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NHS SCOTLAND

Covid-19 and Fertility Treatment in Scotland

Plans for Restarting Treatment – A Framework

June 2020
Updated 01/07/2020

Scottish Government
Riaghaltas na h-Alba
gov.scot

1 Background

The COVID-19 pandemic has triggered a worldwide suspension of all fertility treatments following national and international guidance. In response to the direct threat of COVID-19 to patients, the wider Scottish population and NHS Scotland services, all NHS funded Scottish centres took the decision collectively not to start any new treatments after 17th March 2020. Those already in middle of their treatment, had their embryos frozen to avoid pregnancy. This was to reduce non-essential treatments and associated travel during the lockdown period. It also released staff and other resources from the fertility sector to COVID-related areas. There was uncertainty of the effect of COVID on pregnancy and pregnancy on susceptibility of COVID infection. This complied with HFEA`s General Direction (GD0014)[1].

While stopping of all treatments happened very quickly, restart is anticipated to be more complex, specifically due to safety measures required for staff and patients in clinic. Although not considered urgent services similar to oncology, fertility treatments are extremely time sensitive with increase in female age being the single most important factor determining the success rates. The Scottish Government has been exemplary in funding fertility services and it is important that these services are provided in a timely manner to be effective and cost effective.

Now that the peak of COVID-19 seems to be over, we need to plan for restarting fertility treatment.

2 Principles of Restarting Fertility treatment

Prior to re-introduction of fertility treatment, clinics must formulate a robust and measured plan to resume services which will ensure safe and effective treatment in combination with minimising patient and staff risk of Covid-19. This is an unprecedented situation and there is limited literature to guide a restart strategy. Hence, we will use guidance issued by the professional bodies (ESHRE & BFS/ARCS)[2,3], regulatory authority (HFEA)[4], public health and Government[5]. We will also learn from experiences of colleagues in other countries who are ahead of UK in this pandemic [6] and take in consideration of risks in pregnancy[7].

At all times any decision about fertility treatments will ensure that critical requirements are met as advised by HFEA (Table 1 & 3), abide by principles laid down by the First Minister[5] (Table 2) and professional bodies (Table 4) in the framework for decision making in relation to COVID-19.

Table 1: Criteria in critical decision making (as per HFEA letter to PR on 23/04/20)[1]

- That Government restrictions on social contact and travel are lifted or eased
- That restarting fertility treatment would not have a negative impact on the NHS
- That there was no evidence that Covid-19 impacted on the health of pregnant women or their babies*
- That fertility clinics are able to provide a safe service

* There is further evidence to when this document was released.

Table 2: Principles used in decision making (as per Scottish document, April 2020)[5]

Safe	We will ensure that transmission of the virus remains suppressed and that our NHS and care services are not overwhelmed.
Lawful	We will respect the rule of law which will include ensuring that any restrictions are justified, necessary and proportionate.
Evidence-based	We will use the best available evidence and analysis.
Fair & Ethical	We will uphold the principles of human dignity, autonomy, respect and equality.
Clear	We will provide clarity to the public to enable compliance, engagement and accountability.
Realistic	We will consider the viability and effectiveness of options.
Collective	We will work with our partners and stakeholders, including the UK Government and other Devolved Nations, ensuring that we meet the specific needs of Scotland.

Table 3: Criteria for opening up clinics (as per HFEA letter to PR on 01/05/2020) [4]

- Record the measures that the centre will be taking to comply with current guidance on safe and effective treatment and the mitigating actions taken in relation to each risk;
- Record the risk assessments undertaken by the centre to identify risks arising from the provision of treatment and the mitigating actions in relation to each risk;
- Record the practical and logistical measures the centre will be taking to deliver treatment safely and in a manner that mitigates the risks arising from, or associated with, Covid-19 for both patients and staff;
- Record all new or revised standard operating procedures or protocols which have been developed to enable treatment to resume safely whilst maintaining compliance with the Government's current requirements relating to freedom of movement and social distancing.

Table 4: Five key principles (outlined in BFS /ARCS document released on 06/05/2020)[3]

- Resumption 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.
- Resumption of treatment should not result in an undue burden on the NHS.
- 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.
- 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.

3 Planning for restarting fertility treatment

3.1 Capacity Planning

Fertility Services rely on multidisciplinary and cross-directorate collaboration in order to provide safe and effective treatment which is compliant with the European directive and UK regulation. Prior to resumption of fertility treatment, a detailed capacity analysis will be required involving early engagement with key stakeholders to identify service level decision makers within areas such as anaesthetics[8], diagnostics, virology, microbiology, biochemistry and genetics to ensure that they can support the third-party testing and turn-around times required to provide treatment. Provision of fertility treatment also relies on other services such as routine cervical screening services which are currently suspended.

It is also important to engage with referral pathways to predict estimated numbers of referrals. This will include dialogue with referring Health Boards as well as GP services, wider acute services including Urology, Endocrinology, Gender Identity Service and Oncology.

Clinics may experience an initial reduction in pre-pandemic numbers due to ongoing social distancing measures. However, as social distancing measures are eased and referral pathways resume to normal service, it is reasonable to assume that the numbers of patients accessing the service will increase. It will be important to estimate the impact on waiting times in order for patients to be appropriately informed as soon as it is logistically possible.

