FAQ Coronavirus (COVID-19)

Updated 21 December 2020

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Key questions

Should fertility patients be offered the COVID-19 vaccine? (new)

The Royal College of Obstetricians and Gynaecologists (RCOG) have updated their FAQs to include a section on COVID-19 vaccines and pregnancy, which can be found **here**. This includes guidance from **The Joint Committee on Vaccination and Immunisation** (JCVI) and **Public Health England** who have advised that those who are pregnant, or planning to get pregnant in the next three months, should not have the COVID-19 Vaccine. This is due to the lack of data on the safety of COVID-19 vaccines in pregnancy.

What will happen if there is a localised lockdown due to COVID-19?

If there is a localised lockdown, it will be the responsibility of the PR to assess the risk locally, to decide whether treatment can continue to take place for patients. This decision should be informed by knowledge of local coronavirus infection rates and local measures, if any. This would involve looking at the risks to patients and would need to take into account factors such as the local 'r' rate and any restrictions in place locally. For a centre to be approved to reopen the revised General Direction 0014v2 required centres to have a written Covid-19 Treatment Commencement Strategy. This means clinics will have already put measures in place to ensure they comply with specified guidance on safe and effective working practices during the pandemic. A PR will need to assess whether these are sufficient to be able to protect patients in light of a new lockdown. The HFEA will continue to monitor national and devolved government advice as well as that of the professional bodies and will react in an appropriate manner, should the situation change at any time.

It should be recognised that patients are likely to be anxious about coronavirus infection and its potential effects on pregnancy, Patients should be made aware that the present experience is limited and does not indicate that the severity of infection is any worse in pregnancy. At this stage, there is no evidence of an increased risk of fetal anomalies or adverse pregnancy complications. Nonetheless, patients should be carefully counselled, taking into account their individual clinical situation and risk profile, and the likely persistence of the virus in the local community in the medium term. This counselling and the patient's decision whether or not to proceed with fertility treatment should be documented in the medical record.

What are The Association of Reproductive and Clinical Scientists (ARCS) and British Fertility Society (BFS) U.K. best practice guidelines for fertility clinics during the COVID-19 pandemic?

The revised guidelines prepared by the ARCS/BFS COVID working group were published on 30 September 2020 and are available here: **https://www.britishfertilitysociety.org.uk/wp-content/uploads/2020/09/ARCS-BFS-guideline-Covid-19-version-3-30-September-2020.pdf.** The HFEA suggests that all clinics are familiar with this guidance.

The following principles underpin the approach ARCS/BFS took in revising this guidance:

- Provision of fertility services must take place in a manner that minimises the chances of spread of COVID-19 infection to patients and fertility clinic staff.
- Centres should ensure a fair and transparent approach to any prioritisation policy.
- Provision of treatment should not result in an undue burden on the NHS.

- Clinical judgement and individualisation of treatment according to the needs of the patient remains at the heart of good clinical care. Patients considering treatment should be fully informed about the effect of the ongoing pandemic on their treatment and give informed consent to having fertility treatment at this time, considering their individual risk profile.
- The fertility sector should adopt sustainable changes in working practices that help to build resilience against any future increases in the spread of COVID-19 in the community.

Can clinics continue to offer immunosuppressive treatments?

There are various different treatments associated with reproductive immunology, which are used to suppress the body's natural immunity, and all of which have risks. These include steroids (e.g. prednisolone), intravenous immunoglobulin (IVIg), TNF-a blocking agents (e.g. adalimumab, infliximab) and intralipid infusions.

Immunosuppressive treatments are not recommended because they are of unproven benefit and carry risks (some of which are serious). They are marked as 'red' on our traffic light system. There remains an additional risk in using such treatment during the COVID-19 pandemic. These treatments may make patients more susceptible to the virus and may put them at high risk for developing serious complications from COVID-19.

The professional advice from the British Fertility Society, the Association of Reproductive and Clinical Scientists and the Royal College of Obstetricians and Gynaecologists is that the use of empirical treatments of uncertain efficacy and safety, including immunosuppressive treatments should be avoided

Our advice remains that immunosuppressive treatments should not be offered as there is no evidence that these are effective, and that their use increases the risk to patients during the ongoing pandemic.

Do patients need to be tested for COVID-19 prior to treatment?

