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Winter 2020/21 preparation for Fertility services in Scotland

October 2020

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This document should be read alongside the restart plan and the protocols set out there remain the case.

2 Background

After the closure of all fertility clinics in March 2020 due to COVID-19, fertility services were given permission to resume in May 2020.

Fertility services restarted in phase 1 of the recovery plan as it was acknowledged that it is an extremely time sensitive treatment (https://www.gov.scot/publications/re-mobilise-recover-re-design-framework-nhs-scotland/pages/9/). In addition, the sudden halt to fertility treatments was noted to have added to the distress already faced by these patients (Boivin et al., 2020). The data on COVID-19 and pregnancy are still emerging and more details are set out by Royal College of Obstetricians and Gynaecologists (RCOG) within Coronavirus (COVID-19), pregnancy and women's health and United Kingdom Obstetrics surveillance system (UKOSS) COVID-19 in Pregnancy, with the former updated on a regular basis. Some risks have been identified in specific groups, but the data is largely reassuring.

All four NHS tertiary clinics in Aberdeen, Dundee, Edinburgh and Glasgow have worked together with Scottish Government and the patient stakeholder group-Fertility Network, with twice weekly meetings to create uniform documents and policies with a *Once for Scotland* approachhttps://www.gov.scot/publications/covid-19-fertility-treatment-scotland-plans-restarting-treatment-framework/.

Whilst the initial COVID-19 surge occurred rapidly, with little time for service preparation, there is now an opportunity to prepare for the forthcoming winter, when it is anticipated that Fertility services may be affected again.

NHS Fertility services were paused during the initial peak of the pandemic but have remained open during subsequent local lockdowns. This document sets out some of the issues that might occur in the event of a full lockdown again and how to ensure fertility centres provide services through any future local or full lockdowns, with appropriate measures being put in place in order support their patients in the most efficient and effective way and taking into account the COVID-19 Scotland's Strategic Framework https://www.gov.scot/publications/covid-19-scotlands-strategic-framework/. Table 1 document sets out an example of prioritisation and Appendix 2 includes activity in Tiers as per the Framework.

The intention and ambition of the Regulator, the Human Fertilisation and Embryology Authority (HFEA) is to avoid closure of licensed fertility services (letter from the HFEA Chief Executive, Appendix 1) and the Scottish Government is supportive of this in respect of NHS services as set out in this document.

3 Predicted situation

As lockdown restrictions eased, it was predicted that there would be a resurgence of COVID-19 with local and/or regional outbreaks and this is indeed the current experience. There will be the usual winter NHS pressures including seasonal flu and

will have implications for policies and procedures in the wider NHS, which will in turn affect NHS fertility services.

4 Effect on fertility services

4.1 Impact from other services:

Although fertility treatment is extremely time sensitive and there is a need to continue to provide fertility services, these are not done in isolation. The effect of factors highlighted in section 3 on other services such as primary care, general Gynaecological services, anaesthetics and testing laboratories, predicts that there may potentially be:

- Reduction in referrals for fertility from primary care
- Reduced ability of primary care to provide the initial investigations
- Reduction in referrals from secondary care where secondary care fertility services are not provided alongside tertiary services (i.e. clinics which provide only secondary care fertility services)
- Reduction in face to face appointments due to imposed restrictions resulting in fewer available appointments for Ultrasound scans, blood tests, semen analysis and tubal testing which are essential to determine the appropriate treatment pathway
- Limitation of number of procedures that can be performed in one day due to availability of anaesthetists or ward space
- Delay for those requiring elective Gynaecology surgery prior to fertility treatments as is unlikely to be at pre COVID-19 capacity until 2021,
- Continued pause in donor recruitment will further extend the existing waiting time for those requiring treatment with donor gametes

We are aware that associated services are also putting plans in place to try to ensure continuity of service with their own remobilisation plans.

