The Scottish Pre-implantation Genetic Testing Service

Framework for Decision-Making

Date of issue: March 2021
Version 2.7

This document has been produced by the Expert Panel on Pre-implantation Genetic Testing and can be found on the National Services Division website at www.nsd.scot.nhs.uk

This document was agreed with the understanding the framework would be reviewed again in line with NSD's planned review of PGT Service no later than six months

If you have any queries regarding this Framework document, please contact: nss.sglc@nhs.scot

Date for review: August 2021

Contents

Executive Summary

An Expert Panel for Pre-implantation Genetic Testing (PGT) was established in 2010 to develop a framework for ensuring that decisions made relating to access to and prioritisation of patients in the Pre-implantation Genetic Testing service in Scotland are reasonable, transparent and justifiable.

The panel includes wide representation from those involved in the clinical delivery of the service, to service planners, lay representatives, as well as those working in the field of law and medical ethics. Reasonableness, transparency, justifiability and equitability are central principles embraced by the Panel to ensure procedural fairness and accountability in the decision making processes.

The criteria that should be applied in deciding which individuals should be offered access to the PGT service include:

- Predisposed risk of passing on a genetic condition to their child.
- An accurate test is available and a license has been obtained from the Human Fertilisation and Embryology Authority (HFEA).
- Referrals to be made before woman's 39th birthday.
- Woman to have a BMI between 18.5 and 30. *[Patients should only be placed on a waiting list if their BMI is ≥ 18.5 and ≤ 30].*
- Woman to have anti-Müllerian hormone (AMH) level assessment.
- Both partners should be negative for HIV, Hepatitis B and C.
- Couples must have been co-habiting (living at the same address in case of any doubt) in a stable relationship for a minimum of two years.
- No previous unaffected genetic children as a couple / Couples where only one partner has a child
- One partner has no living genetic child.
- Couples are eligible for up to 3 cycles of PGT *[Previous NHS IVF/ICSI treatment will be subtracted from this].* Eligibility will be reviewed after each cycle.
- Both partners must be resident in Scotland and eligible for NHS treatment.
- Both partners must be non-smoking (including e-cigarettes) and nicotine free for at least 3 months before being placed on the waiting list for treatment. Couples must continue to be non-smoking and nicotine free during treatment.
- Both partners must abstain from illegal substances and/or substances of abuse.
- Both partners must be methadone free for at least one year prior to referral for treatment.
- Neither partner should drink alcohol during the period of treatment.

The Expert Panel will continue to exist as a group which clinicians can consult for an impartial expert opinion and will be the first point of contact for advice and expertise. A decision by the Expert Panel is considered final, but the couple will have right of appeal.

1. Introduction

Difficult decisions are made at all levels of healthcare organisations on a regular basis; whether they relate to the planning and prioritisation of services for the population, or decisions about individual patients. The challenge is to ensure that such decision-making is reasonable, transparent and justifiable.[1] This document provides a framework for ensuring that decisions made relating to access to and prioritisation of patients in the Pre-implantation Genetic Testing Service in Scotland meet these goals.

2. National Services Division

National Services Division (NSD) is a division within NHS National Services Scotland (NSS). Each year, NSD receives secured top-sliced funding from the Scottish Government Health Directorates (SGHD) to commission and to performance manage nationally designated specialist services, National Managed Clinical Networks (NMCNs) and screening programmes on behalf of NHS Scotland. NSD's primary purpose is to ensure the provision of high quality, effective, specialist health and screening services to meet the needs of the population of Scotland. This is done through a continued cycle of performance management. NSD works within the principles of safe, equitable, efficient, effective, person centred and timely care as defined in The Healthcare Quality Strategy for NHS Scotland.[2]

The Scottish Pre-implantation Genetic Testing Service is one of the nationally designated services commissioned by NSD. A full list of designated services can be found at on NSD's website at http://www.nsd.scot.nhs.uk.

