Executive Licensing Panel Minutes

Centre 0144 (CARE Woking)

Interim Inspection Report

Date:	4 May 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Yvonne Akinmodun Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Head of Human Resources Communications Manager
Executive:	Bernice Ash	Secretary
Observers	Catherine Burwood Niamh Marren	Licensing Manager Regulatory Policy Manager

Declarations of interest

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

The panel had before it:

- 9th edition of the HFEA Code of Practice.
- Standard licensing and approvals pack for committee members.

1. Consideration of Application

1.1. The panel noted that CARE Woking (formerly Nuffield Health Assisted Conception) is located in Surrey and has held a licence with the HFEA since 1994. In October 2020, the centre became part of the CARE group of fertility centres and changed its name to CARE Woking; the centre is in the process of embedding the practices and processes of the CARE group of clinics. The centre provides a full range of fertility services. Other activities include the storage of gametes and embryos.

1.2. The panel noted that, in July 2017, a report of a Grade A incident was considered by the Licence Committee (LC). The Executive Licensing Panel (ELP) considered the centre's last renewal inspection in April 2019, requesting an executive update regarding the actions taken after the Grade A incident as it was not assured that the Person Responsible (PR) had established robust processes to prevent a similar event from reoccurring. An executive update was not presented to the ELP as requested, but was provided in the interim report presented now.

1.3. The panel noted that, with regards to the Grade A incident, the PR had provided the required audits and further information as requested by the executive, which provided assurance that processes implemented as a result of this incident are effective in assuring no further reoccurrence. Discussions with the PR at this inspection provided assurance that the procedures implemented are working well. The PR is now auditing patients that are returning for treatment whose results were previously reported as normal to ensure that these results are confirmed as such. There have been no further incidents of this kind at the centre.

1.4. The panel noted that, in the 12 months to 31 December 2020, the centre had provided 947 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a medium sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom has impacted on treatment numbers.

1.5. The panel noted that, HFEA register data, for the period October 2019 to September 2020, show the centre's success rates for IVF and ICSI are in line with the national averages.

1.6. The panel noted that, in 2020, the centre reported 10 cycles of partner insemination, with no pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.7. The panel noted that, HFEA register data, between October 2019 and September 2020, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 7%. This represents performance that is likely to meet the 10% multiple live birth rate target for this period.

1.8. The panel noted that, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA), was conducted for the centre's interim inspection. Following this, it was concluded that any items of concern identified were of relatively low risk and could be reviewed effectively using virtual technology, rather than an on-site inspection. This process removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

1.9. The panel noted that the interim inspection was therefore conducted by DBA, followed by a virtual inspection on 2 March 2021. This considered the centre's own assessment of its service, the progress made in implementing the actions identified at the last inspection, alongside the

on-going monitoring of the centre's performance. The virtual inspection included videoconferencing with key members of centre staff.

1.10. The panel noted that at the time of the inspection, there were two major areas of non-compliance identified concerning the quality management system (QMS) and medicines management. Since the inspection, the PR has provided evidence that actions have been taken to implement the recommendation surrounding medicines management and has committed, where required, to audit the effectiveness of those actions within the required timescales. The PR has given a commitment to fully implementing the non-compliance regarding the QMS.

1.11. The panel noted the centre is well led and provides a good level of patient support.

1.12. The panel noted that the inspection team recommends the continuation of the centre's treatment and storage licence.

2. Decision

2.1. The panel noted that, with regards to the Grade A incident reported in 2017, the PR had provided the requested updates and further information and no further incidents of this type had been reported. The panel hoped that, at the centre's next renewal inspection, the inspectorate is assured that all required actions taken after this incident, had been fully implemented and continue to be in operation.

2.2. The panel was satisfied the centre was fit to have its treatment and storage licence continued.

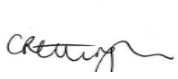
3. Chair's signature

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

Signature

Clare Ettinghausen

Name



Date

10 May 2021

Interim Licensing Report

Centre name: CARE Woking
Centre number: 0144
Date licence issued: 1 October 2019
Licence expiry date: 30 September 2023
Additional conditions applied to this licence: None
Date of inspection: 2 March 2021
Inspectors: Polly Todd (lead); Louise Winstone; Karen Campbell and Sarah Stedman (HFEA observers)
Date of Executive Licensing Panel: 4 May 2021

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, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law). 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).

This is a report of an interim inspection, at the mid-point of the licence period.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

HFEA licensed premises must be inspected on site every two years in accordance with Schedule 3B paragraph (4)(1) of the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended). Whilst the current restrictions of the pandemic do not prohibit on-site inspection, the risks of doing so must be balanced against the need for the Authority to fulfil its legal duties.

This centre was last inspected in April 2019, therefore an on-site inspection should usually be conducted by April 2021. However, following the DBA/RBA for this clinic, it was concluded that any items of concern identified during the DBA were of relatively low risk and could be reviewed effectively using virtual technology rather than on-site inspection.