The key driver in capacity planning will be the number of treatment cycles and the split of treatment types which can be safely processed through the laboratory area while observing safe social distancing practices. Once the laboratory capacity has been determined, the flow of patients entering treatment and all associated appointments can be appropriately planned and clinic templates devised. This planning will be critical in accurately forecasting waiting times and preventing bottlenecks and hidden waiting lists.

3.2 Modifications to practices

In order to meet the principles laid out in section 2, several practices will need to be modified to ensure safety. The following modifications were collectively agreed in meetings on 28/04/20 and 05/05/2020.

<u>Increased use of remote consultations</u>

Most consultations (medical, nursing, laboratory and counselling) will be remote using systems e.g. attend anywhere, near me. This will ensure that whatever can be done without a face to face appointment is done prior to patients attending in person. It will significantly reduce the number of face to face appointments, hospital attendances and staff-patient

contact time, thereby increasing patient and staff safety. **Hence everyone will have remote consultation prior to attendance in person.**

Telephone screening check immediately prior to attending clinic

Telephone consultations to patients a day prior to attending clinic for appointment (e.g. for semen analysis, ultrasound scan, tubal patency check) to check if all immediate pre- test requirements are met (e.g. contraception for tubal patency check & abstinence for semen analysis) to reduce risk of cancelling on the day. In addition, this will ensure patients are still asymptomatic from COVID-19. This will avoid unnecessary travel.

Restricted access to clinics

Most fertility treatments involve couples. Traditionally we have encouraged both partners to attend. However, we would advise restriction for partners to attend unless there was absolute clinical need to do so. This is to ensure footfall is reduced as well as risk of transmission.

Access criteria for treatments

Currently smoking and BMI are access criteria for treatments, and they have traditionally been checked (by carbon monoxide testing and taking height and weight in clinics) at face to face appointments. It was collectively agreed (28/04/20) that this can be done by asking patients in remote consultations. This will be checked and documented opportunistically at the first face to face appointment and patients will only progress with treatment if the eligibility criteria are met. Patients will be made aware of this at remote consultation supported by documentation by letter.

Judicious use of investigations which require face to face appointments, providing a diagnosis but which do not change the treatment plan will be practiced e.g. use of tubal patency test for determining cause of infertility or repeat sperm tests.

After discussion a flow chart has been agreed, if there is a delay in cervical screening (Appendix 3)

Consents

Due to stringent regulations, fertility services need several complex consent forms to be signed prior to commencing any treatment. This has been traditionally done face to face in long appointments.

Online electronic consents specific for fertility treatments are now available, which meet regulatory requirements. They can be completed by patients in their own time and space. Their progress and consent documents can be checked remotely by clinic staff. Clinics are already using it in other devolved nations.

We aim to work collectively across Scotland along with the Government and NSD to procure the dedicated package as soon as possible. This will save time for clinic staff, reduce face to face appointments for patients and will meet regulatory requirements in a realistic manner in addition to being cost effective in long term. An initial meeting with representative of all 4 centers, NSD, SG and procurement was held on 12/05/2020. Further meetings are set up to take this forward.

Use of electronic records

Wherever possible electronic records and communication will be used, as paper and physical records have risk of transmitting infection. Witnessing is important step throughout all fertility treatments.

Safer regimens

Fertility treatments use hormonal medications which have a risk of ovarian hyperstimulation (OHSS). We already use regimens and practices which minimise the risk of OHSS e.g. use of antagonist regimens, GnRHagonist for trigger and low threshold for electively freezing all embryos in those at high risk of OHSS. Empirical immunosuppressants are not used in Scotland.

We will continue to follow the multiple birth minimisation strategy to reduce the risk of multiple pregnancy to keep it to lowest in line with professional and regulatory bodies advice. Anyone at high risk of multiple pregnancy (e.g. young women with good quality embryos) should not have double embryo transfer to reduce the burden on NHS further in line with Government and health board advice (https://fertilitynetworkuk.org/trying-to-conceive/fertility-treatment/fertility-treatment-options/single-embryo-transfer/).

As per guidance issued by BFS/ ARCS, we will agree on a Scotland wide protocol for use of antibiotics in procedures.

Wherever possible protocols will be modified to reduce face to face monitoring requirements, without compromising success rates of the treatments.

Procedures including AGPs will only be performed where strictly necessary and will be avoided where there is a risk of COVID-19. Consideration to alternatives (local or regional anaesthesia, conscious sedation, deferment) will be made and if alternatives are not available consideration given to screening patients beforehand. It is not expected that AGP will form a routine part of most fertility centres work. Any individual cases will be discussed in multidisciplinary team if there is a requirement for AGP.

Consent to go ahead with treatment

Although fertility treatment may start, in the current scenario, all patients will be given a choice of deferring treatment for 6 months without compromising their position on

waiting list (Appendix 1). The 6 months will start from the point that their clinic contacts them with an offer of treatment. Those who chose to defer, must contact their clinic within these 6 months with a view to start treatment.
They would need to actively consent, prior to having any fertility treatment whilst there is a risk that they could contract COVID-19 either during the treatment or if successful, during pregnancy or following delivery. This will be regularly reviewed.