3. Scottish Pre-implantation Genetic Testing (PGT) Service

The Scottish Pre-implantation Genetic Testing (PGT) service was designated as a national service in 2005. Cytogenetic testing for fetal chromosomal structural rearrangements (PGT-SR) is offered at the Glasgow Royal Infirmary, NHS Greater Glasgow and Clyde. On 1st April 2010, the nationally designated PGT service was expanded to provide molecular single gene (monogenic) testing (PGT-M) also at the Royal Infirmary of Edinburgh, NHS Lothian. Pre-implantation genetic testing for aneuploidy (PGT-A) is not included or funded under the remit of the commissioned Scottish Pre-implantation Genetic Testing (PGT) service.

3.1 National funding

National funding cannot be used to fund treatment in private, university, charitable or other non-NHS facilities. NSD has a responsibility with regard to Out of Area (OoA) referrals and can only use providers that are commissioned and quality assured by NHS England, as NSD is unable to quality assure private providers. Services provided in the private sector can still be funded by the NHS, but this has to be a local decision by the appropriate NHS Board, with any funding deriving solely from the NHS Board's budget.

3.2 Out of Area referrals

Once referrals are approved by the PGT Expert Panel for Out of Area (OoA) treatment, the referring Health Board is responsible for submitting the form to the NSD Out of Area referral team (nss.nsd-oats@nhs.scot) for ratification by the NSD panel and to be coded for invoicing purposes. This ensures the appropriate mechanisms are in place for funding and streamlines the referral process.

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[1] National Policy Forum (2010). *Making Difficult Decisions in NHS Boards in Scotland: Report of a short life working group.* Available at: https://www.webarchive.org.uk/wayback/en/archive/20180516082148mp_/http://www.gov.scot/Resource/0039/00392165.pdf. Last accessed: 5 July 2020.

[2] The Scottish Government (2010). *The Healthcare Quality Strategy for NHSScotland.* Available at: https://www.gov.scot/publications/healthcare-quality-strategy-nhsscotland/. Last accessed: 5 July 2020.

The referral form must include the patient's initials, date of birth and postcode and evidence that the patient's Health Board of residence are aware of and supportive of the referral. NSD funds the treatment; it is the responsibility of the Health Board to fund associated costs and expenses including travel and accommodation.

The referral form can be found in Annex 1.

4. Pre-implantation genetic testing

4.1 What is pre-implantation genetic testing?

Pre-implantation genetic testing (PGT) refers to procedures that are performed on embryos prior to implantation or oocytes prior to fertilisation. PGT is a procedure which allows the testing of embryos at an early stage of development to identify whether they are affected by genetic disorder / chromosome abnormality (PGT-SR). It can also be used to determine the sex of the embryo where there is a risk of an X-linked disorder (PGT-M).

Couples undergo a standard in vitro fertilisation (IVF) or intra-cytoplasmic sperm injection (ICSI) procedure with PGT being performed on the resulting embryos. This allows only unaffected embryos to be transferred back to the woman's uterus knowing that any resulting pregnancy should be unaffected by the condition for which diagnosis is performed. PGT thus is an adjunct to assisted reproductive technology, and requires in vitro fertilization (IVF) to obtain oocytes or embryos for evaluation.

4.2 What can PGT be used to identify?

There are over 5,000 diseases that result from a genetic change in one or both copies of a particular pair of genes. Pre-implantation genetic testing (PGT) can only be offered to couples where the genetic change responsible for the disease that their baby is at risk of has been identified.

4.2.1 Chromosomal abnormalities

In the case of chromosomal abnormalities, PGT-SR is mainly carried out for *reciprocal* and *Robertsonian translocations*, and in a few cases for other abnormalities such as *chromosomal inversions* or *chromosomal deletions*.