4.2 Shortage of staff

It is anticipated that during winter months there may be a shortage of staff due to:

- The need to self-isolate due to the member of staff or a member of household testing positive for COVID-19
- The need to self-isolate due to overseas travel, a change in local restriction or government policy at short notice
- COVID-19 risk assessment may impact on patient-facing staffing in NHS especially where there are higher proportion of Black and Ethnic minority (BAME) staff, staff who had previously been shielding or pregnant workers https://www.gov.scot/publications/coronavirus-covid-19-guidance-on-individual-risk-assessment-for-the-workplace/
- Redeployment to other areas/services

4.3 Pace of Restart

Although fertility treatments have started across Scotland in all four tertiary clinics, the restart has been gradual. This was unavoidable due to the multidisciplinary nature of assisted conception and its co-dependence on other medical and laboratory specialities. Furthermore, additional processes to mitigate risk of COVID-19 infection and transmission and to ensure patient and staff safety were required to be put in place prior to commencing treatment.

Before IVF treatment is undertaken, there is a 3-6-week period of patients taking medication and undergoing monitoring in preparation of treatment. Hence patients who were contacted to advise their treatment was restarting in June, underwent IVF treatment in August. All centres initially reopened with reduced capacity and had to limit the numbers of patients treated daily in order to ensure safe working practice. Should an increase in capacity be achievable, it is anticipated that it will be at least a further 6– 9 months before services return to 2019 levels of activity and waiting times, provided there are no further restrictions/ lockdown. It is acknowledged that these approximate timelines may differ slightly for each clinic.

4.4 Impact on waiting times

The controlled and measured restart has compounded pre COVID-19 waiting list times both for patients waiting for fertility treatment, as well as those waiting for fertility clinic appointments and investigations (who will often, if appropriate, be added to the waiting list). Although extra time is being added to both groups as a result of COVID-19,to ensure patients remain eligible for NHS funded IVF, this will not mitigate the effect of age on fertility and success rates (Smith et al., 2020) which is significant as age advances.

Some patients who have previously had successful NHS treatment and have frozen embryos for possible siblings are moving gametes/ embryos to private clinics in order to have earlier treatment. This has a financial impact for the NHS as it increases the burden on NHS staff to arrange legal documentation and couriers for gametes and embryos.

5 Mitigation steps for fertility services

All clinics have undertaken detailed risk assessments with policies and procedures put in place to reduce the risk of SARS-CoV-2 transmission (https://www.gov.scot/publications/covid-19-fertility-treatment-scotland-plans-restarting-treatment-framework/). Several service developments and altered working practices have been adopted, including:

- Increased use of remote consultations due to restrictions imposed by COVID-19. Patients are only attending clinics for procedures that cannot be done remotely e.g. egg collection, embryo transfer, ultrasound, blood tests, tubal patency check and semen analysis. For patients this is convenient, reduces travel time and cost in addition to reducing clinic footfall. This restructuring of

service provision will continue after the COVID-19 pandemic due to the positive impact on patients as well as NHS service delivery

- All meetings are conducted via Microsoft Teams or WebEx, which will continue longer term. This has resulted insignificant cost and resourcing efficiencies along with improving communication

- Counsellors are providing support through remote consultations and this will continue. A recent NHS survey found that patients were positive about remote consultations (https://www.gov.scot/publications/public-clinician-views-video-consultation-executive-summary/)

- Work to introduce an electronic consent system is progressing well with support from the Scottish Government. It is expected that electronic consents will be live later in 2020. This will significantly reduce staff time used in obtaining informed consent and reduce the risk of infection due to reduction in face to face clinic contact. This will also help in mitigating the effect of staff shortages

NHS staff have been advised that holidays that involve travel overseas will only be approved after prior discussion and agreement around self-isolation. https://www.sehd.scot.nhs.uk/dl/DL(2020)20.pdf

We will work on the following steps:

5.1 Flu vaccine:

In order to reduce the risk of developing flu, the vaccine will be recommended to all staff working in fertility clinics. The Flu vaccination will be accessed as per government guidance https://www.nhsinform.scot/healthy-living/immunisation/vaccines/flu-vaccine

5.2 Prioritisation

At the time of restarting, fertility services commenced with frozen embryo transfers. A full explanation for this decision is detailed within restart framework. Those in the older age group were subsequently prioritised at the time of restarting services in order to provide the best possible chance of a successful treatment outcome.