Some clinics may choose to include testing for COVID-19 as part of their treatment strategy for all patients having treatment including patients who are asymptomatic. We have not stated clinics must test all patients as it is not a current recommendation made by Government or the Professional Bodies (BFS/ARCS). If you'd like more information on COVID-19 testing, please refer to **the Government guidance**. You can also request a test on the **NHS website** **if your patient has COVID-19 symptoms**.

Before starting treatment, consideration should be given to antigen testing (or an equivalent test if available, validated and approved).

Information on the process for re-starting treatment

What is the process for clinics wanting to apply to reopen?

The HFEA issued revised **GD0014 (version 2)** on 11 May 2020 which enables any licensed centre to apply to resume treatment services provided it can satisfy certain safety requirements. Clinics are required to have a COVID-19 Treatment Commencement Strategy in order to be able to apply to reopen.

The Strategy records the measures the clinic will be taking to comply with current professional body guidance on safe and effective treatment; records the risk assessments undertaken; the practical and logistical arrangements that will be put in place at the clinic and records all new or revised standard operating procedures (SOPs) or protocols.

The revised GD0014 also requires the clinic to complete the HFEA COVID-19 Treatment Commencement Self-assessment which has been developed to measure the robustness of the clinic's Treatment Commencement Strategy and assess the clinic's compliance with guidance from the UK and devolved governments, professional bodies such as **BFS/ARCS**, ESHRE, as well as

Standard Licence Conditions and guidance in the Code of Practice. Before a clinic can commence treatment, it must have received approval of its self-assessment from its HFEA inspector. Any clinic that commences treatment before having received this approval will be in breach of GD0014 and may face regulatory sanction.

When you are ready to apply to re-open, the clinic's HFEA inspector should be contacted.

What guidance should clinics refer to in preparing the Treatment Commencement Strategy?

The following guidance should be referred to:

- British Fertility Society – COVID-19
- GOV.UK – COVID-19: infection prevention and control (IPC)
- GOV.UK – Getting tested
- ESHRE – COVID-19

This list is not exhaustive, and PRs should incorporate the sections of guidance relevant to local practice. You should keep your Treatment Commencement Strategy under regular review to ensure that it reflects the latest guidance.

What is the procedure for completing the self-assessment tool?

The tool is available from the clinic's HFEA inspector. It is a questionnaire containing 50 questions. The completed questionnaire should be sent to the clinic's inspector who will review the responses within five working days with a view to the proposal to commence treatment services. We aim to complete our approval process within 5 working days of receiving the completed clinic self-assessment.

How will patients know if a centre is open for treatment?

As centres receive approval to reopen, we will publish this information in a list on our website to make patients aware. This list can be found here.

Guidance Note 1: Person Responsible

What if a PR is furloughed?

PRs who have been furloughed due to COVID-19 may remain PR provided they can continue to fulfil their statutory duties as PR during furlough and do not contravene the government's rules around furlough. If this is not possible, it may be necessary for the licence to be varied to appoint someone else as PR.

There are no statutory restrictions on a person becoming PR of more than one clinic. If it is necessary for someone else to be appointed as PR, the Licence Holder will need to apply for a licence variation with the consent of the person they are proposing to become the new PR.

The proposed new PR must also have completed the PR Entry Programme (PREP) test. The HFEA will expedite such applications so they can be dealt with as quickly as possible. When the HFEA allows clinics to resume treatment, clinics will need to consider whether the former PR wishes to resume his/her role as PR and if so, a further application will need to be made to the HFEA.

What if a PR needs to self-isolate?

If a PR is required to self-isolate because of COVID-19 they would need to decide if they are able to continue working from home during this time or whether they would be unable to continue with their role of PR for the duration of their self-isolation. The PR should contact their inspector to discuss their decision on whether they can continue to work during their self-isolation.

If the PR is unable to fulfil their duties as PR, the Licence Holder must apply for a licence variation with

the consent of the person they are proposing to become the new PR. The proposed new PR must also have completed the PREP test. When the PR can resume their duties as PR they would need to be "re-appointed" and the licence variation would need another application to go back to ELP for review.

What if a PR is suddenly unable to fulfil their duties and responsibilities due to COVID-19?

If a PR becomes unwell with symptoms of COVID-19 or is diagnosed with COVID-19 and is suddenly unable to fulfil their duties and responsibilities, they or someone at the clinic must inform their inspector as soon as possible.

Depending on the circumstances, it may be necessary for the Licence Holder to apply for a licence variation to appoint someone else as PR.

