclude that staff do not have the necessary skills or competence to carry out robust and effective audits or develop appropriate standard operating procedures. The centre has a Quality Manager, recently appointed. It is envisaged that she can implement processes that will ensure a safe and effective QMS.

See recommendation 2.

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture, then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- the use of CE marked medical devices
- the content of the centre's website.
- HFEA Clinic Focus articles regarding: screening requirements, patient feedback; information for trans and non-binary patients and prevention of transmission of Hepatitis A.

The centre is not effective in implementing learning from guidance from the HFEA because the centre has not implemented guidance issued between May and September 2017 regarding:

- The screening of patients based on their travel history.
- Provision of information to patients about how to provide feedback to the HFEA.
- Reviewing and embedding information for trans and non-binary patients into their suite of information.
- Incorporating screening for Hepatitis A into practice.

See recommendation 12.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered and disposed of in the correct way.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be non-compliant with guidance because:

- The Controlled Drugs Accountable Officer (CDAO) is one of two people authorised to order controlled drugs and there is concern that this could compromise the accountability of the CDAO position.
- The CDAO has cause to prescribe controlled drugs and the inspection team are not assured that this is in exceptional circumstances or cases of emergency as per regulatory requirements.
- In the event of a concern relating to the CDAO's practice, there is no person to whom she is accountable or open to scrutiny.
- The controlled drugs audit lacks scope (see QMS section for further detail).
- The time of administration of controlled drugs was not recorded in the controlled drugs register in all cases and was also not recorded on the patient's anaesthetic chart.
- Corrections in the controlled drugs register, did not follow the centre's reported procedure or regulatory requirements.
- The inspection team were not assured that the CDAO fully understood her role and responsibilities when questioned.
- The centre did not provide a controlled drugs SOP when requested to do so.

See recommendation 3.

Prescription of intralipid 'off label'

Intralipid is a sterile liquid soybean and egg yolk based fat emulsion which is licensed as an intravenous nutritional supplement for adults and children. Some healthcare professionals consider intralipid therapy may be beneficial to a particular subset of women having IVF. Intralipid is not however licensed for use in fertility treatment and if prescribed in this context, it represents 'off-label' use. Healthcare professionals' responsibilities when prescribing a medicine off-label may be greater than when prescribing a medicine for use within the terms of its licence.

In April 2015, the President of the Royal College of Obstetricians and Gynaecologists, published concerns regarding the evidence base for the use of intralipid in IVF treatment, in terms of its safety and efficacy. In July 2015, the HFEA published guidance to centres regarding the prescribing of intralipid (or other 'off label' therapies) to patients. This guidance required centres to take responsibility for prescribing the medicine and for overseeing the patient's care by:

- reviewing and recording the information provided to patients about intralipid therapy to ensure that the reasons for prescribing it 'off-label' are explained, including that there is currently little evidence to support its use in fertility treatment;
- recording the reasons for prescribing intralipid in the patient's records and;
- ensuring that patients who are prescribed intralipid are properly monitored and followed up.

The process for administering and monitoring patients during intralipid infusion was reviewed and considered not suitable because:

- Whilst the centre's information for patients regarding immunology treatments has been amended following the renewal inspection in 2016, clinicians reported to the inspection team that they prescribe as per the patient's request and do not

undertake an assessment to determine the patient's suitability for immunology treatment.
- The centre does not have an SOP guiding its own practice in the administration of intralipids. The PR was asked to submit a copy to the inspection team after the inspection but has not done so.
- Where patients have attended other licenced centres for previous treatment cycles, clinicians reported that the timing/stage in treatment of administration of intralipids for patients having two infusions, is based on the same treatment pathway they followed at a previous centre. The centre neither confirms the account given by the patient nor makes their own assessment of the situation.
- The centre does not record the reason for prescribing intralipids in the patient records.
- Staff monitoring patients undergoing intralipid infusion have not been trained to do so, and have not had their competencies assessed.
- The inspection team are concerned that only the specific aspects of the non-compliance identified at the renewal inspection have been addressed and that a change in practice and ongoing review and audit has not occurred.

The inspection team conclude that the current practices at the centre pose a significant risk of causing harm to patients and have therefore escalated this non-compliance.

See recommendation 4.

Infection Control

It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

During the inspection, we reviewed infection control practices and found them to be partially compliant with guidance because:

- Temporary closures on the sharps bins were not in use.
- There was no date or signature on the sharps bins as required for appropriate waste management procedures.
- The flooring in some clinical areas was only partially sealed.
- There was skirting board in some clinical areas, some of which, were dusty.
- Seating in some clinical areas was made of porous material and the fabric was frayed in places.
- There was no sink on the phlebotomy room. There is a risk of cross-contamination, by having no hand wash facility in a room in which clinical waste may be handled.
- The men's production room is not routinely cleaned between each patient's use.
- There are no elbow taps in one of the consultation rooms where clinical procedures occur and blood samples are taken.
- There is carpet in one of the consultation rooms where blood samples are taken.
- Clinical linen and staff uniforms are washed on site using a domestic washing machine, which was leaking at the time of the inspection and had not been serviced.
- Boxes of food and water were found to be stored on the floor in a store cupboard.
- Bloods samples were stored in a drugs fridge awaiting collection, the inspection team is concerned that the temperature storage requirements for blood samples are not the same as those for storing drugs, and that this could impact on the samples' suitability for testing.

See recommendation 5.

Equipment and Materials

It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

The CE mark status of the following medical devices was reviewed in the course of the inspection: Vitrolife media; serological pipettes; 5ml tubes and centrifuge tubes. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Screening of donors

It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and embryos. The inspection team were not assured that the centre had robust processes in place to effectively manage donor recruitment, assessment and screening.

The centre's procedures for screening donors are partially compliant with HFEA requirements because:

- Staff reported that they do not consider past travel history when screening donors.
- SOPs do not document the need for Ebola and Zika virus screening ('oocyte donation' and sperm donor SOP).
- In one record reviewed during the inspection the donor had been screened outside the timeframe specified by the Authority.
- The sperm donor SOP does not document the requirement for a physical examination as per professional body guidelines and staff report this is not part of their assessment of sperm donors.
- The 'oocyte donation' SOP is confusing, in that it documents a requirement to take a £500 deposit from an egg donor. Centre staff report that this applies to 'egg share' patients, but the SOP does not make this differentiation and makes no reference to 'egg sharing' only to egg donation.
- The centre's egg sharing information for patients is not in line with guidance in that it states that if the sharer withdraws her consent, she will have to pay the cost of the treatment and drugs. Code of Practice (CoP) guidance states *'If either the gamete provider or the recipient in a 'benefits in kind' arrangement withdraws their consent to treatment after preparation has begun, the centre should bear any financial loss it sustains as a result'.*

See recommendation 6.

Safety and suitability of premises

The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are partially compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm because:

- A large faulty empty nitrogen tank was being stored in a corridor that led to a fire exit. This could impede the evacuation of patients and staff in the event of a fire.
- The patients' emergency call bells in the recovery area are not routinely checked by centre staff.
- The room storing medical gases was non-compliant with statutory regulations because:
    - the store room did not have any ventilation;
    - the content of the room was not clearly labelled on the outside of the room;
    - there was no safety signage in the area, for example warnings prohibiting naked flames and 'no smoking' signs;
    - emergency action notices giving details of emergency actions procedures, were not posted on the outside of the store.

See recommendation 7.

Emergency resuscitation equipment:

The centre is partially compliant with requirements to ensure that appropriate resuscitation facilities are in place because:

- Equipment on the emergency resuscitation trolley had expired in 2015 (for example, syringes and blood bottles).
- The containers in which the emergency resuscitation drugs were stored, had syringes in them that had expired in 2015.
- The emergency resuscitation drugs were not stored on the resuscitation trolley but were kept on a work surface in theatre.
- The equipment on the emergency resuscitation trolley, and the defibrillator had not been checked for more than two weeks. Varying accounts were given by staff as to the frequency of checks and as there was no record of the frequency of the checks, the inspection team are concerned that checks may be missed.
- There was no checklist of equipment that should be present on the resuscitation trolley.
- Emergency resuscitation drugs were not stored in tamper-proof containers.
- Checks that are undertaken are not robust as out of date equipment was found on the trolley by the inspector.

See recommendation 8.

Welfare of the child

The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are partially compliant with HFEA requirements.

See QMS and surrogacy sections of this report and recommendations 2 and 11.

Safeguarding

The centre's procedures are partially compliant with safeguarding guidance because:

- The safeguarding lead was unaware of the content of the centre's safeguarding policy.
- Staff at the centre did not know who the safeguarding lead was.

- The safeguarding lead was unable to identify vulnerable groups, reporting that the population served by the centre 'is not a high-risk population'.
- The safeguarding lead reported she has no competency in this area of practice.
- The centre's policy does not document what to do if a disclosure is made out of normal office working hours or weekends.
- The account given by the safeguarding lead, of actions to be taken in the event of a disclosure, was not in line with the centre's SOP.

The inspection team conclude that the safeguarding lead is not competent to undertake the role.

See recommendation 9.

Surrogacy

It is important to protect the surrogate and any children born as a result of the treatment. The centre's procedures for treatment involving surrogacy are broadly compliant with HFEA requirements because:

- In one record the intended parent had completed a SPP (consent to being the legal parent in surrogacy) consent form. This form should not be completed if 'the surrogate is married or in a civil partnership and her spouse or civil partner consents to the treatment (the surrogate's spouse or civil partner will be the other legal parent)'. When the patient completed this consent form, a surrogate had not yet been found. The inspection team are concerned about the centre's processes for providing appropriate information regarding consent, by getting patients to complete consents that do not apply to their situation.
- The centre report that they have not routinely conducted welfare of the child assessments for the partners of surrogates previously, but have amended their practice now.