Scheduling of procedures

Planning will be done to minimise staff working at various workstations/ procedure rooms especially in the laboratory and in the sharing of equipment as much as possible. Working patterns of staff will be reconfigured to minimize interaction between staff and reduce the number of personnel present within the service at a given time. This will be carefully balanced to ensure that there are appropriate levels of staff to safely carry out clinical activity. This may require working in smaller teams, extending the working day, compression of hours and spreading the work force across a 7-day working model. When planning staff rosters, the appropriate skill mix will be maintained and staff working towards HCPC registration, the certificate of completion of training will continue to be supervised and supported in undertaking laboratory and clinical procedures. Developing new flexible working patterns will take cognisance of the fact that it may be easier for some staff to work flexibly than others. This will need to include Human Resources team locally and Partnership engagement. In making all decisions, considerations will be given to safety of staff and patients as well as ensuring continued suppression of virus.

3.3 Specific issues for Laboratory

Where deemed appropriate, the home production of semen samples for treatment will be considered as an effective way to reduce patient footfall and transmission.
Infection control practices will also be reviewed and amended. This will include increased frequency of hand washing and use of appropriate PPE. The increased frequency of robust decontamination procedures which are not detrimental to gametes and embryos will be employed. Waste management practices will be used to ensure clinical waste is being handled in a manner that will reduce risk of contamination, at the same time disposed of in a timely and sensitive manner.
Any equipment which has been switched off will be monitored over a period of time to ensure it is fully functioning (FAQ Issued by HFEA 22/04/20). All service maintenance of equipment will be undertaken as usual. Clinics will contact the main suppliers that supply laboratory

media and consumables to ensure there is likely to be enough availability of products and that the delivery will be unaffected due to increased demand from the clinics. The main suppliers of IVF products – Vitrolife, Cook, Cooper Surgical and Hunter – have all advised that there is plenty of availability of products and delivery time of products should be as normal.

Currently, there is evidence, although limited, to support the presence of Coronavirus in gametes or embryos, therefore caution will be applied to the handling and processing of samples. It is too early to have data for risk of infection, transmission and persistence. In cases where patients are symptomatic and tests results for COVID are awaited, closed systems or vapour phase storage will be considered to reduce the risk of cross contamination between samples and transferred to an appropriately screened/ confirmed positive storage tank once the results are known.

3.4 Risk assessments at individual clinics

Prior to resuming treatment, all procedures (including lab procedures) will be individually process mapped and risk assessed to identify where risk of transmission and infection can be safely reduced without negatively impacting treatment outcome.

While most decisions and practices will be agreed at Scottish level, there will be individual variations in clinic practices depending on space and staffing availability. Hence individual risk assessments will be required by clinics for each area of working practices including office space, waiting areas, templates for clinic appointments, procedures, recovery area, access to sperm production rooms, practices within the laboratories to ensure social distancing etc. Although done individually, the risk assessments will be shared amongst various clinics to ensure sharing of good clinical practices and work more collectively.

3.5 Start date

On the 1st of May 2020, the HFEA announced that fertility clinics will be able to apply to reopen once a revision to GD0014 has been issued. The HFEA have indicated that the revised GD0014 will be issued the week beginning the 11th of May, with applications to commence treatment to be submitted thereafter. The process for applying to reopen is dependent on completion and approval of the HFEA COVID-19 Treatment Commencement self-assessment tool. Processing is expected to take 5 working days from submission.

Written approval from the centre Inspector must be received prior to resumption of treatments. In addition to fulfilling HFEA`s requirement, Scottish clinics will need permission from Scottish Government as well as local health boards before resuming activity. At the same time consideration will be given to lockdown restrictions that currently are extended till end of May 2020. Travel will be for medical reasons only.

All NHS clinics in Scotland have agreed on a single date (18/05/2020), in agreement with Scottish Government, for application to HFEA to lift General Direction 00014. It is anticipated that the type of treatments prioritised may differ in clinics in the beginning, but all clinics will be able to provide all treatments eventually.

This is because fertility treatments are not done in isolation and require support from other specialties within hospital. A phased and measured introduction of treatment will be required to facilitate safe practice and patient treatment while allowing time to review and improve upon changes which have been made to routine practice during the COVID-19 pandemic. Careful planning will be required to determine the number of treatment cycles and the different types of treatment types that can be safely processed through the laboratory and clinical area while observing social distancing practices. Timing of clinical procedures will be optimised to ensure scheduling which will reduce risk to patients and staff and to allow safe workflow within the clinic without compromising success rates.

4 Working together for Scotland

4.1 Equity of treatment

In order to provide equitable services across Scotland we will prioritise NHS funded treatments across all 4 centres to treat NHS funded patients. There will be no transfer of funding to private centres, even if there was a request for the possibility of earlier treatment. All centres will maximise their capacity by working efficiently to get through waiting lists. However, this will need to be done safely and cautiously taking into considerations of the principles outlined in section 2.

4.2 Communication

At all times communication will be key in managing this unprecedented clinical situation. We will communicate between clinics, within clinics, with primary care colleagues, patients and professional organisations such as HFEA, BFS, ARCS as well as colleagues in other parts of the world, who have already restarted treatments. We will work closely with Fertility network UK (the UK's leading fertility patient organisation) throughout our discussion.
Weekly meetings are booked with representation from Aberdeen, Dundee, Edinburgh and Glasgow.