4.2.2 Single gene testing

PGT-M is also available for a large number of single gene disorders. There are essentially 3 categories:

- *Autosomal recessive disorders* including cystic fibrosis, beta thalassaemia, sickle cell disorders and spinal muscular atrophy type 1.
- *Autosomal dominant diseases* such as myotonic dystrophy, Huntington's disease and Charcot-Marie-Tooth disease.
- *X-linked diseases*, including fragile X syndrome, haemophilia A and Duchenne muscular dystrophy.

5. The PGT Expert Panel

Due to the high profile and difficult ethical issues involved in deciding who should be able to gain access to the Pre-Implantation Genetic Testing service, an Expert Panel on PGT was established. The Panel, which includes wide representation from those involved in the clinical delivery of the service, lay representatives, and those working in the field of medical ethics and law, was tasked with advising on the criteria that should be applied in deciding which individuals should or should not be offered access to the PGT service. **Reasonableness**, **transparency**, **justifiability** and **equitability** were central principles adopted by the Panel to ensure **procedural fairness** and **accountability** in the decision making processes.

The Panel may invite NHS colleagues from the centres to submit expert opinion as required to aid discussion and the decision-making process.

5.1 Remit of the PGT Expert Panel

The Pre-Implantation Genetic Testing Expert Panel was established to:

- Develop a framework for decision making, including agreeing access criteria to be used by the PGT service in determining who is able to gain access to the service.
- Act as a reference panel to offer expert independent advice as a result of changes in legislation, technology or in instances where there are particularly complex cases.

A full list of Panel members can be found at Annex 2.

5.1.1 Number of responses required for decision making

The PGT Expert Panel currently consists of 20 members. It is unworkable to require that all panel members provide a response in order for a decision to be taken. A core group / requisite number of responses for approval or refusal is therefore appropriate.

In cases where 4–5 panel members (including a representative from each of the four genetics centres where possible) reach a consensus, the decision will be considered as agreed. If one or more members disagree, NSD secretariat will request the opinion of more members to reach a decision.

6. How were the criteria for access to the PGT service developed?

6.1 Ethical issues

The group considered ethical issues involved with the service and the following headings attempt to capture the wide discussion that was undertaken.

6.1.1 The primary ethical justification for offering PGT

The primary ethical justification for the offer of PGT is that it can prevent harm to babies who be born with a predisposed risk of a genetic condition.

The harm which can be prevented may be to:

- Possible future children likely to suffer from disease or disability caused by chromosomal abnormalities or genetic mutations.
- Existing children suffering from a genetic condition who otherwise could be treated for this by stem-cells from the cord blood of a tissue matched sibling born after PGT with pre-implantation tissue typing.

6.1.2 Ethical issues in the running of the PGT service

Consent

All relevant patient consents must be in place in alignment with Human Fertilisation and Embryology Authority (HFEA) requirements. For further information, see HFEA Code of Practice[3].

Equity

PGT, in common with other nationally commissioned services, is offered at only two centres in Scotland but it is important that it should be equally accessible to all people in Scotland. The

[3] https://portal.hfea.gov.uk/knowledge-base/read-the-code-of-practice/

referral pathways to access the PGT service must be clearly identified to all relevant health professionals as well as members of the public. [See patient pathway section 9]

Realism
When patients are referred for PGT, the service must be careful not to raise their expectations above what PGT can realistically offer. The technologies used within the service, while proven, continue to evolve and are still being developed, and all must be clear and explicit on what can and cannot be achieved by the service. Patients must therefore be warned both of the risks and uncertain outcomes associated with the procedures and that predictions of long-term outcomes may not be accurate. It is important to remember that resources are limited and are not available for experimental treatments.

The Human Fertilisation and Embryology Authority (HFEA) is the licensing authority for PGT in the UK, and the Expert Panel concluded that the service can only be offered for those conditions licensed by the HFEA. In determining the conditions for which PGT should be licensed, some room for judgements of proportion must be left to the regulators and professionals involved. However, the HFEA currently invites and considers public responses on conditions awaiting consideration for licensing.