See also, record keeping section and recommendations 10 and 11.

Record keeping and document control

Good medical records are essential for the continuity of the patient's care. The centre's procedures for keeping records are partially compliant with HFEA requirements to ensure that accurate medical records are maintained because:

- The centre does not keep a record for each patient in treatments involving surrogacy. In four of the seven records reviewed, the medical information for both of the intended parents had been recorded on a single sheet of paper.
- In one of the records reviewed the intended parents and the surrogate woman's medical history was recorded on one sheet of paper.
- The person by whom the patient's identity is verified is not always documented.
- In one record the scanned consent forms were unclear and unreadable in parts.
- In one patient record a procedure 'observation sheet' was not signed and did not record the time a drug had been administered to the patient.
- In the record of a single woman, the offer of counselling had not been documented in the patient record.
- The centre has not conducted an audit of the records.
- The centre does not have an SOP directing the completion and standard required of clinical records.

See recommendation 10.

Patient experience

During the inspection, no patients were available to speak with the inspectors about their experiences at the centre. The centre's most recent patient survey responses were reviewed, feedback was positive. Of the feedback reviewed, 103 of 116 individuals providing feedback, rated their overall satisfaction with the centre as excellent.

On the basis of this feedback and observations made in the course of the inspection, it was possible to assess that the centre:

- has respect for the privacy and confidentiality of patients in the clinic;
- has staff who are supportive and professional;
- maintains an effective system for responding to patient phone calls.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2016, recommendations for improvement were made in relation to one critical, three major and ten 'other' areas of non-compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales. However, during this inspection it became apparent that the following recommendations have not yet been fully implemented:

- The role of the Controlled Drugs Accountable Officer (CDAO) should be reviewed and practices relating to the management of medicines, including controlled drugs, to ensure that medicines are prescribed and are traceable in accordance with requirements.
- Actions should be taken to further improve the centre's quality management system (QMS).
- The PR should assess whether their current practice of screening egg donors is suitable to inform them of the infection status of the donor 'at the time of donation'.
- Procedures should ensure that all necessary information is recorded in patient records and is protected from unauthorised amendment.
- The PR should ensure the centre's rationale for providing treatment with intralipid 'off label' is consistent with HFEA guidance.

On-going monitoring of centre success rates

Since the last renewal inspection in January 2016,

- the centre has received ten risk tool alerts related to performance, to which the PR has responded appropriately, providing evidence and information that the issues have been addressed.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases, it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

In February 2014, the HFEA asked all centres to audit their practices in this area to ensure they are suitable, to report the findings of the audit to the HFEA and to respond to those findings. The centre provided the report of the audit to the HFEA within the required timeframe and took appropriate action with respect to the issues identified by that audit. Evidence had previously been provided by the centre that their audit was comprehensive, and their procedures for obtaining consent to parenthood are robust.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood.

At the renewal inspection in January 2016, legal parenthood consenting processes were reviewed and an audit of the patient records, where treatment with donor sperm had been provided in circumstances where consent to legal parenthood may be required, showed that the marital or civil partner status could not be easily determined from the records. This could have affected the ability of staff to ensure that consent to legal parenthood had been sought in all applicable cases, and therefore, could have impaired the quality of the centre's previous legal parenthood audits.

As a result, the PR was required to complete a full audit of legal parenthood, using the protocol specified by the HFEA in 2014.The PR complied with this requirement and subsequently, four anomalies were found with legal parenthood consents. The PR has confirmed at this inspection that all four couples have now been awarded parental orders through the courts.

To provide further assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Five sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. Two couples were found to be married, so legal parenthood consent did not apply, and one patient was a single woman. Of the two remaining records reviewed, the inspection team concluded that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements with the exception below:

- The legal parenthood audit reported 100% compliance when anomalies were found with the completion of the Posthumous Birth Registration (PBR) consent forms. See QMS section and recommendation 2.

Annex 1

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the inspection team considers may constitute areas of non-compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be made.

Critical areas of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A critical non-compliance requires immediate action to be taken by the Person Responsible.

A critical area of non-compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team's response to the PR's statement
1. Consent to the storage of cryopreserved material: On inspection one sample, for which the period of consent had expired on 9 January 2018 was not discarded until 6 March 2018 (the day of inspection). In addition, on review of an extended storage consent, a medical practitioner statement	The PR must ensure that there is effective written consent for all stored gametes and embryos. The PR must ensure that all staff are fully conversant with the requirements of the HF&E Act 1990 and extended storage regulations, in relation	Our storage consent expiry audit was completed on 20.2.18 and included any gametes or embryos placed into storage up to 30.6.17. The audit was conducted to ensure all material in our cryobank have effective consent to store, and that the expiry date is accurate. There was a single error from one freeze instance.	The Executive notes the PR's response. Whilst the Executive can appreciate the PR's concerns for patients and the storage of their gametes, the storing of samples without valid consent in place is in breach of the Act. The PR has conceded that this situation would not have

(MPS) had been signed but not dated by the medical practitioner. Staff could not provide assurance that the statement had been completed within the required timeframe, or that the storage consent is compliant with extended storage consent regulations. The PR was asked to provide further information to clarify this matter by 16 March 2018 to which he has not responded. Staff place a reliance on an electronic data system that calculates storage expiry dates incorrectly. The inspection team is concerned this could impact on other storage consents. Schedule 3, HF&E Act 1990 (as amended). Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009. SLC T9(f).	to storage consent requirements. The PR should review the centre's processes for extending consent to store and ensure that there are procedures in place to ensure full compliance with extended storage regulations. The PR should provide a summary report of this review detailing any corrective actions implemented, to the centre's inspector when responding to this report. The PR should also provide the previously requested information relating to the extended storage consent detailed in this report, or provide substantial evidence of why he is assured that the storage consent for this patient is valid, to the centre's inspector when responding to this report. The PR should ensure that there are additional measures	This occurred solely due to an incorrect luteal day 0 being inputted electronically on the treatment database which in turn generated an inaccurate expiry date. This did not therefore lead to a breach of storage conditions. This date was accordingly corrected electronically. A full audit of storage tank contents was carried out in December 2017 which showed a 0.002% error rate. These errors related to data input inaccuracies at the time of freezing with regard to storage location. Again, this audit did not breach licence conditions. With regard to the discarding of the sample on 6.3.18, the consent for which had expired on 9.1.18, this was atypical practice on our behalf and the circumstances surrounding it require further explanation. As PR, I am always concerned about discarding a patient's gametes or embryos against their wishes. Likewise, I am also concerned about the possibility of a couple having	occurred had the centre's procedures been followed. The Executive is concerned that the PR did not have an oversight of these procedures to ensure they were followed accordingly. The Executive is concerned that the PR has questioned the calculation of consent to store expiry dates. The Executive has had further discussion with the PR to clarify this matter. It is expected that the PR will implement measures to ensure that the correct calculation of storage expiry dates is in place. The PR has provided evidence of his assurance that the extended storage consent for the case referred to in this report is valid. The Executive confirms that an email request was sent to the PR on 9 March 2018 requesting further information, to which he did not respond. This was forwarded to the PR again, at

	in place to correctly calculate the expiry dates for storage consents. The PR should inform the centre's inspector of these measures when responding to this report.	separated where one patient forges the others signature as has happened in a London clinic recently. As such, discards are performed by the same two members of staff. We have a system where we set aside time to allow us both to be uninterrupted while carrying out discards. When doing this we occasionally find ourselves questioning signatures on discard forms when compared to signatures on consent forms in notes. Likewise, when (as an example) a patient asks for discard of two frozen embryos when they are currently still pregnant from their most recent transfer, we question whether their intention was actually to discard and whether the form was completed as they had wished. Due to the litigious culture we now work in, clinics perhaps understandably go to great lengths in this regard, meaning that if we are not sure about a given patient's signature for instance, we may defer the	his request, on 27 April 2018 and clearly showed the date and time the original email had previously been sent to the PR. The Executive confirms that the PR has previously responded to information requests. No further action required.

		discard to the next discard date pending further investigations. CRGW always acts in the interest of the patient(s). The patient in question had imported surgically retrieved sperm to us. We wrote to the patient 6 months before expiry and again 2 months before expiry: this is nto a case where we had not taken steps to address the imminent expiry. We completed a MPS form and again contacted the patient this time the day before the discard date. The patient said they would contact us immediately by email but did not do so. When faced with discarding a potentially irreplaceable sample, the discard team felt we needed to make additional checks. Despite further attempts to contact the patient, no response was made so the samples were somewhat reluctantly discarded on our next routine expiry date. All of this is clearly documented in the notes.	