This removed the risks to patients and staff, associated with a HFEA team attending the clinic for an on-site inspection during the Covid-19 pandemic.

This inspection was therefore carried out by DBA followed by a virtual inspection, which included videoconferencing with key members of centre staff.

The current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

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 Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence.

The centre is well led and provides a good level of patient support.

The ELP is asked to note that this report makes recommendations for improvement in relation to two major areas of non compliance or poor practice.

Since the inspection visit, the Person Responsible (PR) has provided evidence that actions have been taken to implement the following recommendation and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major area of non compliance:

- The PR should ensure compliance with medicines management regulatory requirements and professional body guidance.

The PR has given a commitment to fully implementing the following recommendation:

Major area of non compliance:

- The PR should ensure that there is a suitable Quality Management System (QMS) in place.

Information about the centre

CARE Woking (formerly Nuffield Health Assisted Conception) is located in Surrey and has held a licence with the HFEA since 1994. In October 2020 the centre became part of the CARE group of fertility centres and the centre changed its name to CARE Woking. The centre is in the process of embedding the practices and processes of the CARE group of clinics.

The centre provides a full range of fertility services. Other activities include the storage of gametes and embryos.

The centre provided 947 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 December 2020. The Covid-19 pandemic and subsequent closure of clinics for a period in 2020, may have impacted on the centre's activity levels but taking this into account, in relation to activity levels this is a medium centre.

The current licence has been varied to reflect the following changes;

- 29 October 2019 – variation change of premises and change of centre name.
- 9 January 2020 – change of Licence Holder (LH).
- 2 November 2020 – change of LH and change of centre name.

In July 2017 a report of a Grade A incident was considered by the Licence Committee (LC). The committee minutes of the last renewal inspection (April 2019) requested an executive update regarding the actions taken after the incident as the committee was not assured that the PR had established robust processes to prevent a similar event from reoccurring. This was not provided to the committee and is provided in this report.

The PR provided the required audits and further information as requested by the executive, which provided assurance that processes implemented as a result of this incident are effective in assuring no further reoccurrence. Discussions with the PR at this inspection provided assurance that the procedures implemented are working well. The PR is now auditing patients that are returning for treatment whose results were previously reported as normal to ensure that these results are confirmed as such. There have been no further incidents of this kind at the centre.

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 October 2019 to September 2020 show the centre's success rates are in line with national averages.

[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 $p \leq 0.002$.

In 2020, the centre reported 10 cycles of partner insemination with no pregnancies. This is in line with the national average.

Multiple births[2]

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

Between October 2019 and September 2020, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 7%. This represents performance that is likely to meet 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 inspection team was not able to observe any laboratory activities during the virtual inspection but was able to discuss witnessing with staff and review the results of recent audits as part of the DBA. These activities indicated that witnessing procedures are compliant 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, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed with staff. Documentation provided as part of the DBA and discussions with staff during the virtual inspection indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

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 following assessment of information provided as part of the DBA and discussions with the PR during the virtual inspection. The PR regularly reviews staffing requirements in light of changes in working practices due to the Covid-19 pandemic and adaptation to the new CARE organisational processes.

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.

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[2]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 $p \leq 0.002$.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: medicines management; infection control; legal parenthood; witnessing; consent to storage; traceability.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements because:

- The centre was unable to provide evidence of a quality management system review having taken place prior to being taken over by the CARE group.
- The centre provided a quality indicator (QI) audit report which referred to QIs that have been in place since 2010, for example, medical records audits and staff competencies. The inspection team would expect that these indicators would have been reviewed since that date to reflect any changes in practice or procedure.
- Corrective actions; timeframes for completion and confirmation of completion of required actions were not documented (controlled drugs audit; infection control audit; legal parenthood audit).
- Corrective actions documented in some audits were not appropriate when non-conformances were found. For example, there were discrepancies found when auditing the amount of drugs in stock, but the action taken was just to check the stock again in two months. In a controlled drugs audit, discrepancies were found between the amount of drug recorded as being given to the patient in the controlled drugs (CD) register and that recorded in the patient records, but the action was to re-audit in one year's time (see also medicines management non compliance and recommendation 2).
- The legal parenthood audit completed in December 2020 was not robust in that it did not document whether consent was provided before treatment.
- The clinic was unable to provide a standard operating procedure (SOP) which directed what to do in the event of a withdrawal of consent to legal parenthood for the DBA or at the time of the virtual inspection. A copy of CARE's corporate SOP was subsequently provided to the inspection team after the inspection (see recommendation 1).

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:

- leadership;
- information provision;
- data submission to the HFEA;
- the use of CE marked medical devices;
- the centre's audit of legal parenthood.

The centre is effective in implementing guidance from the HFEA.

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.