HFEA states that 'the perception of the seriousness of the condition by those seeking treatment is an important factor' in determining the conditions for which PGT should be licensed. Moreover, one study has observed that 'staff find it hard to argue against women's/couples' own conclusions about what constitutes seriousness in the context of supporting individual autonomy and choice'.[4]

Flexibility
The service is designed to allow testing for known or suspected abnormalities in the embryo, but it may for special reasons go beyond this remit; i.e. recognising the evolving science and taking account of specific cases. Ensuring that the professionals are working within a framework, but have the opportunity to consult the Expert Panel, will ensure that the framework is sufficiently flexible to take these additional factors into account before a final decision is made.

Humanity
It is important that those delivering the service are able to communicate in a clear and compassionate way what it is possible to offer to the individual couple. The issues may be technical and complex. However, it is important that patients should have a good understanding of what they are consenting to and what the impact of their decisions will be. Plain English information sheets should be available and the service must offer the possibility of follow-up consultation.

6.2 Resource decisions

There are resource implications for all services provided by the NHS, and the PGT service consumes considerable resources. This must of course be off-set by the resources involved in caring for a child/person with a particular genetic condition during their lifetime. While not all of this expenditure will come from the NHS budget, there would likely be a cost on the total welfare budget as well as an impact on the family itself if caring for a child/person with the condition during their lifetime. Some may say that cost is not an ethical issue, but resources spent on one service cannot be spent on another (opportunity cost) so questions of equity are relevant and these do have an ethical dimension.

Ensuring that the professionals are working within a framework that considers resource implications will ensure that it is sufficiently realistic, acknowledging that the resources are finite. However, with a focus on clinically justifiable criteria, it is designed to be used as much in hard economic times as in times when funds are more readily available. The criteria can be tightened or

[4] Ehrich K, Williams C. (2010) A 'healthy baby': The double imperative of preimplantation genetic diagnosis. *Health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine* 14(1):41–56.

loosened as appropriate by the Expert Panel, depending on the resources at the service's disposal.

6.3 Justiciability and legal challenges

The Expert Panel on PGT has considered a range of legal cases which highlight the importance of due process in decision-making. Any challenge to clinical decisions will concentrate on the reasonableness of the decision taken. It is therefore important that health professionals are aware of, and routinely use, the criteria developed.

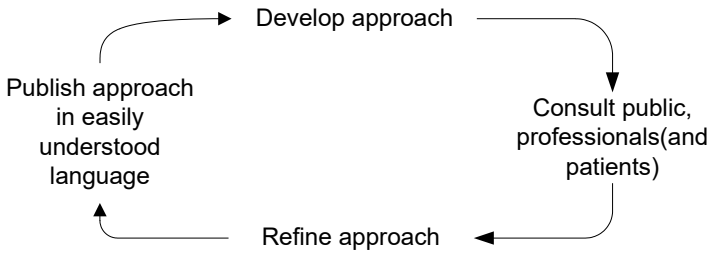
This would be essential to establishing reasonableness, as discussed in the National Planning Forum document, Making Difficult Decisions in NHS Boards in Scotland (2010).

7. The Framework for Making Decisions in the PGT Service in NHS Scotland

The original development of the framework for decision-making in PGT is documented below. This is modelled on the report cited above, and sets out overall procedure and the roles and responsibilities of those involved in the decision-making process, including the Panel and the clinicians providing the service.

The Panel has the role of overseeing the framework as well as making decisions and advising on particularly complex cases.

The framework will help to ensure that the decisions reached when discussing individual cases are reasonable, transparent, procedurally fair, and justifiable. Good communication between the Panel, clinicians, and patients is essential at all stages of the process.