4.3 Prioritisation of treatments

We are aware that waiting lists will be long and many patients would wish to have treatment as soon as possible. All clinics have been keeping lists of those who could not complete treatment and those who could not start, in addition to keeping a list of those on waiting list. It is uncertain at present times as to whether we should treat everyone in order of waiting list or prioritise those with low ovarian reserve or start with those who have embryos frozen. Any decisions will need to take in considerations as outlined in section 2.
During the meeting on 28/04/20, the group agreed that there were benefits in starting treatments for those with embryos frozen as:

- This does not pose risk of ovarian hyperstimulation (which may need unpredictable hospital admission and sometimes multiorgan dysfunction and ITU admission)
- It is simple, safe relatively non-invasive treatment and easy to start and stop, if we need to, in event of second wave of COVID-19 and further lockdown.
- It allows for all staff to adapt to new ways of working and refresh skills
- It does not require sedation, oxygen or anaesthetists, who may be required elsewhere

Evidence up until now suggest that COVID-19 does not have significant impact on pregnancy. However, we have to be mindful that this is new disease and evidence is

continuously evolving, both in terms of data relating to disease symptoms, impact on body systems and long term sequelae. We will continue to monitor evidence on pregnancy and COVID19 as it is evolving[7]. Pragmatic decision based on robust clinical data will be made and modified as clinical and scientific data are available.

In making decisions we will be conscious that fertility treatments involve multiple appointments at hospital i.e. travel, although travel is for medical need but poses risk in current climate. This poses real risk to those who have to travel long distance as treatments are provided in Aberdeen, Dundee, Edinburgh and Glasgow only. At all times considerations will be given to equity, parity, as well as logistics of delivering a safe service alongside patient wishes.

We are aware of the potential need to suddenly stop treatments in the event of a second wave.

Diagnostic services may be started first (e.g. semen analysis and Hydro-contrast sono-salphingography) followed by treatments. This will give a chance for some of the process to be rehearsed and modified before actual treatment start.

We will apply particular caution 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 hypertension, diabetes, severe asthma 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. These will be discussed as part of multidisciplinary group for individualised decision making.

If a patient had COVID -19 which required respiratory support, we will liaise with relevant clinicians. Treatment will only be commenced once a favourable assessment is obtained.

We will work with evolving scientific and medical evidence to prioritise fertility treatment and develop a joint approach which will be transparent and uniform across Scotland.

A Road map has been agreed (Appendix 4) after multiple discussion within the group.

4.4 Access to NHS treatment

The group is aware that there are patients who could not start treatment despite being near or at the top of the waiting list, others could not complete or initiate a subsequent cycle of treatment, while others are waiting for initial referral.

As one of the main access criteria to NHS treatment is based on age of female partner, many fear losing access to NHS funded treatment due to delays imposed by COVID-19, and others may not be able to access their full potential entitlement.

In order to be fair, equitable and ethical, it was agreed that those who are already on waiting list will have this time paused and extra months from 17/03/20 – to whenever the clinics can open (and contact individual patient to offer fresh IVF treatments) will be added to their access for their full treatment journey, as long as other NHS criteria of are met. This is the case both for couples where the partner being treated is under 40 and couples where the partner being treated is aged between 40 and 42.

All those who are referred from primary and secondary care during the pandemic time (01/03/20 - 31/08/2020), will have 6 months added to age eligibility criteria, so that couples, especially where the woman/partner having treatment is older, are not disadvantaged in accessing either one full cycle or three full cycles, if it is clinically appropriate to do so. This takes into consideration that there have been delays in referrals for treatment, both at primary and secondary care. We are also aware that patients have not approached GPs for referral due to the pandemic.

However, all clinics will be working with remote consultations to address these referrals as soon as it is feasible and safe.

Frequently asked questions (FAQs) to patients, which will be put on webpages of all clinics and Fertility Network UK, to provide clarity regarding management of the waiting list so that is transparent and clear.

5 Support

5.1 Support for patients

Counsellors are an integral part of the treatment and support offered by the clinics as per regulatory requirements. Counselling will be offered remotely using telephone appointments or systems e.g. attend anywhere, near me, which will significantly reduce the number of face-to -face appointments, hospital attendances and staff-patient contact time. Information about counselling will be made available on webpages of all clinics.

There is work being undertaken to develop online/video psychosocial educational groups as well as possible support groups. As a result of welfare of the child considerations or case complexity, on occasion face to face counselling or assessment may still be required in the medium term.

We plan to host Webinars for patients instead of face to face patient information evenings (PIE) that are usually attended by multiple patients together, to keep the interaction and be able to answer the queries. We also aspire to do sessions for patients for specific causes of infertility e.g. male factor, endometriosis etc. using online platform, jointly across Scotland. This will not only maximise the use of resources but will help in providing consistent information to patients across Scotland.

All clinics will ensure support for patients by increasing the capacity to answer queries via telephone and emails. In addition to sharing the good practices, clinics will share any online resources so that there is no duplication of efforts e.g. no delays by NHSG.