		As such, while I acknowledge the practice meant we discarded after the expiry date, I would hope the HFEA can recognise that this was entirely with the patient in mind. We acknowledge that adhering to our recall system (attached as B) would have prevented this happening and have amended our practice to ensure this is the case in future similar scenarios. It should be mentioned that the day of inspection was additionally a routine discard day for the embryology team with 13 discards being carried out and only one of them (the scenario outlined above) being discarded after expiry date. In the case of the extension to storage form signed but not dated, I accept that this is an example of human error. I have reminded the team to be diligent when completing forms. In regards to the request for further information from our inspector, I was unaware of the receipt of the request for	

		further information from the HFEA that was requested by 16.3.18 and was unsure in what format it had arrived. I requested this be re-sent on 26.4.18 in response to this report and received this in email format on 27.4.18. It was apparently sent on 9.3.18 but was not seen by the PR. The HFEA Executive is aware that I usually respond immediately to information requests (as outlined at the top of this report) and I have emails expressing thanks for my 'quick reply' so the HFEA has evidence that it would be very atypical for me to not reply to such an email. As such the PR refutes any suggestion that the failure to respond to this was in anyway intentional or evidence of any wider failure on my part. Please see attachments Y and F in relation to this correspondence. A summary report as requested above can be found it attachment ZF.	
2. Quality management system:	The PR must ensure that there is an effective and robust QMS	Please see attachment ZE for individual responses to bullet	The Executive acknowledges the PR's response and

Extensive and wide-ranging issues with the centre's QMS have been identified at this inspection (see body of report for details). Non-compliances with the QMS were identified at the last inspection in 2016. Due to the nature and extent of the issues identified at this inspection, the QMS has been graded as a critical non-compliance. SLC T32; T33; T34; T35; T36.	in place to improve the quality and effectiveness of the service provided in accordance with standard licence conditions and HFEA practice guidance. The PR must complete a comprehensive review and overhaul of the QMS, this includes, but is not exclusive to: Reviewing all SOPs to ensure they are compliant with regulatory and statutory requirements; ensuring there are SOPs for all activities for authorised by the licence, and that required standards for quality are established. The PR must address all QMS issues detailed in this report. The PR must ensure that staff have the appropriate training and competence to undertake effective audits of practice and procedure. The PR should provide detail of this review, including staff	points made earlier in this report regarding the QMS. Our current practice manager (PM) started at CRGW in early 2017. The PR and directors felt in 2016 that the QMS amongst other things needed ownership as it was then being managed by multiple individuals and so was becoming inefficient. We had previously employed a PM who was not fitted to the job. We therefore interviewed again and nobody was deemed suitable for the post this time. We again re-interviewed and employed our current PM. In response to non-conformities with QMS at the 2016 inspection, my comments to our inspector at the time were as follows: All CRGW audit templates have been amended post inspection. These now include a question of why the audit is being performed, a methodology, number audited and rationale for number chosen, which patients records	commitment to implementing this recommendation. The renewal inspection in January 2016 was prior to the appointment of the new PM/QM in 2017. It is the actions that have been implemented by the PM/QM, since her arrival that have been reviewed during this inspection. The evidence provided by the PR with this report shows that the PR acted on the recommendation, but did not maintain an oversight to ensure that the actions had been implemented into practice. The extensive issues found at this inspection would suggest that actions implemented by the PR since the last inspection have not been effective in maintaining compliance as some issues noted at the inspection in 2016 have re-occurred. The PR has provided information subsequent to this

	training requirements and timescales for implementation of the actions to be taken to rectify the shortcomings of the system, to the centre's inspector when responding to this report. It is expected that the centre will have a fully compliant and effective QMS in place by 6 September 2018.	were audited, corrective actions, date of corrective actions implemented and later evaluation of implementations (~6 months later). An audit of equipment traceability was performed post inspection on 16/2/16 and showed 100% compliance in randomly selected patient notes. This in now a routine part of our traceability audit. Consent to storage of gametes and embryos: We have begun a full audit of all stored gametes and embryos in regards to checking consent forms against medical records and will have the results of this audit in the next few months. We have added this also to our routine full yearly audit of stored gametes and embryos so that each years storages are audited against consents. As part of QMS improvement we will develop the facilitation of the provision of information by SOP's and have made part of the audit of information to question whether information provided is appropriate.	report of further actions he plans to implement, which are encouraging. The Executive will continue to work closely with the PR to ensure that progress towards a compliant QMS is achieved. Further action required.

		I have begun an SOP for non clinical emergency which will be completed by the end of March. (It was completed by that date) The response from the HFEA in the 2016 report stated as follows: The PR has provided a suitable summary of actions, including audits, that have been taken. We request the PR forwards copies of new SOPs drafted in response to this recommendation by 13 July 2016. We await further audit summaries due January 2016 As such the inspector in 2016 made seven comments about the QMS. Five of these were believed to be fully actioned. Two of them were ongoing improvements required to the QMS for which we employed the PM who is skilled in working with QMS. At our inspection on 6th and 7th of March 2018, our current inspector appeared to be happy with the progress made by our practice manager. Our	

		inspector spent time with the PM and saw our master index for all of QMS which was put into place in June 2017 i.e. prior to inspection. Our inspector thought the document was a good idea. She also agreed with the PM on the progress so far and the plan for another overhaul of the audit process. Our inspector observed our new audit calendar and she agreed with the accountabilities being applied on auditors and staff producing policies. As such, the HFEA have seen evidence that corrective actions for the QMS were employed immediately after the first inspection and that our employment of a PM and her work to date evidences corrective actions in regards to the QMS which will be completed by 6.9.18. With regard to training on audits, the PR set up new format audits with explanations as to their use after the 2016 inspection which the inspector was happy with (see	

		attachments Z and ZA). Since the arrival of our PM we started progressing this further in 2017 by being descriptive (observed by our current inspector) to avoid personal interpretation of audit conditions by the auditor. This again shows progressive action by the clinic before inspection. For current staff training requirements there is going to be a presentation to members of the whole team by the newly formed 'audit committee' of 4 team members. There is now going to be an audit meeting where the team can look at timescales and ensure audits are progressive with corrective measures implemented. The PR maintained a traffic light system email with the team after the 2016 inspection showing all points raised at inspection were actioned. The majority of these were not checked at our inspection in March 2018. (Attachment C)	

		A summary report as requested above can be found it attachment ZF. Additionally see attachment ZR.	
3. Medicines management: During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be non- compliant with guidance because: • The Controlled Drugs Accountable Officer (CDAO) regularly orders controlled drugs. • The CDAO has cause to prescribe controlled drugs and the inspection team are not assured that this is in exceptional circumstances or cases of emergency as per regulatory requirements. • In the event of a concern relating to the CDAO's practice, there is no person to whom she is accountable or open to scrutiny.	The PR must ensure that medicines management practices at the centre are compliant with regulatory requirements. The PR must investigate why non-compliances identified at the renewal inspection, have not been addressed. The PR must review the requirements of the CDAO role and ensure that the person undertaking this role fully satisfies these requirements. This should include, but is not exclusive to, having the necessary competence, knowledge and authority to undertake the role. The PR must ensure that there is an appropriately skilled person to oversee the CDAO, in the event of a concern	Contrary to the draft report, the CDAO does not and has not ever 'regularly ordered' controlled drugs. This conclusion may be erroneously drawn from the 2016 report which stated the CDAO 'regularly orders controlled drugs'. At that time in 2016, a different CDAO was in post who did order and prescribe controlled drugs. From 1 May 2017 to 1 May 2018, controlled drugs have been ordered four times. None of these four orders were placed by the CDAO. This cannot be said to constitute 'regular ordering'. The most recent audit of the CDAO showed that she prescribed / or witnessed the prescribing of CD's in 5% of cases which we believe to be exceptional circumstances and only occurred in the event of	The Executive acknowledges the PR's response and confirms that the CDAO is one of two people authorised to order controlled drugs and has amended the report accordingly. The Executive cannot reconcile the PR's claims in his response but acknowledges the actions taken and commitment to implementing this recommendation. No further action beyond submission of the medicines management audit report due by 6 September 2018.

• The controlled drugs audit lacks scope (see QMS section for further detail). • The time of administration of controlled drugs was not recorded in the controlled drugs register in all cases and was also not recorded on the patient's anaesthetic chart. • Corrections in the controlled drugs register, did not follow the centre's reported procedure or regulatory requirements. • The inspection team were not assured that the CDAO fully understood her role and responsibilities when questioned. • The centre did not provide a controlled drugs SOP when requested to do so. Medicines management was a major non-compliance at the renewal inspection so has been escalated to critical non-compliance at this inspection.	relating to the CDAO's practice. The PR should provide a summary report of the review including actions taken to implement this recommendation, staff training requirements and timescales for implementation, to the centre's inspector when responding to this report Three months after the implementation of corrective actions, the PR should audit medicines management practice to ensure that actions implemented have been effective in achieving and maintaining compliance. A summary report of this review should be provided to the centre's inspector by 6 September 2018.	one of the other medics being on annual leave. This has changed since February 2018 when a further medic joined the CRGW team. The CDAO is accountable to the PR who, as of 1.5.18, has to sign off on any occasion on which the CDAO has to order CD's or prescribe them. The PR emailed all staff on 9.5.18 outlining how they could report any concerns of the CDAO to the PR (or indeed HIW or the GMC). Accountability to the PR was in place previously but is now documented to record incidences of, for example, the CDAO prescribing CD's to patients and the PR acknowledging and signing before hand the exceptional nature of the circumstance. That the controlled audit lacks scope has been addressed by the restructuring of audits as mentioned elsewhere and evidenced in attachments. The issue of time of administration not always being recorded in the	