Requirements	Approach	As applied to PGT
Communication and Involvement Publicise, consult and involve professionals, patients and public in the development of approaches to be used in difficult decisions Ensure clear communication of decisions		The Expert Panel met to agree the approach, and to develop the framework including the criteria and process for decision making. The Expert Panel to publish the framework document. The PGT service in partnership with patient representatives to develop the patient information leaflet.
Making difficult decisions Identify and clearly define: - the people involved in making the decisions and their roles, responsibilities and qualities - criteria that trigger the decision-making process - values/principles for specific contexts	Identify the dilemma Identify the values/principles which frame the decision to be taken and where there is agreement and disagreement over these values/principles Consider application of values/principles to the evidence presented; consider possible outcomes of preferring one option over another a) If agreement: identify justification and assess reasonableness of decision b) If disagreement: consider reasonableness of disagreement and relative justifications; revisit core considerations if necessary Decisions should be communicated back to clinicians/ managers and patients	Clinical geneticists and the clinicians involved in the running of the PGT service use the framework to decide who has access to the service. a) apply framework b) Where there are difficulties in applying the framework, the Expert Panel will convene to discuss individual cases.
Ensure the ability to appeal decisions with clearly defined referral criteria and process	If the decision is contested then there should be an appeals process, and this should be well publicised and meet the conditions of good decision-making summarised in the text	If the decision of the Expert Panel is appealed by the patient (or a clinician), then it will be presented to and considered by NHS Greater Glasgow & Clyde's Exceptions Panel (as the primary host NHS Board of the nationally designated PGT service).
Enforcement Ensure accountability and responsibility at NHS Board level	The planning/prioritisation cycle, individual treatment request panels and appeals panel should report direct to the NHS Board, and should each include representation at director level	

8. Access Criteria for the Scottish Pre-Implantation Genetic Testing Service

Access to the Scottish Pre-implantation Genetic Testing (PGT) service is dependent on individuals meeting the following criteria:

Criteria	Type of decision	Evidence
1. Predisposed risk of genetic condition	Clinical	PGT can prevent harm to babies who are predisposed to a risk of a genetic condition. The harm which can be prevented may be to: • Possible future children likely to suffer from disease or disability caused by chromosomal abnormalities or genetic mutations. • Existing children suffering from a genetic condition who otherwise could be treated for this by stem-cells from the cord blood of a tissue matched sibling born after PGT with pre-implantation tissue typing. • Cross contamination of siblings with compromised immunity e.g. cystic fibrosis. The perception of the seriousness of the condition by those seeking treatment is an important factor in determining the conditions for which PGT should be licensed. Further details are available from the Human Fertilisation and Embryology Authority (HFEA) website.
2. An accurate test is available and a licence has been obtained from Human Fertilisation and Embryology Authority	Clinical safety	A full list of tests is available from the Human Fertilisation and Embryology Authority (HFEA) website.
3. Referral to be made before woman's 39th birthday	Clinical	Referrals to be made before the woman's 39th birthday to ensure there is appropriate time to allow work up of PGT which can be complex and time consuming process. HFEA data in 2016 shows 60% of PGT patients were aged under 35 and the birth rates per embryo transferred for PGT treatment cycles were 30% for fresh and 36% for frozen cycles. *Fertility treatment 2014–2016: Trends and figures (2018)*. The Expert Panel agreed that a success rate of 10% should inform the upper age limit at which NHS funded infertility treatment should be offered. In instances where a women seen for PGT have potentially low ovarian reserve and may not have embryos for biopsy and transfer and/or there is a requirement to do the work which is and time consuming the Workup If Suitable Embryos (WISE) approach may be used. [5]

[5] January 2021 - WISE Protocol being worked up and documented by Scottish PGT centres and will be available for reference once complete.