As part of information during the treatment patients will be advised that other services in NHS e.g. Early Pregnancy Assessment Units may have different policies during COVID-19.

Patients have already been advised through communication put on the website that clinics are not open yet but can apply to open in the week beginning 11th May. Clinics will be in touch with patients on the waiting lists as soon as they can proceed with treatments safely. Prior to any treatment patients will be provided with information relating to the risk of Covid-19 by coming to hospital, in pregnancy and be offered the choice to defer treatment by signing the consent form (Appendix 1).

Fertility Network is the leading patient-focused fertility charity and provides free and impartial support as well as advice at practical and emotional level to improve information and understanding. Patients have access to a support line manned by a retired fertility nurse and a community of people affected by fertility problems at https://fertilitynetworkuk.org/ or Scotland Coordinator: 07411 752688 or Support line: 0121 323 5025

Patients can also access more information from following webpages

- HFEA COVID-19 guidance for patients
- British Infertility Counselling Association
- Fertility Friends
- https://www.gov.scot/coronavirus-covid-19/
- https://www.nhsinform.scot/illnesses-and-conditions/infections-and-poisoning/coronavirus-covid-19/coronavirus-covid-19-general-advice

5.2 Support for Staff

As there will be a number of significant changes in the ways of working, clinic leads will ensure communication within their own multi-disciplinary teams. This is especially important as many staff have been redeployed. They will need to be recalled, when safe and feasible to do so. There will be a period of retraining, mock drills and refining the process to ensure that new ways of working are feasible and are abiding by the principles outlined in section 2. Good practices will be shared across all clinics in regular weekly meetings. Staff support policies and procedures will be in place in each clinic to ensure that:

- The mental well-being of staff is considered and reviewed as necessary
- Staff support and counselling systems are in place should they be needed
- Staff continue to be engaged and encouraged to provide feedback on progress and potential improvements to treatments during the COVID-19 pandemic
- Peer support is available as needed
- Staff safety in the workplace is paramount and centres should ensure that risk assessments are in place where appropriate to minimise the risk of infection

There are individual health board web pages e.g.
https://covid19.nhsgrampian.org/for-nhs-grampian-staff/
http://intranet.lothian.scot.nhs.uk/StaffRoom/StaffHealthAndWellbeing/Pages/default.aspx
https://www.nhsggc.org.uk/your-health/health-issues/covid-19-coronavirus/
There was also support amongst group to share the staff continuous professional development (CPD) sessions as they will now all be done remotely. This will not only enhance communication but will reduce the variability of practices across Scotland.

5.3 Code of conduct for Staff

All staff members will be asked to read and sign a code of conduct when clinics reopen, as required by HFEA (Covid -19 Self-assessment questions 11,12,13) as a prerequisite to grant permission to provide licenced treatments. This will instruct to avoid unnecessary exposure (both at work and in private) as per current government policies for social distancing. This will be emphasised in team briefs. Attendance at work will be tied to respecting this Code of Conduct. Staff members will inform their line manager of any infringements of the Code of Conduct previously signed.

If triage questionnaire (e.g. in Appendix 2) is completed, answering *Yes* to any question in the questionnaire, staff may be advised isolation/testing as per local policy advised by Public Health Scotland. In addition to following Government guidance, Staff who are shielding or who live with someone who is shielding, will not be involved in care of patients.