SLC T2; T15(a) CoP 25.21; 25.23. Controlled Drugs (Supervision of Management and Use) Regulations 2013. The Misuse of Drugs Regulations, 2001; Section 20(c)		controlled drugs register or patient chart has been checked by the PR since this issue was raised at inspection. All timing of administration of controlled drugs has been recorded since inspection and the PR assures compliance in this regard. At renewal inspection (2016) I responded to the HFEA: The controlled drugs officer has been to changed to Amanda O'Leary since inspection who does not have daily access to the controlled drugs as Hatel Tejura did when giving conscious sedation. This change can be observed / confirmed on the HIW website. Therefore the prescribing docs and the CDAO are no longer the same person. A controlled drugs stock check is now performed daily by 2 members of staff (lead nurse +1), the amended SOP reflects this new practice. The updated SOP also describes exactly how amendments or corrections are recorded and also how unused drawn up	

		controlled drugs are recorded in the register. These new practices are subject to a new audit in October. Our inspector then responded: The SOPs submitted have been reviewed and based on these and the PR's response, we are satisfied that appropriate action has been taken to address each observation noted in this recommendation. As such we clearly responded and were told that the HFEA was satisfied. Attached are our medicines management SOPs (attachments D&E). These were NOT requested at inspection and were therefore not seen by the inspectors. We submitted these SOPs to the Home Office in December 2017 and the Home Office were satisfied with them. At the time, the Home Office stated that they were happy for remarks to errors to be written clearly in the body of text and not as a footnote (as stated in the Home Office guidance	

		information sheet). This is stated in our SOP as statements to errors can be written in either place so it is incorrect in this report to state that corrections in CDR did not follow our SOP or regulatory requirements. As the HFEA did not request to see these SOP's (as suggested) it would be implausible to state knowledge of the content of them. During inspection one of the inspectors asked how we knew that nurses were 'competent to count the controlled drugs stock' and had we 'assessed their competency in counting'. The nature and tone of this enquiry was patronising and insulting. The inspector then proceeded to count our midazolam stock and incorrectly counted five instead of ten ampoules. Two inspectors stated that our CDAO was not able to prescribe controlled drugs OR fertility drugs. We informed the inspector at the time that this was incorrect. This statement was later reiterated to the PR	

		by the senior inspector. The PR also responded that this statement was incorrect but the senior inspected reaffirmed it was her view. She then proceeded to check on her computer and both inspectors accepted that we were correct and that the CDAO COULD prescribe fertility drugs. There was therefore no confusion on the role as CDAO by the CDAO the only confusion was with HFEA inspectors. To say that the CDAO acted outside of the code of practice for medicines management and that no one would challenge her misrepresents the centre and is insulting to other clinical professionals. All other doctors and nurses work within their professional guidance and if the CDAO were to act inappropriately she would be challenged. Our CDAO is open to scrutiny and accountable to every clinical staff member. Finally, we had our Home Office renewal of controlled drug license inspection two	

		weeks before the 2018 interim HFEA inspection. The Home Office inspectors deemed our current CDAO to have the knowledge, competence and authority for the role to enable the granting of our current license. A summary report as requested above can be found it attachment ZF. Additionally, the attachments ZN and ZO are our SOPs for management of controlled drugs.	
4. Prescription of Intralipid 'off label': The process for administering and monitoring patients during intralipid infusion was reviewed and considered not suitable because: • Whilst the centre's information for patients regarding immunology treatments has been amended following the renewal inspection in 2016, clinicians reported to the inspection team that they prescribe as per the patient's request and	The PR must ensure that the processes for prescribing, administering and monitoring intralipid infusions 'off label' are compliant with professional body guidance. The PR should ensure that there is an SOP in place to direct the assessment of patients, and the prescription, administration, and monitoring of intralipid infusions. The PR should provide a copy of this SOP to the centre's	There is no formal assessment of suitability for intralipids except for allergies to peanuts, eggs and soya and previous adverse reactions to intralipids which we have always undertaken and documented, and which is on the consent form signed by intralipid patients. We do have and always have had an SOP for intralipids. It is therefore incorrect to suggest that we do not have an SOP in place (see attachment F). When a patient tells us their previous clinical history with	The Executive cannot reconcile the PR's response that staff training for the care of patients undergoing intralipid therapy is the same as oocyte collection. The document (ZB, post oocyte collection) to which the PR refers, states that observations are undertaken every 15 minutes, yet the SOP for intralipid infusion (submitted with this report), which the PR states in his response, has always been available, requires that observations are taken every 20 minutes. Therefore, if staff training is the same as

do not undertake an assessment to determine the patient's suitability for immunology treatment. • The centre does not have an SOP guiding its own practice in the administration of intralipids. The PR was asked to submit a copy to the inspection team after the inspection but has not done so. • Where patients have attended other licenced centres for previous treatment cycles, clinicians reported that the timing/stage in treatment of administration of intralipids for patients having two infusions, is based on the same treatment pathway they followed at a previous centre. The centre neither confirms the account given by the patient nor makes their own assessment of the situation.	inspector when responding to this report. The PR should ensure that staff are appropriately trained and assessed as competent to care for pateints undergoing intralipid treatments. Following a comprehensive review of the process for providing intralipid treatment to patients, the PR should provide a report to the centre's inspector of the actions to be taken, with timescales for their completion, to address the issues identified in this report. It is expected that the report will be submitted by 6 June 2018. Three months after the implementation of corrective actions, the PR should audit practice to ensure that they have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the	intralipids, we mirror it if it was successful, just as other clinics do. We do and have always recorded the reason for prescribing intralipds in the patient records - contrary to the opinion stated by the inspectors. These reasons are set out in the progress notes on IDEAS which would have been readily accessible to the HFEA at inspection. Staff training for doing observations on intralipids patients is the same as taking observations on egg collection patients. Evidence can be seen in attachment 'ZB' As a clinic we have offered intralipid infusion on a very small scale. This has typically been when patients have asked us for intralipids having had previous successful treatment including intralipids, or when having treatment elsewhere from a clinic 'requesting' intralipids, or when a patient has read about intralipids and wants the therapy as an add-on with the	oocyte collection observations the training is not in-line with the centre's intralipid SOP. This would cause the Executive further concerns about the practices at the centre, however, as the PR has stated that the centre will no longer be undertaking intralipid therapies, no further action is required.

• The centre does not record the reason for prescribing intralipids in the patient records. • Staff monitoring patients undergoing intralipid infusion have not been trained to do so, and have not had their competencies assessed. • The inspection team are concerned that only the specific aspects of the non-compliance identified at the renewal inspection have been addressed and that a change in practice and ongoing review and audit has not occurred. Intralipid use was non-compliant at the renewal inspection and the inspection team conclude that current practice poses a significant risk of causing harm to patients, therefore, this non-compliance has been escalated. SLC T2; T9(f); T12; T15 (a) and(b).	centre's inspector by 6 December 2018.	perceived benefit to certain individuals of inhibiting pro-inflammatory factors or reducing the cytotoxic effects of NK cells. Unlike other clinics in the sector who 'recommend' intralipids and IVIG liberally to patients for a multitude of reasons or theories, we have offered it rarely, never 'recommended' it, and accompanied its use with a waiver confirming that current evidence does not support its use. There appears to be disparity in the response of the HFEA to clinics offering 'immune treatments' as several clinics particularly in London continue to recommend intralipid (and IVIG) routinely and use it liberally in many patients. These clinics' inspection reports indicate a lack of consistency in at inspection by the HFEA. CRGW are concerned as to the disparity as to how the HFEA applies its rules against differently across clinics in the sector in	

RCOG guidance April 2015. HFEA Clinic Focus July 2015.		circumstances where we are being singled out for limited use of immune therapies when other clinics are allowed to continue infusion without any required remedial action. In any event, we have decided to stop our rare use of intralipids as of 1 June 2018 which allows us to treat patients who have already requested intralipid treatment and who are currently in treatment. See attachments F and F1 for intralipid SOP and intralipid patient consent. At the 2016 inspection, I emailed the team my monthly email in response to my receipt of the HFEA Focus email in July 2015 (as I do each month) which detailed potential issues with off-label intralipid use. Using the Focus HFEA bullet point recommendations and the MHRA guidance on off-label use of medicines on its website, I personally	

		formulated the attached (document F1)intralipid off label use waiver. I believe that this patient information sheet addressed HFEA and MHRA requirements. We did and have continued to consider the RCOG guidance in the use of intralipids at CRGW. Since the 2016 inspection we added a system of traceability of batch numbers for intralipid with the SOP being ammended accordingly. While there is still a lack of solid evidence, intralipids are very cheap (certainly at CRGW if not elsewhere), well tolerated, have few side effects (we screen for allergies at consent) and relatively no risks compared to blood products like IVIG used elsewhere (at very high cost) with the same outcome. Studies have shown suppression of NK cell cytotoxicity by the action of intralipids modulating NK cell activity and with the small costs and risks mentioned above this could be the difference between being	

		pregnant and not in occasional patients. Following our 2016 inspection, the HFEA responded that “The PR’s response and accompanying patient waiver clearly outlines that the use of intralipid is off-label and is consistent with HFEA guidance”. No further action required.” As such the HFEA inspectors remarks suggested compliance.	

‘Major’ area of non-compliance

A major area of non-compliance is a non critical area of non-compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties;
- which can comprise a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

A major area of non-compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
5. Infection control: On inspection the following issues were noted: • Temporary closures on sharps bins were not in use. • There was no date or signatures on the sharps bins as required for appropriate waste management procedures. • The flooring in some clinical areas was only partially sealed. • There was skirting board in some clinical	The PR should ensure that the that infection control measures and practices are compliant with regulatory and best practice guidance. The PR should review the premises in relation, but not exclusively, to the issues identified in this report. The PR should seek pathology advice regarding the appropriate storage of blood samples prior to their transportation to a laboratory	At inspection, the inspection team observed one out of thirteen sharps bins in the clinic to not have partial closure. As such, the description of 'temporary closures on sharps bins were not in use' is factually incorrect as this suggests more than 1 bin. At inspection, the inspection team observed 1 sharps bin out of the 13 sharps bins in the clinic that was not dated or signed when opened. As such the description of 'there was no date on the sharps bins as required' is factually incorrect	The Executive notes the PR’s response and confirms that more than one sharps bin was found to be non-compliant with infection prevention and control requirements. The non-compliance has been graded in relation to the culmination of the issues identified at the inspection. Good infection prevention and control practices and procedures are essential for the safety of patients, staff and service users.