Criteria	Type of decision	Evidence
4. BMI between 18.5 and 30 Patients should only be placed on a waiting list if their body mass index is ≥18.5 and ≤30 Women should be offered support to assist them to achieve a BMI within the normal range prior to referring for any investigations or treatment	Clinical	Obesity and being overweight are associated with decreased pregnancy rates, increased requirement for gonadotrophins and a higher miscarriage rate. Elevated BMI is also associated with increased technical difficulty during egg collection and an increased obstetric risk. Obesity decreases successful pregnancy rates in both natural and assisted conception cycles, with fertility being partially restored if weight loss can be achieved. Balen AH, Anderson RA (2009). Impact of obesity on female reproductive health: British Fertility Society, Policy and practice guidelines. *Human Fertility* 10(4):195–206. Maheshwari A, Stofberg L, Bhattacharya S (2007). Effect of overweight and obesity on assisted reproductive technology – A systematic review. *Human Reproduction Update* 13(5):433–444. Norman JE (2010). The adverse effects of obesity on reproduction. *Reproduction* 140(3):343–345.
5. Both partners should be negative for HIV, Hepatitis B and C	Clinical	The service is unable to provide the PGT service to people who test positive for Hepatitis B, C and HIV due to risk of cross contamination and risk to staff. This is in line with UKAS requirements.
6. Anti-Müllerian hormone (AMH) levels	Clinical	Plasma AMH is a superior predictor of live birth and anticipated oocyte yield compared with follicle stimulating hormone (FSH) and age, facilitating individualisation of therapy prior to first assisted reproduction treatment (ART) cycles. The use of circulating anti-Müllerian hormone (AMH) to individualise treatment strategies for controlled ovarian stimulation (COS) may result in reduced clinical risk, optimised treatment burden and maintained pregnancy rates. The female partner must have an anti Müllerian hormone (AMH) level assessment and an antral follicle count ultrasound scan to confirm ovarian reserve if deemed necessary.
7. Couples must have been co-habiting (living at the same address in case of any doubt) in a stable relationship for a minimum of two years.	Welfare of the child / need for supportive parenting	The Expert Panel agreed that professional clinical judgement should be exercised in this area. The importance of being able to screen extended family members was also noted by the Panel.

Criteria	Type of decision	Evidence
8. No previous unaffected genetic children as a couple	Resource allocation	This issue was debated in detail by the Expert Panel. Members agreed that, in a world where resources for the service are finite, there was an inherent fairness in trying to give more couples one child rather than, for example, one couple having two or more children and one couple remaining childless. Couples where only one partner has a child can access NHS funded treatment as long as all other access criteria are met in full. If the couple have a child affected by another disorder that PGT is not being used to detect, they may be classed as having no previous unaffected genetic children as a couple. Referrals will be discussed on an individual basis by the Expert Panel to establish if the exclusion criterion of unaffected/healthy child is or is not satisfied.
9. One partner has no living genetic child	Equity of access	This criterion is about ensuring each partner within a couple has an opportunity to be a parent including those whose partner has had a child from a previous relationship.
10. Couples are eligible for up to 3 cycles of PGT. [Previous NHS IVF/ICIS treatment will be subtracted from this.]	In line with NHS IVF treatment in Scotland.	Response to treatment must be clinically assessed at the end of each cycle. Where indications are that further treatment is unlikely to be clinically effective, no further treatment will be given.