5.4 Code of conduct for Patients

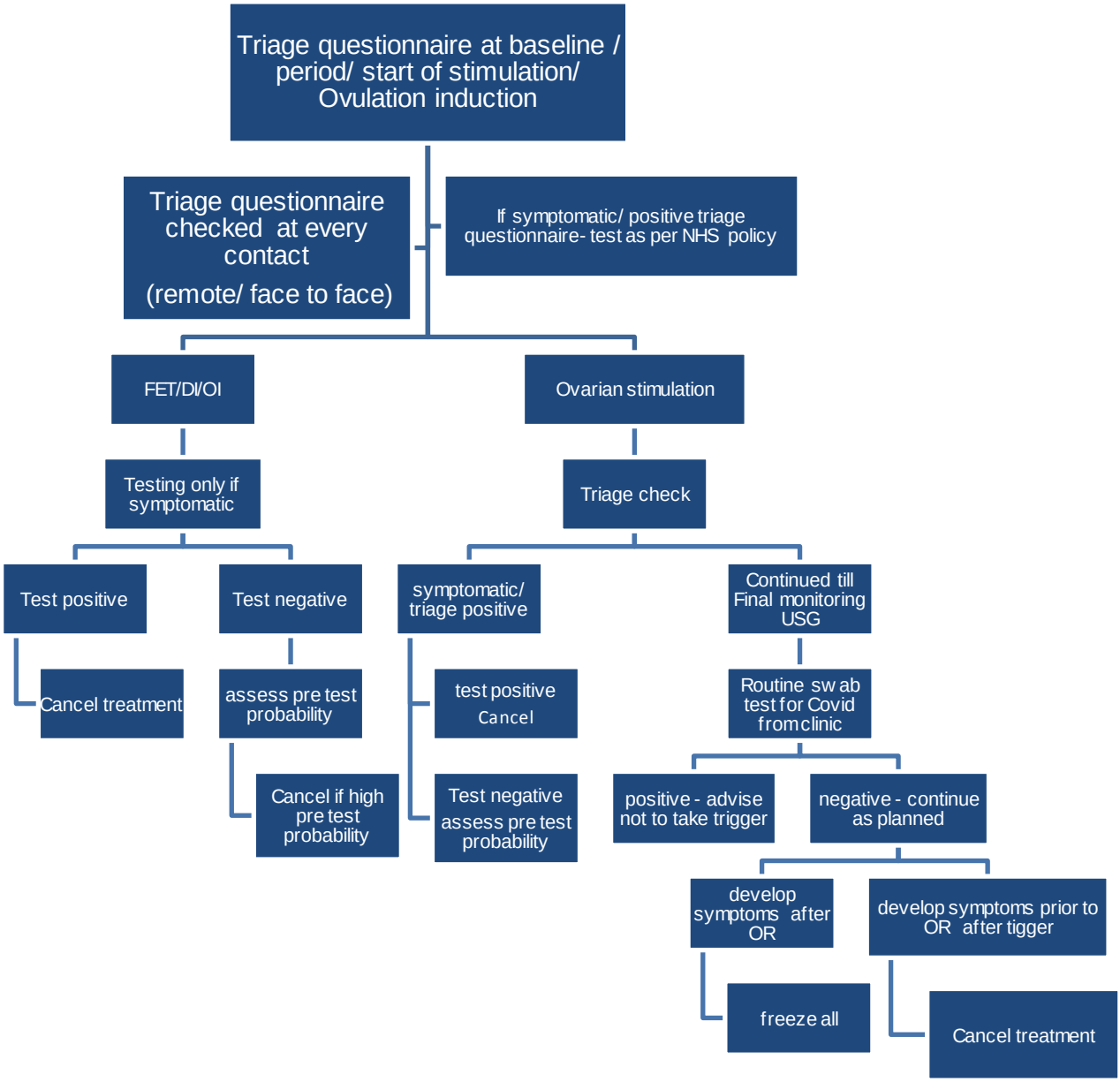
All patients will be instructed to sign a consent prior to commencing any treatment, which will incorporate the code of conduct to avoid unnecessary exposure (both at work and in private) as per current government policies for social distancing. The triage questionnaire (Appendix 2) will be filled in 2 weeks prior to commencing treatment and will be confirmed at each interaction.

6 Uncertainties

6.1 Testing strategies

Although European (ESHRE) guidance provides a good framework for creating a COVID-19 free environment in fertility clinics, the testing strategies they advise are not approved in the Scotland yet. In addition, there are still uncertainties about sensitivity, specificity and availability of various tests especially in asymptomatic patients.
https://www.gov.scot/publications/coronavirus-covid-19-getting-tested/pages/overview/
It is important for consistency that all clinics are following similar protocols, hence further guidance from virology was sought..
We liaised with the Clinical Lab/Virology Cell in Health Protection Scotland for further advice on guidance for Fertility treatment and COVID-19 testing. We propose the flow chart as in figure 1, based on these discussions.

Figure 1: Flow chart for test and decision making



If pre-test probability[9] is high, treatment will be cancelled irrespective of the test.

The time point of testing prior to OR (oocyte retrieval) is taken in line with other pre operative testing. Testing will be requested at last monitoring USG, which is approximately 40-48 hours prior to the procedure.

Patients (as per consent) will be asked to follow government guidance for isolation preoperatively during the course of treatment,

There will be no financial implications/ full access to NHS funded treatment if the treatments are cancelled due to COVID-19.

6.2 Use of Personal protective equipment

Safe distancing will be practiced wherever possible. It is accepted that some processes (e.g. diagnostic, operative and laboratory work) will require working within close proximity to colleagues. Although most procedures are not aerosol generating, appropriate PPE (https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe) and application of infection control measures will be required for each area to reduce the risk of infection.

A suggested guidance for PPE for specific processes in fertility treatment is given in Table 5. **Securing PPE will be a challenge when we are competing with other specialties.**

Table 5: PPE requirements for specific fertility procedures

Setting (triage negative/ test negative)	disposable gloves	Plastic apron (single use)	Fluid resistant overall	Fluid resistant surgical mask	Eye/face protection
Reception				sessional use	
patients				single use	
Examination / USG/ HyCoSy	single use	single use		sessional use	
venepuncture	single use	single use		sessional use	
Egg collection (operator)	single use		Single use	sessional use	sessional use
Egg collection (other staff in room)	single use	single use		sessional use	
ET/IUI	single use	single use		sessional use	
Andrology lab	single use	single use		sessional use	
Embryology lab	single use	single use		sessional use	

Use non embryo/gamete toxic cleaning material for clean room and egg collection/ embryo transfer procedures

6.3 Second wave

Although the current lockdown may ease, we recognise that there is a possibility of second wave especially during winter flu season, and thus a possibility of restrictions being re-imposed. Although it is not possible to predict timing and/or duration, this may cause further impact on provision of fertility services, which will need to be factored in, to decision making at a later date.

7 Review of Strategy

Regular review of any decision making will be done by initially weekly meetings through ms teams. It is anticipated that the strategy will evolve as more evidence and experience comes.