What happens if in the interim period between the removal of a PR and the appointment of a new one something occurs at the clinic that requires a PR's urgent decision/action?

If a PR is currently not in their position at the clinic due to COVID-19 and a new PR has not yet been appointed, but an issue or concern has arisen that requires the PR's input, the next in-line manager should contact the centre's inspector or the HFEA incident team with their plan of action. The HFEA would take any necessary regulatory proportionate view on the issue/concern that has arisen.

Guidance Note 2: Staff

What guidance should clinic staff follow regarding working from home?

The Human Fertilisation and Embryology Act 1990 (as amended) ('the Act') does not preclude clinics from allowing certain administrative tasks to be undertaken by clinic staff working from home, where it is essential for those tasks to be undertaken. However, it is important that clinics ensure appropriate safeguards are put in place to maintain patient confidentiality and that staff who are working from home understand the strict confidentiality provisions which apply both under section 33A of the Act and under Data Protection legislation. Before permitting clinic staff to work from home, clinics should develop appropriate home working and security policies in consultation with IT staff, data protection advisors and/or legal advisors. Consideration should be given to matters including:

1. access to patient data or records over secure networks and ideally access should only be via a laptop or computer provided by the clinic which is password protected and encrypted;
2. staff understanding of the confidentiality requirements of section 33A of the Act and a reminder that disclosing patient data in breach of section 33A is a criminal offence;
3. Data Protection requirements that might apply when accessing patient data or patient records from home;
4. practical steps that staff should take when working from home to avoid inadvertent breaches of patient confidentiality or unlawful disclosure of patient records. For example, preventing staff from being able to print out any patient records or patient data at home;
5. measures that can be taken to ensure that other people at the staff member's home cannot see or access any patient data or patient records on the staff member's work computer or laptop;
6. preventing staff members from taking hard copy patient records home;
7. reminding staff members to ensure that personal or private medical matters relating to a patient are not discussed within earshot of their family or friends, ideally (if possible) one would want staff to have a private space in their home where they can work away from family etc.;

8. the need to develop a “Data Protection and Patient Confidentiality Policy for home workers” which sets out what is expected of staff, what they can and cannot do etc. and what they need to do if there is unlawful access to patient data or an inadvertent data protection breach;
9. the need to comply with the usual information security arrangements that are in place in clinics whilst in the home environment. For example, clear desks, locking screens when away from the desk and storing laptops securely when not in use;
10. what staff members are expected to do if there is a data breach or if they suspect that the security of their network or device may have been compromised by malware or unauthorised hacking or other IT security event;
11. the importance of ensuring that all email communication is addressed to the correct recipient(s) before it is sent, and that appropriate security measures are put in place if staff need to send sensitive personal data/patient records electronically. For example, two factor authentications (password sent via telephone or in separate email).

What should a clinic include in their lone working policy?

Each clinic should have updated their lone working policy to now include any aspects specific to lone working during the COVID-19 pandemic. This should include but is not limited to;

- a procedure for staff to follow if they are working on their own e.g. a telephone number of someone they have to notify when they arrive and when they leave
- an updated safety procedure if an emergency or accident occurs whilst someone is working alone, this should include emergency contacts
- safety of staff who need to perform certain duties e.g. maintaining the liquid nitrogen dewars
- use of PPE by all staff
- planning to contact the providers (of liquid nitrogen etc) to discuss any supply chain issues, when they should be placing their order and ensure that the provider knows that the clinic would be considered a critical service

Are clinic staff ‘Key Workers’?

Public Health England have confirmed that any healthcare staff engaged in the completion of current fertility treatment cycles are considered Key workers.

Are fertility clinic staff eligible for Coronavirus testing?

According to the latest **guidance on testing**, clinic staff are covered under testing where they are showing symptoms or someone they live with is showing symptoms. Anyone providing a medical service is classified as a key worker, including:

- doctors, nurses, midwives, paramedics, social workers, care workers, and other frontline health and social care staff including volunteers
- support and specialist staff required to maintain the UK’s health and social care sector
- those working as part of the health and social care supply chain, including producers and distributors of medicines and medical and personal protective equipment.

What to do if a staff member or patient tests positive for COVID-19.

If any staff member or patient tests positive for COVID-19, this must be reported to the HFEA via the HFEA incident reporting system and investigated appropriately. Centres should ensure cases or suspected cases are reported appropriately to facilitate the **Track and Trace** programme. This will also ensure early identification of an outbreak within a centre.