A contingency plan will be made by each clinic based on number of staff available in each discipline (medical, nursing, admin and laboratory). This plan will be used to prioritise clinic activity in the event of staff absence due to winter and COVID-19. Although the principles governing this process can be agreed nationally, the decision will need to be made by each clinic based on their local risk assessments, as each team will need to have critical number to run the service, especially scientists.

Further discussion and adaptation will be needed locally depending on the timing of a second and subsequent wave(s) and where individual clinics are in the restart plan when this occurs.

Table 1 shows an example of what a local plan may entail.

Table 1: An example of prioritisation

Staffing level	Continue	Reduce/Pause
100% staff	Full activity	
75% staff	Continue those in treatment	Reduce clinics
50% staff	Fresh IVF ICSI treatments Frozen embryo transfer Donor inseminations Ovulation inductions	Pause non urgent fertility preservation Pause clinics
25% staff	Consider pausing Fresh IVF/ICSI treatments only* Donor inseminations Ovulation inductions	Pause Frozen embryo transfers*
10% staff	Urgent fertility preservation only	Pause all treatments

***whether fresh or frozen treatments are prioritised will depend on individual clinic staffing in each domain**

As it was anticipated that winter pressures will hit services from November onwards, therefore tertiary clinics have utilised a window of opportunity (August to October) to prioritise those who will need face to face appointments, to mitigate against service disruption and treatment delay (for example):

- Those who need ovarian stimulation (fresh IVF treatments)
- Those requiring face to face appointments for diagnostics such as ultrasound/ Blood tests/ semen analysis

5.3 Patients with medical illness

During the initial peak of the pandemic, treatment of those with co-morbidities (e.g. well controlled diabetes, or those who were shielding) was postponed however, as shielding is no longer required, treatment for these patients has resumed. All clinics have systems in place to liaise with obstetric colleagues as and when required for those with medical illness and to ensure that an individualised plan is made.

5.4 Increasing capacity

In the restart framework fertility services previously discussed extending the working day and week. All clinics will continue to review the situation locally and jointly with other clinics, to increase capacity wherever possible with the aim to reach pre

COVID-19 waiting times. However, this will need to be done in conjunction with local risk assessments and provision of safe services.

Flexibility provided with the increased use of remote consultations and using electronic systems will help in reducing waiting times for consultations but may lead to a surge in patients placed on the waiting lists for treatment. Centres will further explore the use of more electronic systems e.g. In HealthCare and Lensus Digital to increase the capacity for more consultations.

5.5 Cross working between clinics

In this speciality, like most tertiary specialities, there are a limited number of staff trained to perform procedures. With this in mind, staff absence can reach a critical level fairly quickly within smaller teams. Although IVF is a national programme, staff are employed by a local health board and are currently unable to travel to other clinics without lengthy Human Resources (HR) procedures. Experience to date has been that it can take months to process an honorary contract despite all staff being employed within NHS Scotland. It is anticipated that these HR procedures may result in cancellation of patient treatment due to staff shortages.

Ideally cross working between clinics would be possible with staff working between boards and with appropriate legal cover if an individual has a contract with any health board in Scotland. Cross working has also been recommended by the UK professional body, the British Fertility Society in their guidance.

Our current contingency plan already allows patients to be transferred between units for procedures. This has already happened during the pandemic between the Centres in Edinburgh and Dundee. However, in certain situations, it may not be possible for patients to travel.

5.6 Communication with Primary care

We have had feedback that primary care colleagues are sometimes unsure as to which services are running in secondary and tertiary care. While some referrals are been sent to secondary care, it is possible that others may be holding back referrals. This will impact on the pathway and eventual success rates for patients as age is the single most important factor affecting success rates.

We will continue to work on communication with primary care so that initial secondary care consultations continue. All modalities such as email, intranet/ website update and social media will be used.

5.7 Support for patients

Centres will work with Fertility Network UK to continue to support patients during these unprecedented and unpredictable times, aiming to provide updates to patients by regular webinars hosted by Fertility Network UK and delivered jointly by four tertiary clinics. The first one took place on 30th June and a second on 25th August. Clinics will continue to frequently update local websites as a method of ensuring

patients are provided with up to date information. All clinics have already increased capacity to answer phone calls. All counsellors have been working throughout the pandemic and will continue to do so remotely. Cross clinic working of counsellors will be considered between the clinics as per existing contingency arrangements.