This will then potentially lead to changes in protocols at both national and local level to provide more effective care by efficient use of resources.

At all times this will be collective decision across Scotland using a multidisciplinary approach.

Patient and staff feedback with new practices will be key part in reviewing the strategy

8 List of Abbreviations

ARCS	Association of Reproductive and Clinical Scientists
AGP	Aerosol Generating Procedure
BFS	British Fertility Society
COVID-19	Corona Virus Disease 2019
ESHRE	European Society of Human Reproduction and Embryology
EU	European Union
FET	Frozen Embryo Transfer
FFP3	Filtering Face Piece Mask 3
HCG	Human Chorionic Gonadotrophin
HFEA	Human Fertilisation and Embryology Authority
HyCoSy	Hydrocontrast Sono-salpingography
ITU	Intensive Treatment Unit
NHSG	NHS Grampian
PR	Person Responsible
PPE	Personal and protective equipment
UK	United Kingdom

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10 Membership of the group

Fertility Network UK
Gwenda Burns – Chief Executive

Aberdeen
Alison McTavish, Unit Manager and Licence holder
Abha Maheshwari, Lead Clinician and Person Responsible
Elizabeth Ferguson, Laboratory Manager

Dundee
Sarah Martins da Silva, Consultant Gynecologist and Person Responsible
Suresh Kini, Consultant Gynecologist

Edinburgh
Joo Thong, Lead Clinician and Person Responsible
Dave Wales, Quality Manager

Glasgow
Helen Lyall, Lead Clinician
Joanne Leitch, Person Responsible
Scott Nelson, Professor of Obstetrics & Gynaecology, Nominal HFEA license holder
Michelle Mclauchlan, General Manager, Obstetrics and Gynaecology
Isobel Traynor, Lead Nurse Assisted Conception & Gynaecology

Scottish Government
Sarah Corcoran, Team Leader, Maternal and Infant Health
Louise McCue, Senior Policy Manager, Maternal and Infant Health Team

NSD
Carsten Mandt, Senior Programme Manager, Scottish Perinatal Network

11 Appendix 1

Suggested text for letter to be send to patients prior to planning treatments

Dear ……

You are currently on the waiting list for fertility treatment. Following regulatory approvals, we are now in position to be able to offer you treatment. As per current evidence there does not appear to be an increased risk of miscarriage, risk of pregnancy complications or any effect on the baby. However, you need to be aware that the data is limited, and this may change as we continue to gather information. Provision of treatment will however require you to attend hospital which will incur a small risk of viral transmission as compared to social isolating at home. Comprehensive procedures are in place to minimise this risk for all patients.

Please contact us on XXXX to inform us whether you wish to proceed with treatment or remain on the waiting list at this time. We will then be able to provide you with a date to discuss next steps.

If you would rather not attend hospital during this time then you will remain on the waiting list and will be offered another date in the future.