Guidance Note 3: Counselling and patient support

What information can clinics refer their patients to?

There are websites that can provide support and/or information to patients at this time of uncertainty including:

- HFEA COVID-19 guidance for patients
- Fertility Network UK
- British Infertility Counselling Association
- Fertility Friends
- Coronavirus (COVID-19): what you need to do (Government advice)
- NHS advice

Centres should ensure patients have access to information regarding the effects of coronavirus infection during pregnancy. Each clinic should state if they are able to offer telephone or online counselling to their patients.

Can partners attend fertility appointments? (updated)

The Royal College of Obstetricians and Gynaecologists have introduced a framework to allow partners to be able to attend maternity services in England, including fertility treatments. They recommend using a stepwise approach, following a documented risk assessment, so you can make any necessary changes before relaxing any current approaches you may have in place. Your policies on permitting access to partners should be regularly reviewed, be tailored to your local context and take account of current risks and government policy.

The updated guidance from The Association of Reproductive and Clinical Scientists (ARCS) and British Fertility Society (BFS) says that centres should minimise the number of accompanying persons, and should carry out risk assessments to ensure the attendance of a partner at appointments is safe.

New NHS guidance sent to trusts in England has said that further to a risk assessment, women should have access to support from a person of her choosing at all stages of her maternity journey and that all trusts should facilitate this as quickly as possible.

Guidance Note 4: Information to be provided before consent

How should refunds be handled if treatment is cancelled or postponed due to the ongoing COVID-19 pandemic?

Before a patient begins treatment, consumer protection law states that clinics should explain in writing the circumstances in which treatment may be cancelled or postponed, and explain a patient's rights and obligations should treatment be cancelled or postponed e.g. whether they are entitled to a refund of any prepayments.

The Competition and Markets Authority (CMA) has recently published guidance which sets out its views in relation to cancellations and refunds within the context of the COVID-19 pandemic. This explains the circumstances in which the CMA would expect a consumer to be offered a full refund where no services are provided as a result of COVID-19. This guidance also explains that in circumstances where a patient has already received some services they have paid for in advance, that they would be entitled to a refund of the services not already provided.

Guidance Note 5: Consent to treatment, storage, donation, and disclosure of information

Can patients complete and sign their consent forms at home if they cannot come into the clinic?

In the Code of Practice, we provide guidance on obtaining consent in Guidance Note 5.11. Consent should be given at the clinic (with both parties present if a couple is being treated) or a documented process should be in place to ensure that consent forms signed outside the clinic are signed by the correct person, have been correctly completed and the consent is valid.

Therefore, if clinics have a documented process in place to ensure the identity of their patients, and to ensure the forms are completed correctly, consents can be signed outside of the clinic.

Guidance Note 11: Donor recruitment, assessment and screening

What guidelines should be referred to for donor screening?

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) updated their guidelines on **Microbiological Safety Guidelines**. Please refer to Annex 1: Organs, tissue and cells used in transplantation and SARSCoV-2 (page 61), which contains guidance for gamete donors. In addition to this there is signposting to NHSBT guidance for tissues and organs.

The following applies:

> **Symptomatic gamete donor** – The donor should be deferred if, at the time of donation or in the preceding 7 days, the donor has a new continuous cough or a temperature >37.8ºC. The donor can donate after 28 days from full recovery.
>
> **Asymptomatic gamete donor** – If the donor is asymptomatic, government advice about those who should self-isolate should be considered including the implications this may have on the donation process.

JPAC (Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee) recently issued a new Change notification regarding live tissue, which states also that person with confirmed symptomatic Coronavirus infection must not donate if less than 28 days since resolution of symptoms. All latest guidance can be found on the **JPAC website**.

Can a donation take place if the gamete donor tests negative for COVID-19?

If an apparent symptomatic donor gamete is tested for COVID-19 and tests negative, the current SaBTO advice should still be followed as expert consultation would be needed on the diagnostic reliability of tests at different stages of infection before making any change.

Do patients and donors travelling to England for fertility treatment need to self-isolate?

The Health Protection (Coronavirus, International Travel) (England) Regulations 2020 can be found **here**. There is also a guidance document on GOV.UK, which can be found **here**.