areas, some of which, were dusty. • Seating in some clinical areas was made of porous material and the fabric was frayed in places. • There was no sink on the phlebotomy room. There is a risk of cross-contamination, by having no hand wash facility in a room in which clinical waste may be handled. • The men's production room is not routinely cleaned between each patient's use. • There are no elbow taps in one of the consultation rooms where clinical procedures occur and blood samples are taken. • There is carpet in one of the consultation rooms where blood samples are taken. • Clinical linen and staff uniforms are washed	The PR should provide a summary report of this review, including the actions taken to achieve compliance and timeframes for implementation to the centre's inspector by 6 June 2018. It is expected that all aspects of this non-compliance will have been fully addressed and compliant by 6 September 2018.	as this suggest more than 1 bin. As PR, I have walked the clinic twice since inspection and all sharps bins are fully compliant. An email was been sent the team to clarify requirements. In November 2017 at an inspection at another clinic, sharps boxes were not labelled and open. The HFEA labelled this as an 'area of improvement' and not a major non-conformance. The same clinic also had out of date syringes in an emergency box which again was labelled by the HFEA as an area for improvement. This shows further disparity in the assessment of clinics by the HFEA. Partially sealed floors (which have always been deemed complaint prior to this years inspection) were fully sealed on 8.5.18. (see attachment J). During the inspection, the inspectors observed one skirting board that had some	The Executive acknowledges the actions taken to implement this recommendation. No further action required.

on site using a domestic washing machine, which was leaking at the time of the inspection and had not been serviced. • Boxes of food and water were found to be stored on the floor in a store cupboard. • Blood samples were stored in a drugs fridge awaiting collection. SLC T2; T17. CoP 25.19; 25.20. DH Health Building Note 00-09: 'Infection control in the built environment' 2013. DH Health Building Note 00-10; 'Flooring' 2013. DH Health and Social Care Act 2008: Code of practice on the prevention and control of infections and related guidance.		dust on it in one room. The phrase 'there was skirting board in some clinical areas some of which were dusty' is therefore factually incorrect as this suggests more than one skirting board showed dust. The checking and cleaning of the skirting boards has been forwarded as an action for reminder on the cleaners' checklist. All porous patient chairs were replaced by new chairs on 1.5.18. (see attachment J) Some leather (in milimeters) was observed peeling on one consultation room chair (one out of 71 chairs in the centre). These chairs are used by clothed patients who are not undergoing procedures. As with other statements above, the inspectors' statement suggests that such fraying was evident in more than one chair which is factually incorrect. , This chair was in any event replaced on 1.5.18. (see attachment J)	

DH Health Technical Memorandum 07-01 Safe Management of Healthcare Waste (2013).		In July 2017 at another clinic, seats in clinical areas were found by inspectors to be non-wipable. This was deemed to be 'an area of improvement', not a major area of non-compliance, again showing disparity in the application of requirements between clinics. It is correct that there is no sink in the phlebotomy room. At our previous inspection (the joint HFEA and HIW inspection) we were told that alcohol gel sufficed in the absence of a sink for that room and were therefore compliant. Therefore conditions are being applied differently and inconsistently at different inspections. Furthermore, a statement from HIW regarding a sink in the room (attachment G) shows us to be compliant. The men's production room now has sign off for cleaning on back of door between patients (see attachment J). The consultation room that did not have elbow taps had them	

		installed on 30.4.18 (see attachment J). The only consultation room (one of four) where examinations were NOT carried out and was therefore carpeted has now has had carpet removed and vinyl put down on 4.5.18. (see attachment J). The washing machine has never leaked before or after inspection so must have been incorrectly closed. The machine is in full warranty so can have engineer checks if there are any problems. The wash cycles are validated with calibrated digital thermometer which is placed inside the drum on a washing cycle and then downloaded. (Attachment H) Further temperature logs were carried out to ensure compliance with HSE standards 2013 for washing of infected linen. Current recommended treatments to ensure cleaning and disinfection of used (soiled and foul) linen:	

		• A 65 degrees C temperature hold for a minimum of 10 minutes within the wash cycle; or • A 71 degrees C for not less than 3 minutes. The temperature test log confirms theses are being met Washing machine temperatures document attached (H). Food and water in the upstairs store cupboard and sterile water in embryology store room have both been moved to elevated positions post inspection as requested. Regarding blood samples being stored in a temperature monitored fridge rather than at room temperature as suggested by the inspector, please see the guidelines that we follow regarding sample storage (attachment I) which confirms our working practice in this regard as correct.	
6. Donor screening: On inspection the following issues were noted: • Staff reported that they do not consider past	The PR should ensure that donor screening practices are compliant with standard licence conditions, regulatory	The draft Report states that past travel history is not considered This is incorrect: it is in the IDEAS checklist and is considered at consultation.	The Executive notes the PR's response, however, the inspection team found that practice did not align with centre procedures.

travel history when screening donors. • SOPs do not document the need for Ebola and Zika virus screening ('oocyte donation' and sperm donor SOP). • In one record reviewed during the inspection the donor had been screened outside the timeframe specified by the Authority. • The sperm donor SOP does not document the requirement for a physical examination as per professional body guidelines and staff report this is not part of their assessment of sperm donors. • The 'oocyte donation' SOP is confusing, in that it documents a requirement to take a £500 deposit from an egg donor. Centre staff report that this applies to 'egg share' patients, but the SOP does not make this differentiation	and professional body requirements. The PR should review donor screening practice and ensure measures are put in place to ensure compliance with this recommendation. A summary report of this review including corrective actions taken should be provided to the centre's inspector by 6 June 2018. The PR should ensure that the centre's SOPs are compliant with the requirements to screen donors, by making the necessary revisions and implementing revised practice. A copy of the revised SOPs should be provided to the centre's inspector by 6 June 2018. Three months after the implementation of corrective actions, the PR should audit donor screening practice to ensure corrective actions have	It is also clearly covered in our SOP (see attachment ZS). We now have a sign visible around the clinic asking patient to inform clinical team if they have visited an Ebola or Zika effected country. Oocyte donor and sperm donor (attachments ZP and ZT) now do contain that we 'screen' for having travelled into an affected country. The inspectors reviewed the instance of a 'donor screened outside the timeframe specified by the authority' correctly at inspection. The donor's screening bloods were taken on 11.11.16 with the first sperm banking being carried out on 31.3.17 (which meant the screening was 2.5 weeks outside the ideal 3 month screening window). As such, we do accept this is a non-compliance as indicated in the draft Report and as a result of this a second set of screening bloods will be undertaken on sperm donors upon completion of consent forms prior to the first sperm	The Executive cannot reconcile the relevance of the PR's comment referring to the 2016 inspection actions. The PR has acknowledged in his response to this report that he accepts that donor screening was non-compliant and has taken action to address the recommendation. The Executive acknowledges the PR's commitment to implementing this recommendation. No further action required.

and makes no reference to 'egg sharing' only to egg donation. • The centre's egg sharing information for patients is not in line with guidance in that it states that if the sharer withdraws her consent, she will have to pay the cost of the treatment and drugs. Code of Practice (CoP) guidance states *'If either the gamete provider or the recipient in a 'benefits in kind' arrangement withdraws their consent to treatment after preparation has begun, the centre should bear any financial loss it sustains as a result'.* Donor screening was a non-compliance at the renewal inspection. SLC T52; T53(b).	been effective in maintaining compliance. A summary report of this review should be provided to the centre's inspector by 6 September 2018. The PR should review the centre's 'egg sharing' information for patients and ensure it is compliant with CoP guidance, and is clear in outlining egg sharing arrangements. The PR should provide a copy of the revised patient information leaflets to the centre's inspector by 6 September 2018. The PR should review the centre's 'oocyte donation' SOP to ensure it is compliant with regulatory requirements and clear in its differentiation between egg sharing and egg donation. A copy of the revised SOP should be provided to the	freeze to prevent this reoccurring. We have amended the Donor SOP to include a physical examination of each donor as per ESHRE guidelines. Team instructions and an action plan were sent to key staff members on 4.5.18, checklists were amended and the SOP has been updated (see attachment ZT). The Oocyte Donation SOP updated now states that a £500 deposit is from egg share patients not altruistic egg donors. Egg sharing information is now in line with CoP that we bare financial loss (see attachment ZU and ZV). Following our 2016 renewal inspection, I wrote the following to our inspector after receiving the HFEA report: "I contacted Dr Cheuk Yan William Tong (Consultant Virologist at Barts) who spoke at Fertility 2016 in Gateshead. I emailed him on 14.1.16 explaining the aim to tighten	

Advisory Committee on Dangerous Pathogens (ACDP) 2017 Ebola. European Centre for Disease Prevention and Control (ECDC) 2017 Zika virus. CoP 11 and 12.	centre's inspector by 6 September 2018.	the screening window while allowing sufficient time to receive virology results and prevent patients starting stimulation medication unnecessarily before we have the results in the event of a seroconversion. His response was "…With this in mind, screening within 3 weeks before donation would give the lowest possible risk of transmission through seroconversion. As it usually takes 1 -2 weeks for results to be reported back to the clinic, 3 weeks seems a very reasonable time frame as well". As such this is now current practice for egg donors at CRGW." I received the following response from our inspector, Douglas: "Appropriate action has been taken. No further action required." As such this again suggests the HFEA believed us to be compliant at this time.	