Documentation provided as part of the DBA and discussions during the virtual inspection indicate that the clinic's processes for medicines management and the safe storage, disposal and administration of medicines are partially compliant with guidance because:

- In one entry of the CD register an error had been recorded but was not witnessed or signed (page 36).
- The form, strength and/or concentration of the controlled drug is not entered in the register in all cases (pages 21, 22, 23 and 37).
- There are illegible entries in the CD register (page 22) and in some entries it is unclear what is meant by the entry, for example, on page 22 of the register the carry-over of the drugs from one page to another is recorded as being carried over from page 22(3). It was unclear to inspectors or to clinic staff, questioned during the virtual inspection, what this entry means.
- On one page an entry has been obliterated (page 21). In the absence of an SOP directing staff how to make corrections in the CD register it is expected that the regulatory requirements are followed.
- The CD audit was not robust as it did not identify the issues noted at this inspection (see also QMS section of this report) (see recommendation 2).

Prescription of intralipid 'off label'

Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

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.

Documentation provided as part of the DBA and discussions during the virtual inspection indicate that the clinic's infection prevention and control practices are compliant with guidance.

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'.

We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

Patient experience

Patient support

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Patient feedback

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only nine patients have provided feedback in the last 12 months, giving an average 4.5 star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it is important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility, and this will be followed up at the next inspection. The centre's own most recent patient survey responses were therefore reviewed for the period 1 January 2020 to 31 March 2020. Forty seven responses were provided during this period. Feedback was comparable to that provided by the HFEA which was generally favourable. The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to.

There were also some negative comments regarding phone calls being answered promptly and these were discussed with the PR. He advised the inspectors that actions have already been taken to address this matter.

This was a virtual inspection so no patients were available to speak to.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- treats patients with empathy and understanding.

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 HFEA standard licence conditions

Information submitted by the centre in their self assessment questionnaire, the pre-inspection assessment and observations during the visit to the centre, indicate that the centre is compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2019, recommendations for improvement were made in relation to three major and one 'other' area of non compliance.

The PR subsequently provided information and evidence that all of the recommendations were fully implemented within the required timescales.

On-going monitoring of centre success rates

Since the last renewal inspection in April 2019, the centre has not received any performance related risk tool alerts.

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.

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 last inspection in April 2019, legal parenthood consenting processes were found to be robust.

To provide 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. Four 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. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements with the exception noted in the 'QMS' section of this report.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

Annex 1

Areas of practice that require the attention of the Person Responsible

This 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	Executive review
None			

‘Major’ areas 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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Quality Management System: There were several issues found in the QMS which are detailed in the main body of the report. SLC T32; T34 and T36.	The PR should ensure that there is a suitable QMS in place. The PR should review the QMS including, but not exclusively, the issues noted in this report and provide a summary report of that review, including any corrective actions taken, to the centre’s inspection by 2 June 2021. Three months after the review the PR should audit the QMS to ensure that any corrective actions implemented have been effective in achieving	We had identified issues regarding the QMS prior to the inpection and will forward a summary report of the review by 2nd June 2021 but of course we were changing from our existing QMS to the CARE Fertility QMS which I note has been accepted in inspections of other CARE Fertility units. The follow up audit will occur with any corrective actions and a summary report submitted by 2nd September 2021.	The executive acknowledges the PR’s response and commitment to implementing this recommendation. Further action required.

	compliance. A summary report of this audit should be provided to the centre's inspector by 2 September 2021.		
2. Medicines Management: There were several issues noted on inspection with medicines management as detailed in the main body of the report. SLC T2. Misuse of Drugs (Safe Custody) Regulations (2001). The Royal College of Anaesthetists (RCA) and the Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Good practice, a guide for departments of anaesthesia, critical care and pain management' (2006). NICE Guideline [NG46] 'Controlled drugs: safe use and management' (2016).	The PR should ensure compliance with medicines management regulatory requirements and professional body guidance. The PR should review medicines management practices and procedures and provide a summary report of this review, including timeframes for implementation of any corrective and preventative actions and any staff training requirements, to the centre's inspector by 2 June 2021. Three months after the review the PR should audit medicines management practices and procedures to ensure that any corrective and preventative actions taken have been effective in achieving and	Since the inspection on 2nd March 2021 we had identified the disrepancies in medicine management including all the items identified by the inspector and arranged an external review of our medicines management doumentation. Further training has already occurred and I have asked for continued training for all members of staff involved with medicines management with follow up continued rolling audits until any identified discrepancies are eliminated. If the inspectororate wish a further summary report by 2nd June 2021 I will supply this but confirm that a further report will be submitted by the PR as specificied prior to 2nd September 2021with the results of a summary audit	The executive acknowledges the PR's response and commitment to implementing this recommendation. No further action required beyond submission of a summary report of the audit of medicines management practices due 2 September 2021.

	maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 2 September 2021.		

‘Other’ areas of practice that require improvement

‘Other’ areas of practice that require improvement are any areas 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	Executive review
None			

Additional information from the Person Responsible