While the Regulations state that people arriving in England must self-isolate for 14 days (effective 8 June 2020), there is an exception to this requirement for certain recipients of healthcare. The following people do not have to self-isolate:

- a person who has travelled to the United Kingdom for the purpose of receiving healthcare here, has made arrangements with the fertility clinic before travelling to the UK, and has written confirmation from the clinic that they have agreed to provide the healthcare;

- a child (or children) who the patient has responsibility for and who arrived with the patient, to allow the patient to attend the fertility clinics or to travel to and from;
- a live donor of gametes and embryos who is donating the material to a UK fertility clinic. The donation must be for the purposes of healthcare being provided and arrangements to make the donation must have been made with a fertility clinic in the UK in advance with written confirmation provided of those arrangements.

Can a donation take place if the gamete donor has received a COVID-19 vaccine? (new)

If donors have received the Pfizer/BioNTech COVID-19 vaccine or the AstraZeneca COVID-19 vaccine, they must not donate if less than seven days have passed after the most recent vaccination was given. If the donor feels unwell after the vaccination, they must not donate for 7 days after the resolution of symptoms.

If donors have received any other COVID-19 vaccine, including participants in clinical trials or donors vaccinated outside the UK, clinics should refer to a Designated Clinical Support Officer for individual risk assessment. Additional information can be found **here** in change notification no 74.

Guidance Note 15: Procuring, processing and transporting gametes and embryos

Is the HFEA making any provisions for extending the 3-month validity for screening blood tests given that cycles have been delayed?

The screening requirements for patients undertaking IVF are set out in the Act (and most originate within the EUTCD).

Because of the requirement to cease treatment imposed by General Direction 0014, clinics may not be able to be undertake the necessary screening within the required timeframes. This may result in the validity of certain screening tests being compromised as the gap between screening blood sampling and treatment is extended beyond three months for those patients planning a first treatment cycle, or two years for those attending for further treatment. Whilst it remains a legal requirement for clinics to satisfy all screening requirements, the HFEA will adopt a proportionate approach to any regulatory action where the time between screening blood sampling and treatment has extended beyond what is permitted because of the requirement to cease treatment by virtue of General Direction 0014, or other circumstances arising as a consequence of COVID-19 or that are directly attributable to COVID-19, provided a risk assessment indicates that the safety of patients and storage systems has not been compromised and the patient is fully informed of the non-compliance.

Do people travelling to the UK to transport gametes or embryos need to self-isolate?

There is an exception to the requirement to self-isolate for people who have travelled to the UK for the purpose of transporting to a UK healthcare provider certain material (blood, blood components, organs, tissues, cells, stem cells, gametes and embryos), which are to be used for the purpose of providing healthcare. More information can be found on **GOV.UK**.

Do people travelling from the UK to transport gametes or embryos need to self-isolate on their return?

There is an exception to the requirement to self-isolate on return to the UK for people who have travelled to another country for the purpose of transporting from a UK healthcare provider certain material (blood, blood components, organs, tissues, cells, stem cells, gametes and embryos), which are to be used for the purpose of providing healthcare. More information can be found on **GOV.UK**.

Guidance Note 16: Import and exports

Can imports and exports continue as a result of the Coronavirus pandemic?

HFEA requirements and guidance pertaining to gamete and embryo imports have not changed during the COVID-19 emergency. While treatment was suspended during the emergency by General Direction 0014, a suspension of imports and exports was not required by the HFEA and therefore can continue as normal.

Guidance Note 17: Storage of gametes and embryos

Where can I find information on the new Coronavirus Storage Regulations?

On 27 April 2020, the DHSC announced plans to introduce new regulations to help patients who have been affected by the COVID-19 emergency. In the circumstances set out in the regulations, the 10-year statutory storage limit will be extended by 2 years. The new Regulations will come into force on July 1 2020, and can be found here: **The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020**. We have also released a Chair's letter and FAQs for clinics, which can be found **here** and a new consent form (the CVS form) which can be found **here**.

Under the new Coronavirus Regulations, who will be eligible to extend their storage to 12 years?

Patients whose gametes or embryos are in storage at a licensed treatment, storage or research clinic will be able to extend their storage for 12 years provided:

- their gametes or embryos are in storage on 1 July 2020, the date the Regulations come into force, and
- they consent in writing to their gametes or embryos being stored for at least 12 years. This consent can be provided before, on or after 1 July 2020.

Should clinics be contacting all patients who have samples in storage to tell them about the extension to 12 years?