7. Safety and suitability of premises: On inspection the following issues were noted: • A large faulty nitrogen tank was being stored in a corridor that led to a fire exit. This could impede the evacuation of patients and staff in the event of a fire. • The patients' emergency call bells in the recovery area are not routinely checked by centre staff. • The room storing medical gases was non-compliant with statutory regulations because: o the store room did not have any ventilation; o the content of the room was not clearly labelled on the outside; o there was no safety signage in the area, for	The PR should ensure that the premises are safe and fit for purpose. The PR should ensure the faulty gas tank is removed from the corridor and placed in a safe, suitable location until its disposal. The PR should confirm to the centre's inspector that this has been done, when responding to this report. The PR should review the gas storage facilities and ensure they comply with regulatory requirements. The PR should provide a summary report of the review, including corrective actions taken, to the centre's inspector by 6 June 2018. It is expected that full compliance with this recommendation will be achieved by 6 June 2018.	The liquid nitrogen tank was not faulty as described, but it had lost efficiency, prompting us to order a new one to reduce liquid nitrogen deliveries (which can impact upon patient parking for several minutes). A 240 litre liquid nitrogen tank (when empty) weighs 140kg which is the equivalent of a 22 stone person. Due to this we were arranging for four people to help move it. The tank was 68cm at its widest. The corridor is 151cm wide, therefore providing an 83cm gap. As doors should have a minimum clear opening width of 800mm (830mm is preferred) for a wheelchair, we used the same standards to apply to the temporary location of the empty vessel. The mobile operating table in theatre would also pass through the same gap. The liquid nitrogen tank has been relocated since the inspection. It is not being disposed of since it is not faulty but rather	The Executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required.

example warnings prohibiting naked flames and 'no smoking' signs; o emergency action notices giving details of emergency actions procedures, were not posted on the outside of the store. CoP 25.4(b) and (e). DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006). DH Health Technical Memoranda (2013).		going into storage for backup use. Patients' emergency call bells while checked were not recorded daily. This practise began when this was mentioned on the day of inspection and daily checks and signoffs are now performed and recorded at the nurses station. (see attachment J). The medical gasses room has been complaint at all previous inspections and has never raised concerns by BOC or medical gas piping installation companies so has always been assumed compliant. Regardless of this, a fire regulated door ventilation grille has been purchased and installed (see attachment J) The content of the room is now clearly labelled on the outside of the door with all safety stickers and emergency procedures applied. (see attachment J) The HFEA statement that there was no safety signage in the area is factually incorrect	

		as there is and was at inspection a 20cmx25cm bright yellow warning sticker on the door for compressed gas. All tanks stored inside the gas room are non explosive, non flammable compressed gas. As such no smoking signs would be irrelevant. At a clinic inspection in 2017 at another clinic, cylinders in the gas room were not chained and secure. The HFEA labelled this as only 'an area of improvement', again highlighting a disparity in the application of standards. Emergency notices giving details of emergency action procedures now posted	
8. Emergency resuscitation equipment: On inspection the following issues were noted: • Equipment on the emergency resuscitation trolley had expired in 2015 (for example, syringes and blood bottles). • The containers in which the emergency	The PR should ensure that the emergency resuscitation equipment is complete, fit for purpose and compliant with best practice guidance. The PR should ensure there are documented procedures in place for the checking and management of the resuscitation equipment, including, but not exclusive to,	We acknowledge the out of date syringes and blood bottles identified during inspection. These were removed and replaced on the same day this was discovered at the inspection and our new checklist and use of tamper proof boxes prevent this happening again. Attachment ZC explains our new daily and monthly	The Executive notes the PR's response and re-iterates that it is the culmination of issues identified at this inspection that have led to concerns for the safety of patients and therefore the grading of this non-compliance. The Executive cannot reconcile the PR's claim that a checklist of the contents of the

resuscitation drugs were stored, had syringes in them that had expired in 2015. • The emergency resuscitation drugs were not stored on the resuscitation trolley, but were kept on a work surface in theatre. • The equipment on the emergency resuscitation trolley, and the defibrillator had not been checked for more than two weeks. Varying accounts were given by staff as to the frequency of checks. • There was no record of the frequency of emergency equipment checks and as staff gave varying accounts as to when these checks should take place, the inspection team are concerned that checks may be missed. • There was no checklist of equipment that	the frequency of which the checks will be completed and a list of equipment that should be contained on the trolley. The PR should ensure that emergency resuscitation drugs are contained within a tamper-proof container as per Resuscitation Council requirements. The PR should provide the centre's inspector with a summary report of the actions taken to ensure compliance with this recommendation, by 6 June 2018. Three months after implementing corrective actions, the PR should audit the management of the emergency resuscitation equipment to ensure that corrective actions implemented, have been effective in maintaining compliance. A summary report of this review should be provided to	checklist of the resuscitation equipment. We note that another clinic recently had out of date consumables on their resucitation trolley for which the HFEA labelled this to be 'an area for improvement' only. This again shows a disparity in the application of license standards between clinics. We acknowledge that all emergency drugs were located in the same place in theatre (a desktop in clear plastic labelled containers) meaning the resuscitation. Drugs were not on the resuscitation trolley but rather two steps to the left of the trolley with the two other emergency drugs boxes for anaphlaxis and for reversal of sedation drugs. These drugs are now stored on the resuscitation trolley in newly purchased tamper proof clear plastic containers (see attachment J) The frequency of checks on the resuscitation trolley had	emergency resuscitation trolley was available at the time of the inspection when it was not produced on request of the inspector. The Executive is concerned by the PR's comment regarding the location of the emergency resuscitation drugs. Patients, service users or staff could collapse anywhere in the centre, at any time, and in an emergency, practitioners should expect that all essential equipment and medication is contained within the emergency resuscitation trolley, ready for use. The Executive acknowledges the action taken by the PR to implement this recommendation. No further action beyond submission of an audit of the management of the emergency resuscitation equipment, due by 6 September 2018.

should be present on the resuscitation trolley. • Emergency resuscitation drugs were not stored in tamper-proof containers. • Checks that are undertaken are not robust as out of date equipment was found on the trolley by the inspector. SLC T2. Resuscitation Council (UK) 2015: Quality standards for cardiopulmonary resuscitation practice and training.	the centre's inspector by 6 September 2018.	historically been fortnightly at CRGW but the team that inspect our trolley from Royal Glamorgan Hospital showed guidelines to be monthly between checks hence differences in the accounts of staff. The person performing the checks however knew the checks to be monthly. There was and still is a checklist of the contents of the trolley hanging from the side of the trolley at the time of inspection but the inspector neither looked at is or asked for it. As such the statement that no checklist was present is factually incorrect (see attachment J). New system of checking resuscitation trolley is robust and airtight. The resuscitation cart is now fit for purpose, compliant and within best practice guidelines. Documented procedures for checking and managment of resuscitation equipment is attached. The frequency of checks andlist of equipment contained on the trolley are	

		both evident. Emergency resuscitation drugs are in tamperproof container as per resuscitation council. Two people currently witness and sign off resuscitation equipment. On the 22.5.18 the resuscitation team from Royal Glamorgan Hospital are attending CRGW to externally assess confirm compliance with the resuscitation council requirements.	
9. Safeguarding: On inspection the following issues were noted: • The safeguarding lead was unaware of the content of the centre's safeguarding policy. • Staff at the centre did not know who the safeguarding lead was. • The safeguarding lead was unable to identify vulnerable groups, reporting that the population served by the centre 'is not a high-risk population'.	The PR should ensure that a suitably competent and knowledgeable safeguarding lead is appointed. The PR should review the centre's safeguarding policy and safeguarding practices and ensure they comply with CoP requirements. The PR should ensure that staff are conversant with the centre's safeguarding policy and the actions to be taken in the event of a disclosure.	Attachments K and K1 have been re-read and signed off by Safeguard lead with amendments for out of hours and weekend contact details included as requested by inspection team. PR emailed the whole team prior to receiving the inspection report re-iterating and defining safeguarding and reminding the team who the safeguarding lead was (attachment L). That the safeguarding lead was unable to identify vulnerable groups is	The Executive notes the PR's response and confirms receipt of the independent assessment of the centre's safeguarding lead, undertaken after the inspection (3 May 2018). The Executive also notes the additional recommendations from this assessment and trusts that these will also be implemented by the PR. The Executive is assured, by this assessment, that the centre's safeguarding lead has now attained a level of

• The safeguarding lead reported she had no competency in this area of practice. • The centre's policy does not document what to do if a disclosure is made out of normal office hours or weekends. • The account given by the safeguarding lead of actions to be taken in the event of a disclosure was not in line with the centre's SOP. • The inspection team conclude that the safeguarding lead is not competent to undertake the role. SLC T2; T12. CoP 25.33; 25.34; 25.35; 25.36.	A summary report of the review, including corrective actions taken, and a copy of the revised SOP demonstrating compliance with this recommendation should be provided to the centre's inspector by 6 June 2018.	completely and strenuously denied by CRGW. Also the statement used of "not a high risk area" to try to demonstrate by the inspector that the safeguard lead was not competent shows the inspectors' lack of understanding of safeguarding assessment, rather than our safeguarding lead's lack of competency. Various publications and Department of Health guidelines do not currently recommend routine assessment in low risk clinical settings, apart from in areas deemed to be high risk, such as antenatal settings and forensic gynaecology services. That the safeguarding lead reported that she had no competency in safeguarding is completely and strenuously denied by CRGW and the safeguarding lead. The safeguard lead has carried out two level 3 courses on safeguarding, as requested by previous HFEA and HIW inspection teams in 2016. The	knowledge and competence to carry out the role. The Executive cannot reconcile the PR's denial of the account given by Dr O'Leary to the inspector regarding her competency in safeguarding, when, it is understood that he was not present during any of these discussions. The PR makes a number of references in his response to the 'current inspector'. The centre's current inspector did not review this area of practice during the inspection. The Executive acknowledges receipt of the revised copy of the safeguarding policy and confirmation of the action taken by the PR to inform staff of their responsibilities. No further action required.