Fertility Network UK has worked tirelessly to provide patient support with an increased number of calls, and both SG and clinics are enormously grateful for the support they have given to patients and clinics during this period.

5.8 National and international guidance

We are developing national guidance in conjunction with emerging evidence from national (BFS) and international professional societies (ESHRE) as well as the advice from Scottish Government and Public Health Scotland.

5.9 Donor gametes

Recruitment of donor gametes was put in phase 5 of the restart framework road map. This was because recruitment campaigns need significant mobilisation of staff and requires donors to come to hospitals thereby putting them at risk of infection, when they themselves are healthy.
Donors will also increase the footfall which in turn may increase risk of transmission.

Given the concerns of winter as highlighted in section 3, it is unlikely that we will be able to start recruiting donors until spring 2021. This will have a major impact on the group of patients who require donor gametes.

In Scotland we have worked together with the National Infertility Group and Scottish National Blood Transfusion services (SNBTS) to have a centralised storage system for gametes and embryos (both for donation and fertility preservation). This will also create a central donor gamete bank. SNBTS have received approval by the regulatory authority, the HFEA, and this was to have its launch by the Minister for Public Heath, Sport and Wellbeing, on the 17th of June 2020 but has been paused due to COVID-19.

Plans are in place to get all documentation and processes ready for recruitment for donors so that the campaign can be launched as soon as possible, when the risk of COVID-19 and concerns with winter are reduced. This will be prioritised as soon as it is safe to do so. Centres will look to share the donor gametes they currently have in storage at present, where possible.

5.10 Waiting for elective surgery

Those waiting for surgery prior to IVF will continue to have IVF treatment if they can safely do so. However, their embryos will be frozen rather than immediate transfer as without surgery chances of the implantation are less e.g. hydrosalpinx/ fibroid resections.
Those who need surgery even to facilitate IVF and are nearing the upper age limit to access funding, will be escalated through local health boards, if possible.

5.11 Self-funded patients

Self-funded patients will be treated in conjunction with local agreed policies and previous organisational structures. This will ensure appropriate budgetary management and avoid the unnecessary burden of organising specialised transport and legal documentation to enable gametes and embryos to be transferred to independent sector facilities.

6 Support for staff

Joint teaching sessions
We will do joint teaching sessions remotely through Microsoft Teams/ Zoom for staff across the Scotland rather than just local teachings.

Complex case MDTs
Complex case MDTs have been set up every Friday morning to discuss cases requiring multidisciplinary input and challenging situations. Membership consists of patient representatives, clinical academics, clinicians, scientists and government.

Regular meetings
Regular meetings will continue to happen within ACU leads group (the group responsible for this report), once every fortnight or more frequently if needed.

7 Specific Issues

7.1 Face coverings

Face coverings will be used in clinics as set out in Scottish Government and local Health Board guidance, both by staff, patients and those accompanying patients for support.

If a patient refuses to wear a mask, clinics have the right to refuse to treat them, unless there is a medical reason that they cannot wear a mask. Staff and patients should not be exposed to any unnecessary risk.

7.2 Training

All training will need to continue during the winter months and beyond. How training is delivered will be modified. Wherever possible, electronic modalities will be used, however where hands on training and attendance at clinic is required, it will need to be accommodated within clinic working. This is in line with RCOG as well as BFS guidance.

Everyone attending the clinic will need to adhere to Scottish Government and local Health Board guidance.