It is a local decision as to when clinics decide to contact their patients to tell them about the possibility of extension; they may choose to do this now or when their patients are nearing the end of their initial storage period. Sometimes it can be challenging to contact patients, and this should be taken into account when centres decide when to contact patients about this complex consenting situation, so as to ensure effective storage consent is continuously documented for all stored samples. Patients who may have been affected by clinic closures should be prioritized.

Guidance Note 18: Witnessing and assuring patient and donor identification

Is it possible to use different measures for witnessing if the number of available clinic staff is limited?

Licence conditions and the Code of Practice require a witnessing protocol to be in place, and a robust risk assessment to be carried out if the protocol is changed. Due to social distancing measures that clinics are required to have in place, an example of a new witnessing protocol that is acceptable is to use live video conferencing. Before this new protocol is used, it should be risk assessed to allow any potential problems to be identified, such as who is in the room with the remote witness, and whether or not the video conferencing platform is encrypted.

Guidance Note 25: Premises, practices and facilities

Where can we find information about travel within England?

The Health Protection (Coronavirus, International Travel) (England) Regulations 2020 can be found **here**. There is also a guidance document on GOV.UK, which can be found **here**.

What guidance should be followed regarding COVID-19 laboratory testing?

- NHS: **Guidance and standard operating procedure COVID-19 virus testing in NHS laboratories**
- Department of Health and Social Care: **Guidance for organisations seeking to support the COVID 19 Testing**
- Department of Health and Social Care: **Coronavirus (COVID-19): Scaling up our testing programmes**

If a patient has had a COVID-19 test performed by another lab and it tested negative, but it is unclear whether this is an accredited test to ISO 15189, is this a valid test or should it be repeated?

All tests that have been performed via the government approved route are valid tests. There should be no need to repeat the test if the patient tested negative unless there was concern that there had been recent exposure since the last test. For more information, please see **Guidance and standard operating procedure COVID-19 virus testing in NHS laboratories** for more information.

The government, NHSE, and DHSC issued guidelines regarding the scope of accreditation for this test and in accordance with Public Health England (PHE) have devised strict validation processes to ensure the test is accurate and reliable.

Does this apply to the new COVID-19 Antibody tests (test to see whether IgG levels to COVID-19 are present) that are currently being evaluated and implemented across UK Medical Laboratories?

Yes, this guidance is also applicable to the COVID-19 Antibody test. Although not all laboratories have a supply of these reagents as their supply is being nationally coordinated by NHSE and DHSC.

It is important to follow all government NHS/DHSC/PHE guidance regarding Covid-19 testing to ensure the most recent guidelines regarding testing are being adhered to. Please refer to relevant government guidelines for the current validated tests available.

Can clinics charge for COVID-19 tests?

The current guidance is that, with reference to Government and professional body guidance, centres should consider implementing a testing policy as reliable serological tests become more widely available. **If a patient has symptoms of COVID-19**, you should inform them that they can access a test on the NHS website.

Can clinics charge for PPE?

Covering costs is acceptable but again any price should be fair.

As the Government has relaxed its policy related to screening and has provided a timeframe for the lifting of shielding, can clinics follow Government guidance on shielders or should the BFS/ACRS guidance still

be followed?

The BFS/ARCS guidance states that 'particular caution should apply to patients with underlying medical problems whose co-morbidity places them at a higher risk of complications in the event of contracting coronavirus infection. This includes patients with obesity, hypertension, diabetes and those receiving immunosuppressive medication. It may be appropriate for such patients to delay conception until epidemiological evidence shows a sustained reduction in the community spread of the infection'. This echoed the government advice that people who are vulnerable from Covid-19 should shield.

On 22 June the government set out a series of steps for further relaxing shielding guidance which will come into effect on 6 July and 1 August. From the 1st August shielding will be paused. The guidance does state that caution and strict social distancing is required, and the advice is still to stay at home where possible. We would therefore expect clinics to assess patients classed as vulnerable on a case by case basis and risk assess how and if treatment can be undertaken safely.

Guidance Note 26: Equipment and materials

What procedure should the clinic follow if equipment needs servicing during the period that clinics are closed/not providing treatment?

For a period of four months from the date the HFEA allows clinics to resume treating patients, we will not take regulatory action against clinics that have been unable to service equipment that required servicing during the lockdown period.