		safeguarding lead has also been competency assessed by an external assessor (a Clinical Director of a large NHS trust, whose service covers safeguarding issues) on 03.05.18- (see attached document M) who has undergone safeguard training to level 3. This same assessor also assessed our safeguarding service and has suggested measures to update our staff training which are being put in place so that staff feel more comfortable dealing with child sexual exploitation and female circumcision issues should these arise. As such the PR is satisfied that the safeguard lead continues in the role accordingly. As a support to the safeguarding lead and in the event of the safeguarding lead being absent from the building if a disclosure is made the PR has also booked on to level 3 safeguarding courses to support the role and offer an alternative point	

		of contact for the CRGW team. The inspector was very patronising when discussing safeguarding. When our safeguard lead stated that at our 2016 inspection it was raised that no one had completed level 3 training in safeguarding, the HFEA inspectors said that a member of staff would need to do this training and that an online training course would be suitable. Our current inspector, however, said that she did not think that online training was suitable to show competency, as if she "undertook a training day course to do brain surgery it wouldn't mean that she would be competent to do surgery". We replied that day courses to do brain surgery do not exist and that safeguarding is an add-on skill to training already undertaken and not a new career skill such as brain surgery.	
10. Record keeping:	The PR should ensure that proper records are maintained	The first bullet point is questioned by the CRGW	The Executive notes the PR's response and is concerned

On inspection the following issues were noted: • The centre does not keep a record for each patient. In four of the seven records reviewed, the medical information for both of the intended parents had been recorded on a single sheet of paper. • In one of the records reviewed the intended parents and the surrogate woman's medical history was recorded on one sheet of paper. • The person by whom the patient's identity is verified, is not always documented. • In one record the scanned consent forms were unclear and unreadable in parts. • In one patient record a procedure 'observation sheet' was not signed and did not record the time a drug had been	as specified the Authority and professional body guidance. The PR should review record keeping practices and address all the issues identified in this recommendation, ensuring that actions are implemented to achieve compliance with regulatory and professional body requirements. The PR should provide the centre's inspector with a summary report of this review by 6 June 2018. Three months after the implementation of corrective actions, the PR should audit patient records to ensure that corrective actions implemented, have been effective in maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 6 September 2018. The PR should provide a copy of a record keeping SOP to	team as all IVF clinics put couples (intended parents or not) on the same history sheet. Historically, we saw surrogate / surrogate couple and intended parents together (if they wished to be seen together) where notes were recorded on the same file for IP's. We have since stopped this practice and one of our consultants has since completed a record keeping course to update and confirm practice meets guidance (see attachment N). The administration team write 'this is a true likeness of…' on the back of patient photos. The PR has emailed all members of admin to remind them to sign / initial / print name on the photo also. (see attachment O). In regards to unclear / unreadable consent in one patient scanned record, it is difficult to action this in regards to the hundreds of documents that are scanned	that the PR should justify non-compliant activity at his centre by the measure of other centres. The PR has a responsibility to ensure he is compliant with SLCs within his centre not that of other clinics. The Executive is concerned by the PR's response in relation to the completion of patient observation sheets. These should be completed at the time the patient is receiving care. If large volumes of paperwork are being completed, as the PR claims, the Executive is concerned as to whether patients are being appropriately monitored. The Executive notes the PR's response about the offer of counselling and remains concerned at the PR's dismissal of being unable to evidence that the offer of counselling was made to the patient in question, when this is a legal requirement.

administered to the patient. • In the record of a single woman, the offer of counselling had not been documented in the patient record. • The centre has not conducted an audit of the records. • The centre does not have an SOP directing the completion and standard required of clinical records. HF&E Act 1990 (as amended) section 13. SLC T33(b); T36; T37; T38; T39; T46; T47	the centre's inspector by 6 June 2018.	each day. If in received medical notes a particular note is already lightly printed this may then be hard to read after scanning also. It would be impossible to check every scanned document for clarity then this has not proven to be an issue. To action this therefore the random checking of a sample of notes will form part of the new record keeping audit. One patient observation sheet was not signed and did not record the time a drug had been administered. This is an example of human error when large volumes of forms and paerwork are completed. There is no evidence of a trend in this regard and it is of course the centre's usual practice to ensure that all records are properly completed. In ONE record of a single woman there was no documented offer of counselling. This does not evidence that counselling was not offered to this patient.	The Executive acknowledges receipt of a record keeping SOP. No further action beyond submission of a record keeping audit due by 6 September 2018.

		This has been added to our IDEAS checklist so that evidence will be available for all patients The new template for the audit of record keeping and safeguarding have been completed (see attachment ZL). Our SOP for completion and standard required for clinical records can be reviewed at attachment ZW.	

‘Other’ areas of practice that requires improvement

Areas of practice that require improvement are any area of practice in which failings occur, which cannot be classified as either a critical or major area of non-compliance, but which indicate a departure from statutory requirements or good practice.

An ‘other’ area of non-compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
11 Surrogacy: On inspection the following issues were noted: • In one record the intended parent had completed a SPP consent form. This form should not be completed if ‘the surrogate is married or in a civil partnership and her spouse or civil partner consents to the treatment (the surrogate’s spouse or civil partner will be the other legal parent)’. When the patient completed this consent form, a surrogate had not yet been found. • The centre report that they have not routinely	The PR should ensure that the centre’s procedures for managing surrogacy treatments are compliant with Code of Practice requirements. The PR should review its surrogacy procedures to ensure they are compliant with CoP requirements and investigate why an intended parent was encouraged to complete a consent to legal parenthood form which was not appropriate at the time of her consultation. A summary report of the review and investigation, with corrective actions implemented, should be provided to the centre’s	The member of staff completing the SPP form with the patient did write 'awaiting surrogate' with the aim to show the patients intention. Our staff member considered completing a SPP form to be appropriate at the time in order to allow the couple to have all the information they required before they had confirmed their surrogate, as the female intended parent was very clear about wanting to be nominated as the second parent which she confirmed again (post inspection) at the treatment planning session as they have now confirmed their surrogate. Our staff member is fully aware of the legalities underlying legal parenthood in surrogacy	The Executive notes the PR’s response and remains concerned that the PR shows a lack of understanding of the statutory requirements of legal parenthood consents. The current law is clear, that if a surrogate is married/in a civil partnership and her husband/civil partner consent to her treatment, they will be the legal parents of any child born. The Executive would expect that this information was provided to the intended parents so that they could fully understand the implications of the treatment they were embarking on and the reasons why completing this form in the absence of a surrogate was inappropriate.

conducted welfare of the child assessments for the partners of surrogates previously, but have amended their practice now. CoP 5.3; 5.4; 8.4	inspector by 6 September 2018. Three months after the review, the PR should audit practice involving surrogacy to ensure that corrective actions have been effective in achieving and maintaining compliance with CoP guidance and the centre's SOPs. A summary report of the audit should be provided to the centre's inspector by 6 December 2018.	and did the SPP in good faith in order to protect the patients wishes. We accept that we had not routinely conducted WoC on the partners of surrogates but had amended practice before the interim inspection. Our SOP (attachment ZX) has been updated to reflect this as has our surrogacy GP letter (see attachment ZY).	No further action beyond submission of audit report due by 6 December 2018.
12. Implementing learning from guidance from the HFEA. The centre has not implemented compliance with guidance issued between May and September 2017 regarding: • The screening of patients based on their travel history. • The provision of information to patients about how to provide feedback to the HFEA. • Reviewing and embedding information for trans and non-binary	The PR should ensure that guidance from the HFEA is incorporated into practice. The PR should review the guidance issued by the HFEA since the renewal inspection and ensure compliance with the requirements of the guidance. The PR should provide a summary report of this review, and the actions taken to implement guidance, to the	I do not accept that we have failed to implement or incorporate HFEA guidance into our practice. I emailed the entire CRGW team about screening based on travel history on 5.4.17 (this was followed up at clinic meeting) (attachment R) this was added to the IDEAS treatment planning documents. On 8.5.17 I emailed the team about transgender issues (attachments U and U1) On 26.9.17 I emailed the team about trans patients and also	The Executives notes the PR's response and confirms receipt of actions taken in 2017 in response to HFEA guidance. However, the Executive is concerned that the PR has failed to have oversight and ensure that HFEA guidance, and his instructions have been implemented into practice, which has led to this non-compliance. The Executive would wish to clarify that centre's ratings on the HFEA website are

patients into their suite of information. • Incorporating Hepatitis A prevention into screening practices. SLC T32.	centre's inspector by 6 September 2018.	about the provision of patients feeding back to the HFEA (attachment U). We were sent HFEA leaflets / posters about patients giving feedback, but had a number of concerns about the accuracy and fairness of the inspectors rating of CRGW (as described elsewhere) so we did not display these. This will be addressed via our new website which is due to go live in May / June 2018. A Hep A email was sent to the team on 2/8/17 (see attachment V) Systems have been introduced by the PM to ensure accountability and that such requests are actioned. The PR also recognises that the process of implementation at the point of informing staff was suboptimal which has since been addressed.	inspection, not inspector, ratings and are based on the length of licence issued by a Licence Committee or Executive Licence Panel. The Executive acknowledges the PR's actions in implementing this recommendation and his acknowledgement that previous processes were 'suboptimal'. No further action required.