8 Abbreviations

ACU	**Assisted Conception Unit**
ARCS	**Association of Reproductive and Clinical Scientists**
BAME	**Black, Asian and Minority Ethnic**
BFS	**British Fertility Society**
COVID - 19	**Corona Virus Disease 2019**
HFEA	**Human Fertilisation and Embryology Authority**
HR	**Human Resources**
ICSI	**Intracytoplasmic Sperm Injection**
IPC	**Infection Prevention and Control**
IVF	**In vitro fertilisation**
MDT	**Multi-Disciplinary Team**
NHS	**National Health Service**
PPE	**Personal Protective Equipment**
PR	**Person Responsible**
RCOG	**Royal College of Obstetricians and Gynaecologists**
SARS CoV-2	**Severe acute respiratory syndrome coronavirus 2**
SG	**Scottish Government**
SNBTS	**Scottish National Blood Transfusion Service**
UK	**United Kingdom**
UKOSS	**United Kingdom Obstetrics surveillance system**

9 References

https://www.gov.scot/publications/re-mobilise-recover-re-design-framework-nhs-scotland/pages/9/

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https://www.britishfertilitysociety.org.uk/wp-content/uploads/2020/09/ARCS-BFS-guideline-Covid-19-version-3-30-September-2020.pdf

https://www.eshre.eu/Home/COVID19WG

10 Appendix 1: Letter from HFEA to all PRs

HFEA statement on fertility treatment services – effective 13 October 2020

In light of the worrying increase in Covid-19 cases and changes to local lockdown, the HFEA wants to provide some reassurance about fertility treatment.
The changes that clinics put in place from May 2020 onwards, to comply with professional guidelines and keep patients safe, mean that we hope a new national closure of fertility clinics should not be necessary.
All HFEA licensed clinics had to set out a Treatment Commencement Strategy in May 2020 showing how they could provide a safe service for their staff and patients during the pandemic. These strategies are kept under regular review by clinics and our inspectors, and all clinics should follow the latest guidance from the UK professional bodies - the British Fertility Society and Association of Reproductive and Clinical Scientists.
As the pandemic continues, we recognise that individual clinics may face circumstances where they will have to consider whether they can continue to maintain a safe service for a period of time – for example if they have a high level of staff sickness or their local hospital trust decides to restrict some patient services.
We expect clinics to follow professional and local guidance and to review and adapt their treatment strategy to ensure fertility treatment can continue to be provided safely.

11 Appendix 2: Tiers

Level 0 (baseline) and Level 1 - Within these levels, we would expect to see low incidence of the virus with isolated clusters, and low community transmission. Broadly, these levels are the closest we can get to normality, without a vaccine or effective treatment in place, before conditions will allow us to move to Phase 4 of the Route Map. They would be similar to the measures in place during the summer, once we reached Phase 3. The Baseline and Level 1 are designed to be sustainable for longer periods.

Levels 2-3 - Within Levels 2 and 3, we would expect to see increased incidence of the virus, with multiple clusters and increased community transmission. There would be a graduated series of protective measures to tackle the virus, focusing on key areas of risk – broadly, indoor settings where household mixing takes place with less, or less well-observed, physical distancing and mitigations. The measures would be intended to be in place for relatively short periods (2-4 weeks), and only for as long as required to get the virus down to a low, sustainable level.

Level 4 - Within this level we would expect to see very high or rapidly increasing incidence, and widespread community transmission which may pose a threat to the NHS to cope. It is likely that this level would see the introduction of measures close to a return to full lockdown. Measures would be designed to be in place for a short period, to provide a short, sharp response to quickly suppress the virus.

Tier **Level 0 (baseline) and Level 1** **1 - Living with Covid**	**Tier 2 -** **Levels 2-3 Enhanced Measures depending on local virus prevalence**	**Tier 3 –** **Level 4:** **Restricted Measures**
Donor recruitment		
Services resume to pre-COVID level but with new ways of working as highlighted in section 5.	Continue with remote consultations Restrict face to face appointment Continue with fertility services where staffing permits as per HFEA guidance and restart plan already published Appropriate use of PPE both by patients and staff Low threshold for freeze all	Remote consultations continue Face to face only when absolutely necessary Prioritisation of services as per section 5.2 Prioritisation for those at greatest risk of fertility decline Urgent fertility preservations to continue Staff encouraged to work from home wherever possible Consideration for freeze all for suitable patients to reduce ovarian hyperstimulation (OHSS) Appropriate use of PPE both by patients and staff

Road map agreed in restart strategy will be refreshed as needed.

This publication is available at **www.gov.scot**

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