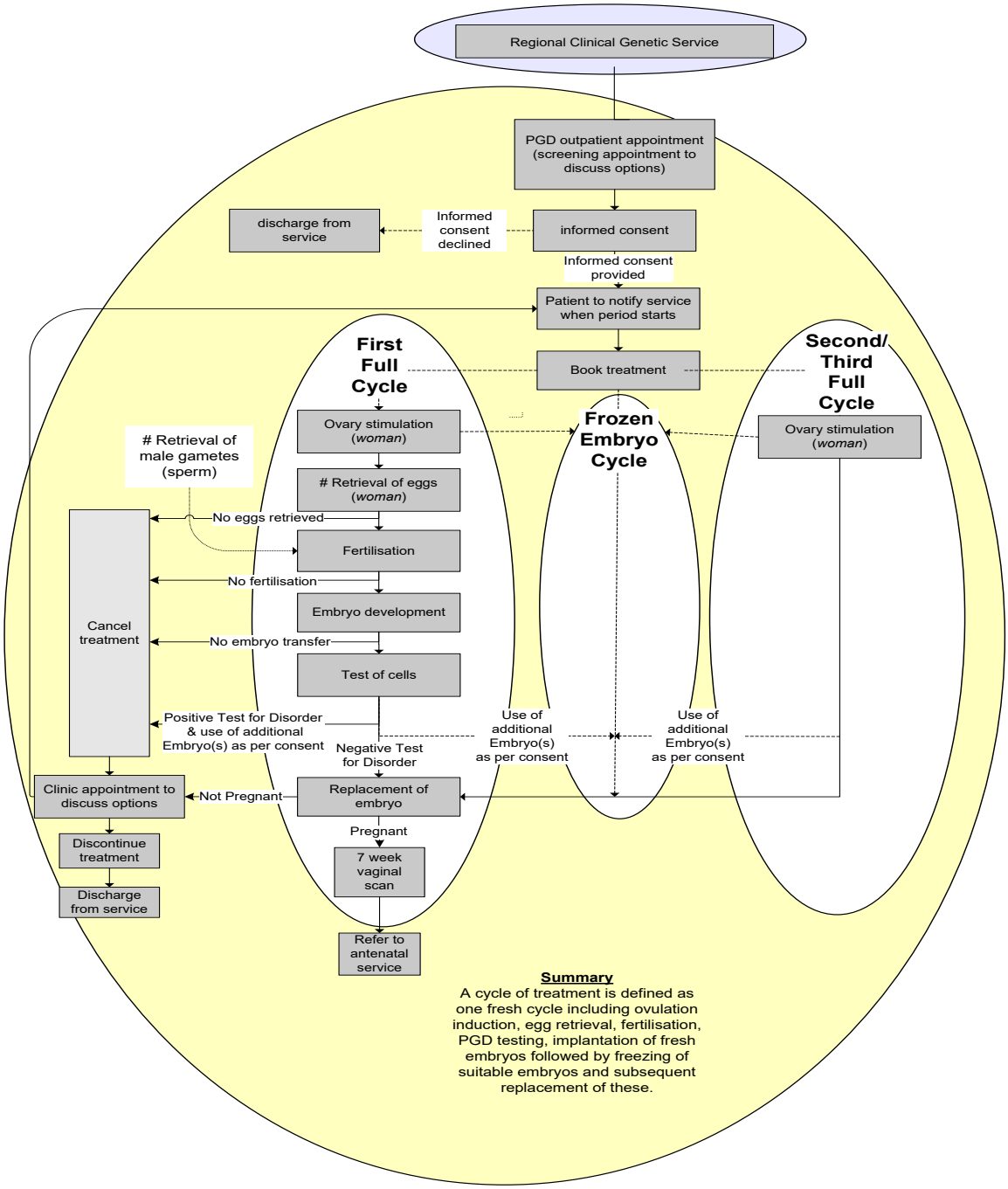
Criteria	Type of decision	Evidence
11. Both partners must be Scottish residents and eligible for NHS treatment	Establishing the Responsible Commissioner. The Panel recommend that a national decision is made on who is eligible for treatment.	In understanding who pays for a patient's care the Department of Health has published a framework for establishing responsibility for commissioning an individual's care within the NHS, i.e. determining who pays for a patient's care. Legislation for Wales, Scotland and Northern Ireland provides that the responsible authority for an individual's healthcare provision is the one where a person is usually resident and is not based on GP practice registration as provided by English legislation. Department of Health (2013) *Who Pays? Determining responsibility for payments to providers.* Available at: https://www.england.nhs.uk/wp-content/uploads/2014/05/who-pays.pdf. **Charging for other UK residents** Assuming that there is no diminution in the service made available to Scottish residents, UK residents may be treated under this agreement with the associated costs being paid by the responsible commissioner. **Other international patients** Treatment of European residents can be offered through reciprocal health arrangements. The associated costs should be paid by the responsible commissioner. Anyone not covered by reciprocal health care agreements is considered a private patient and must provide / be able to provide proof of funding (either personal or from their own health system) before any referrals can be accepted.