Additional information from the Person Responsible
It is noteworthy that the sad death of a baby in the 3rd paragraph of this report takes such overall prominence. The death, though tragic for all concerned, is acknowledged in the Trust's report to have been caused by obstetric complications. Had the baby's obstetric care been sufficient, the intended parents would have a child today. At no point in the draft Report or in any of the preceedings correspondence with CRGW do the HFEA acknowledge the detailed list of obstetric shortcomings described in the Trust's report but rather seek to attribute blame on the clinic that created the pregnancy. All obstetric experts consulted about this case have agreed that the outcome was due to obstetric failures. Additionally, there appears to have been an intentionally limited time for CRGW to reply to extremely lengthy HFEA documents in less than two weeks in circumstances where the HFEA Executives had worked on them for eight weeks, and when the HFEA Executives do not have the additional workload of having patients to treat concurrently. Furthermore, we were actively discouraged from putting in a detailed response by Ms Todd who wrote that she would not grant us an extension for our response since there was "not a substantial amount of work for you to do" – notwithstanding the depth and gravity of the allegations made, and the reasons given for requesting an extension. It would appear this is to prevent a clinic having ample time to reply sufficiently so as to allow the HFEA a stick to wield against the clinic in terms of its performance. The inspectors also appear to have been selective in parts in their wording in this report to make some circumstances sound considerably worse than they were, such as using pleural terminology when only singular events were observed. Further, the HFEA's position of 'there is no such things as human error' is at stark odds with a multitude of published evidence to the contrary. IVF has become more complex due to the adoption of highly technological laboratory procedures. In addition, the patient population being treated has broadened and often includes not only the intended parents but also gamete donors or gestational surrogates. As in other fields of medicine, these complexities have led to the adoption of more stringent control measures, to reduce the risk of errors. International data indicate that more than 99.9% of procedures proceed with no non-conformance event and most non-conformances are minor. This, again, attests to the excellent processes implemented by programmes. There is also an evident persistence by the HFEA to apply its conditions differently at different inspections of the same clinic; differently between different clinics, and even differently between clinics that have the same senior inspector. Such disparity is confusing and frustrating to clinics, and it shows a lack of internal validation and inspector competency assessments. There is a clear ambiguity in the way standards and licence conditions are applied between clinics and by inspectors. After the 2016 renewal inspection, our inspector recommended a 4-year licence. This was not granted by the Licence Committee, rather they granted a 3-year license as they believed that I 'had not engaged with the multiple birth issue'. Our senior inspector acknowledged that my perceived 'lack of engagement' at the time could not have been further from the truth and that I engaged thoroughly. He apologised that he did not know where the Licence Committee had got that impression from and he agreed that I had engaged, but that the HFEA 'didn't have a mechanism for change'. Further, the report incorrectly described our legal parenthood audit

as finding additional anomalies. This was not the case and our inspector again said he had no idea where the Licence Committee had gleaned this from but again that there was 'no mechanism for change'. He asked if I wanted to escalate this and spoke with another inspector to pass on all of the information we had discussed. In what other business or authority is 'no mechanism for change acceptable'?
I had a lengthy and detailed telephone discussion with the Sharon Fensome-Rimmer HFEA on 28.7.17 during which I was assured this would be investigated and fed back to me. To date I have heard nothing. I was again reminded that I had been promised that this would be dealt with by the HFEA on 21.12.17. To date, again, I have heard nothing. (Please see attachment X).
As outlined above, I did not say I 'did not wish to be hasty' in discarding samples. This is a rather selective recall of the conversation where I clearly stated the rationale for the late discard of the sample in question. I explained that (as mentioned in detail above), occasionally a patient's choice to discard may be brought into question by the treating team due to their particular circumstances or a discard signature may not be a perfect match to a signature on a consent filled out previously. In such a circumstance the clinic will act completely in the interests of the patient and request further information prior to discard as was the case in the gametes outlined above that were in storage after their official expiry date. In a case of us discarding them on the date of expiry and the patient later challenging our discard and our due diligence in contacting them in that regard we would expect no support from the HFEA in such a circumstance which effectively puts us in a 'damned if you do and damned if you don't' scenario. Given the recent case in a London clinic where a patient forged her husband's signature, clinics are now very nervous in that regard. It is significantly more difficult when we actually deal with patients, their gametes and embryos and their hopes and dreams, compared to making black and white judgements on patients from the benefit a non-clinical viewpoint where patients and their individual circumstances are not known to the decision makers.
All of this is aimed at supporting and protecting the patient and their gametes and embryos. Most clinics fear the seemingly inevitable discard of the gametes of a patient when it is actually against their wishes. These same clinics expect no support from the HFEA when this occurs and rather a 'you should have done due diligence' culture. As such, you have the PR's word that we will discard any patient's gametes or embryos even if a question does hang over the completion of the form if the expiry date passes as per HFEA request.
In this report there are several references to non-compliances not being dealt with from the 2016 renewal inspection when comments from our inspector at the time showed we were complaint after making changes. All non-conformances were acted upon following the 2016 inspection as can be evidenced.
There is also an accusation that the PR did not respond to a request for information. The PR however, cannot respond to a request that he was unaware had been sent or received. As outlined above, when receiving RBAT alerts I have always responded.
The HFEA is unwilling to share best practice but quick to criticise when it sees something that is doesn't regard as best practice. It is unclear why the HFEA is unwilling to share a pre-inspection questionnaire that is robust and would allow us to check such things as a new requirement for ventilated doors in a gas storage room. The HFEA requests new protocols at every inspection but is unwilling to

specify a list of protocols clinics should have as a bare minimum. The HFEA is unwilling to provide electronic consent forms which would prevent erroneous input or omissions but is quick to criticise human error when a form is incorrectly completed
This report shows no recognition for the enormous hard work done at CRGW and the care the patients receive. We have amongst other things driven down the cost of treatment in Wales and the South West, pushing our ethos of 'patients before profit'. We offer treatment options to patients for free that other clinics charge large sums of money for. We offer patients an unrivalled access to the treating team meaning that members of the team can be taking phone calls and emails from patient late into the night most days. Patients feel extremely well looked after at CRGW and we often get told that their previous experiences at other clinics have been 'not a patch' on the care at CRGW. We treat patients that other clinics refuse to treat as it may affect their pregnancy rates. We do not therefore 'cherry pick' patients but give them and honest and realistic expectation of their outcomes to allow them to make informed consent. Having visited many other clinics I am assured that the service we offer exceeds patient expectations which is evidence in patient feedback and was observed by the senior inspector in the clinics patient satisfaction chart which the inspector was happy with. Curiously, the inspectors say in the draft Report that there were no patients to speak to on the inspection days when in fact there were plenty, the reason for which is questionable.
We are reassured that the HFEA:

- viewed staffing levels at the clinic to be suitable for the activities being carried out;
- observed patients being seen promptly on arrival;
- felt the atmosphere in the clinic was calm at all times; and
- felt that staff in the lab were able to carry out activities without distraction.

Given that we have already completed a large proportion of the non-conformances outlined at this inspection, the HFEA should clearly be reassured that remaining non-conformances will also be completed in a timely fashion while licensed activities continue in the viewed comfortable and calm surroundings.

Executive response:
Paragraph one:
At no stage, during the Executive's investigation has any allegation been made that the centre was responsible for the death of the baby. The Executive was asked to investigate the centre's practices and procedures relating to an incident involving a surrogate woman, which they have done.

Paragraph two:
The Executive cannot reconcile the PR's claim of an' intentionally limited time' for a response to the inspection report. The compliance team have a key performance indicator (KPI) for sending reports to the PR following an inspection of 20 – 28 working days. The PR

received this report, which he acknowledges was lengthy, in 32 working days of the inspection (four days later than the usual KPI). PRs are usually given ten working days to provide a response. The PR was granted an extension to provide his response, although this is not usually afforded other PRs that have lengthy reports.

The Executive cannot reconcile the PR's belief that the HFEA wish to wield a stick against the centre. The HFEA strive to ensure high quality care for patients, donors and donor conceived people, and work with the sector to achieve this. The centre's performance has fallen short of expected standards, as evidenced by the findings of the inspection and the investigation into a serious incident reports, and the PR has conceded to some of the non-compliances noted in both reports.

The Executive is concerned that where an investigation into an incident concludes 'human error' as its cause, the real root cause may not be identified (ie, why did the human make a mistake?) and as such, this will impact on the effectiveness of preventative and corrective actions taken as a result.

As has been explained in the report, the culmination of non-compliances within a given area of practice has affected its grading in this and other reports to which the PR refers.

The PR believes that the licence was not granted for four years because he had 'not engaged with the multiple birth issue'. Licence Committee minutes 17 March 2016 (application for treatment and storage renewal) state the decision for granting a three-year licence rather than the usual four at the last renewal inspection was that:

'The committee expressed deep concern regarding the number and seriousness of non-compliances found at inspection, in particular that relating to the centre's multiple pregnancy rate. The committee noted that at the time of the centre's interim inspection, undertaken in 2014, the centre's multiple pregnancy rate was 26 percent. The committee noted that at the time of the centre's renewal inspection its multiple pregnancy rate was still 27 percent.

The committee noted that, since the inspection, the centre has initiated an independent review of their eSET processes in relation to addressing the centre's multiple pregnancy rate.

The committee also expressed concern that, at the time of inspection, the centre had not yet carried out a full audit of legal parenthood. The committee noted the PR's response that an audit is currently being undertaken and that the centre is currently reviewing the procedure for recording the information required to establish consent to legal parenthood requirements.

The committee was also concerned that no one at the centre, including the person providing conscious sedation, was trained in life support to a higher level than basic. The committee noted that the two doctors performing egg collection and giving conscious sedation are attending courses in June.

The committee also noted that Intralipid continues to be prescribed by the centre off-label, in cases of patient request, despite concerns being raised by the Royal College of Obstetricians and Gynaecologists over a lack of evidence of safety and efficacy'

The Executive notes that in the 2016 renewal inspection report, considered by the Licence Committee, the PR had been asked to initiate an independent expert review of eSET practice in relation to the centre's high multiple birth rate, that he *had not* implemented from the 2014 interim inspection.

The Executive notes the actions taken to date, by the PR towards implementing the recommendations in this report. The Executive would wish to see that the PR has an oversight of activities at the centre so that he can be assured that the actions he has implemented are embedded into practice and facilitate sustained improvements and compliance.