Clinics may continue using such equipment for up to four months from the date that the HFEA allows clinics to resume treating patients notwithstanding that the equipment has not been serviced, provided:

- The clinic has monitored the equipment during the lockdown period without non-conformances in performance being detected, OR an in-house re-validation of the equipment (as a minimum an EQR) has been performed before use in treatment, without non-conformances in performance being detected. The monitoring/validation of the equipment must be completed by a staff member who has the technical knowledge to do so and the processes followed must be fully documented.
- The clinic is confident that the equipment is in good operational order for use to resume.

The clinic must arrange for servicing to be completed by the manufacturer or a reputable agent that specialises in servicing of such equipment, within four months of the clinic resuming treatment.

What procedure should the clinic follow if equipment needs servicing involving preventative maintenance during the period that clinics are closed/not providing treatment?

Failure to perform preventative maintenance may undermine the ability of equipment to perform according to specification. The degree of potential inhibition of equipment performance if preventative maintenance is not undertaken will depend on multiple factors; for example the nature of the preventive maintenance required, the service life of the components changed or cleaned during preventative maintenance, the service history of the equipment piece, and the time beyond the preventative maintenance period. Manufacturers are best placed to assess whether a piece of equipment can be safely used past a scheduled preventative maintenance visit for a short period. Monitoring may allow equipment to be used past a scheduled preventive maintenance visit in some cases.

Where the recommended preventative maintenance period on a clinic's equipment expired during the period in which fertility treatment was suspended, the HFEA will not take regulatory action against clinics and clinics may continue using the equipment for up to four months from the date that the HFEA allows clinics to resume treatment provided:

- The clinic has monitored the equipment during the lockdown period without non- conformance in performance being detected, OR an in-house re-validation of the equipment (as a minimum an EQR)

has been performed before use in treatment, without non-conformances in performance being detected. The monitoring/validation of the equipment must be completed by a staff member who has the technical knowledge to do so and the processes followed must be fully documented.

- The clinic has written confirmation from the equipment manufacturer that operation of the equipment beyond the recommended preventative maintenance period, for up to four months after the centre commences treatment activity, is highly unlikely to undermine equipment performance.
- The clinic is confident that the equipment is in good operational order for use to resume.

The clinic must arrange for the preventative maintenance visit to be completed by the equipment manufacturer or a reputable agent that specialises in maintaining the equipment, within four months of the HFEA allowing clinics to resume treatment.

What procedure should the clinic follow if equipment develops a fault requiring repair during the period that clinics are closed/not providing treatment?

Failure to repair equipment may lead to the use of equipment performing out of specification or which fails. It is however possible that a fault may be in a non-essential system, so equipment performance may remain in line with specifications. The degree of potential inhibition of equipment performance if a fault develops and repair is not undertaken will depend on multiple factors, best considered by the manufacturer.

Where equipment has developed faults before or during the lockdown period, the HFEA will not take regulatory action against clinics and clinics may continue using such equipment for up to four months after the HFEA allows clinics to resume treatment provided:

The clinic has monitored the equipment during the lockdown period without non-conformance in performance being detected, OR an in-house re-validation of the equipment (as a minimum an EQR) has been performed before use in treatment, without non-conformances in performance being detected. The monitoring/validation of the equipment must be completed by a staff member who has the technical knowledge to do so and the processes followed must be fully documented.

The clinic has written confirmation from the equipment manufacturer that operation of the equipment with the fault, for up to four months after the HFEA allows clinics to resume treatment, is unlikely to undermine equipment performance.

The clinic is confident that the equipment is in good operational order for use to resume.

The clinic must arrange for a repair visit to be completed by the equipment manufacturer or a reputable agent that specialises in repairing the equipment, within four months after the clinic has resumed treatment.

Guidance Note 32: Obligations and reporting requirements of centres

What should clinic staff do regarding providing information under EDI timescales?

The HFEA will not necessarily take regulatory action against any clinics that fail to comply with the requirements regarding the provision of information on EDI forms where their failure to do so is directly attributable to coronavirus or circumstances arising as a consequence of it. The clinic must assure the HFEA that the data is being collected, to be collated and reported once the clinic is able to resume its normal functions.

Clinics must not post any forms required for providing information to the HFEA until further notice because the office is now closed for the foreseeable future with all staff working from home. For further guidance about what to do instead of sending urgent postal correspondence, please send an email to enquiriesteam@hfea.gov.uk.

What is the process if a staff member wants to 'whistleblow'?

Clinic staff are aware that they are able to use our incident email (Incident.Reporting@HFEA.GOV.UK) to whistle blow if they have any concerns about working practices within their clinics during the Covid-19 emergency.