12 Appendix 2

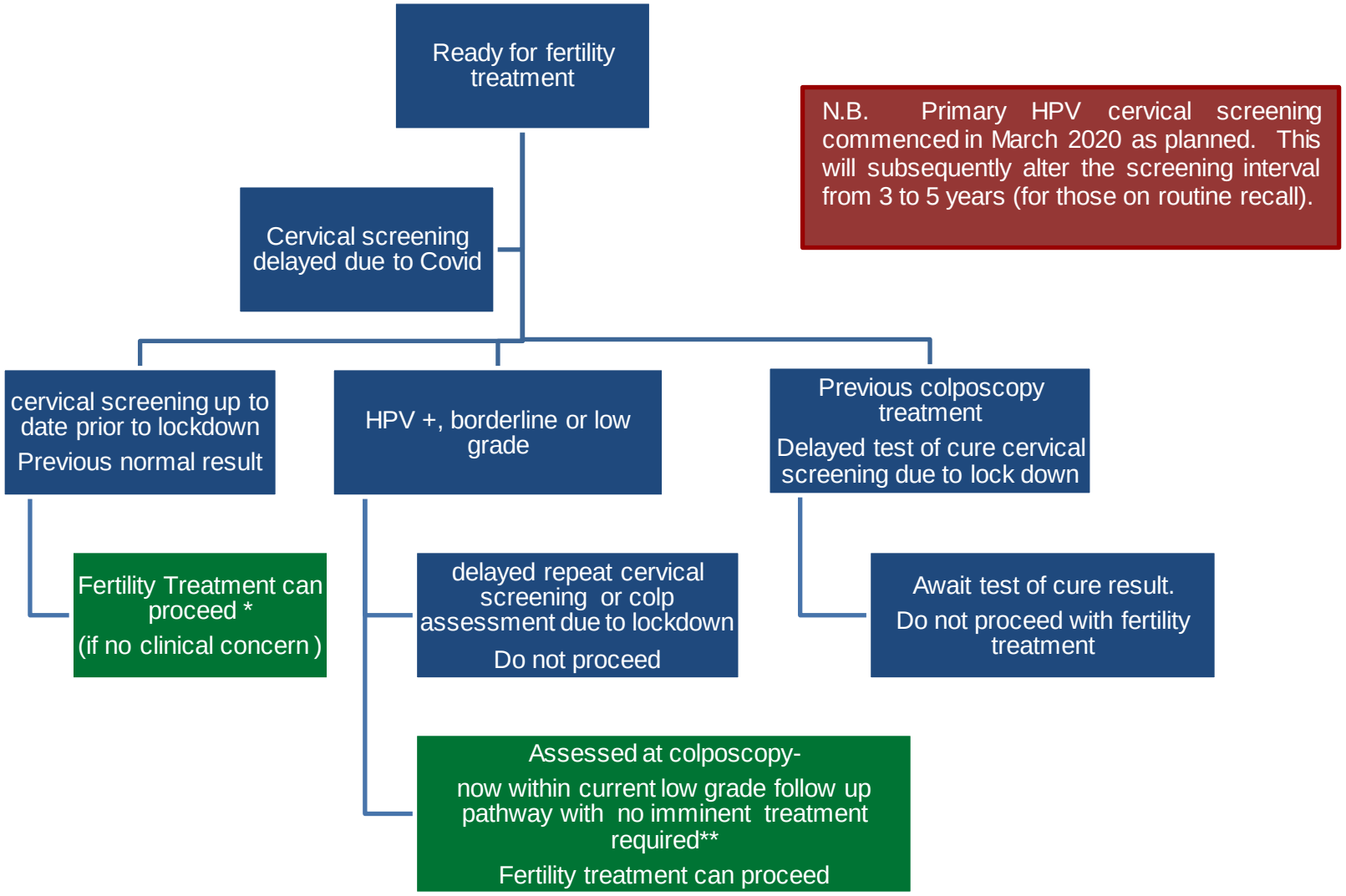
Triage Questionnaire

1. Have YOU or YOUR PARTNER or ANY MEMBER OF YOUR HOUSEHOLD been diagnosed with Covid-19? (not for staff questionnaire)
2. Have YOU or YOUR PARTNER or ANY MEMBER OF YOUR HOUSEHOLD had any of the following symptoms in the last 2 weeks

- Fever (feeling hot or a temperature above 37.8 degrees Celsius)
- Persistent cough
- Loss of the sense of smell
- Loss of the sense of taste
- Sore throat

3. Have YOU been in contact with anyone in the last 2 weeks who has any of these symptoms or has been diagnosed with Covid-19?
4. Have you travelled abroad recently?
5. Have YOU or YOUR PARTNER been asked by NHS Scotland to shield?
6. Do you have a severe medical condition like diabetes, respiratory disease, chronic kidney or cardiac disease, etc.? (not for staff questionnaire)

13 Appendix 3 - cervical screening



* Inform patient that exception has been to usual protocols due to time sensitive manner of their fertility treatment – if patient accepting of this and not able to have cervical screening obtained by local team prior to commencing treatment, then the overdue screening test should be obtained at next available opportunity e.g. postnatal or between cycles.

** Consider discussion with local colposcopy team if scheduled repeat colp assessment/cervical screening due < 3months.
As previously - any patient with an unresolved high grade cervical screening test result, suspicious cervix/symptoms or awaiting a colposcopy treatment should not proceed with fertility treatment until the matter is resolved. Urgent appointments have continued during lockdown.

14 Appendix 4 – Road map

	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Treatments that can be done Only if patients wish to proceed	Urgent Fertility preservation Frozen embryo transfer Donor insemination (DI) (natural cycle only) Diagnostics where feasible **Treatment for only those without comorbidities**	In addition to phase 1 Start of stimulation in older women (≥ 40 years) Ovulation Induction (oral) **Treatment for only those without comorbidities**	In addition to phase 2 Ovulation Induction (injectables) DI with stimulation Start of stimulation in younger women **Treatment for only those without comorbidities**	In addition to phase 3 Non urgent Fertility preservation **Treatment in those with co morbidities**	In addition to phase 4 Donor recruitment
Conditions to be satisfied to move to next phase	Easing of lockdown restrictions progressing as planned No further suspension of activity by HFEA No evidence of detrimental effect of Pregnancy on Covid and vice versa	In addition to requirements in phase 1 Low incidence of OHSS Staff returning from deployed areas as planned	In addition to requirement in phase 2 Low incidence of OHSS	In addition to requirement in phase 3 Full staff complement Social distancing rules relaxed	Full resumption of all services back to pre - Covid state
Conditions to step to previous phase	Government Ease down restriction tightening Complications during treatment Not adequate staff (either deployed/ self- isolation)	Government Ease down restriction tightening Complications during treatment Not adequate staff (either deployed/ self-isolation)	Government Ease down restriction tightening Complications during treatment Not adequate staff (either deployed/ self-isolation)	Government Ease down restriction tightening Complications during treatment Not adequate staff (either deployed/ self-isolation)	

Assumptions for Road map

- Emergency fertility preservation will continue throughout, this include sperm cryo preservation when immediate IVF/ICSI not possible, and sperm count declining
- Moving in phases is not dependent on testing strategies as that will be covered in Government policies
- Diagnostic means semen analysis (which all centres may not wish to proceed) and HyCoSy and USG as that will be required prior to DI and other treatments
- Those waiting for surgery (due to any reason) will need to wait for NHS theatre lists

Pre- implantation Genetic testing – depends on NSD s decision as to which phase they can be done.

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