Criteria	Type of decision	Evidence
12. Both partners must be non-smoking (including e-cigarettes) and nicotine free for at least 3 months before being placed on the waiting list for treatment. Couples must continue to be non-smoking and nicotine free during treatment.	Clinical Testing will be applied before placement on the waiting list.	Smoking is associated with reduced fertility. The evidence is consistent, through a range of pathways affecting both male sperm production and many female aspects including hormone levels and egg development. There is compelling evidence of a negative effect of smoking on IVF outcome which has been shown to apply to females in relation to active and passive smoking, and in addition there is evidence of reduced success with male smoking. Scottish Government (2016). *National Infertility Group Report*. Available at: https://www.gov.scot/publications/national-infertility-group-report/. Last accessed: 5 July 2020.
13. Both partners must abstain from illegal substances and/or substances of abuse.		Any substance misuse during pregnancy will reach the developing baby and may cause harm.
14. Both partners must be methadone free for at least one year prior to referral for treatment.		There is a responsibility on patients to follow these access criteria which are in the interest of the welfare of the child and the effectiveness of treatment. Clinicians may conduct testing to ensure that patients adhere to the criteria, and in the event of a positive result, the patient will not be given treatment. Where there is a known history of former drug addiction, alcohol abuse or domestic violence, patients must receive appropriate counselling prior to being referred as suitable for treatment, and will still be required to meet the criteria for the welfare of the child. NHS Boards should ensure engagement with the appropriate counselling services.

Criteria	Type of decision	Evidence
15. Neither partner should drink alcohol during the period of treatment.		Every pregnant woman in Scotland is given a copy of the NHS Health Scotland and Scottish Government publication Ready, Steady, Baby24 which states that there is no 'safe' time for drinking alcohol during pregnancy and no 'safe' amount. Drinking no alcohol in pregnancy is the best and safest choice. The National Institute for Health and Care Excellence (NICE), which advises healthcare professionals (GPs and nurses), says: • Pregnant women, and women planning to become pregnant, should be advised to not drink alcohol in the first three months of pregnancy, because there may be an increased risk of miscarriage. • Women should be advised that if they choose to drink alcohol while they are pregnant, they should drink no more than one or two units of alcohol, once or twice a week. There is uncertainty about how much alcohol is safe to drink in pregnancy, but if a low level is consumed there is no evidence of harm to an unborn baby. • Women should be advised not to get drunk or binge drink (drinking more than 7.5 UK units of alcohol on a single occasion) while they are pregnant, because this can harm their unborn baby. • If women want to avoid all possible alcohol-related risks, they should not drink alcohol during pregnancy, as the evidence on this is limited.

9. Pre-implantation Genetic Testing Patient Pathway

Once it has been agreed that individuals meet the criteria, up to three cycles of treatment may be offered with a full review after each cycle. If it is decided that the treatment is unlikely to benefit the couple, further treatment should not be offered. Frozen embryos from each cycle should be replaced before another fresh cycle is given. Subsequent cycles should be available without patients returning to the end of a waiting list after each cycle. A cycle of treatment is defined as one fresh cycle including ovulation induction, egg retrieval, fertilisation, PGT testing, implantation of fresh embryos followed by freezing of suitable embryos and subsequent replacement of these. It is good practice that all couples are offered counselling before, during and after receiving PGT services.



Annex 1: PGT Expert Panel Referral Form

Specialist Healthcare Commissioning

National Services Division (NSD)
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB
Telephone 0131 314 1523
www.nsd.scot.nhs.uk

NHS National Services Scotland

Pre-implantation Genetic Testing (PGT) Expert Panel Referral Form

This form should be completed and submitted for cases in which consideration for PGT is required by the Expert Review Panel.

Date request sent	
Basic patient identifier *Initials / Date of Birth / Postcode*	
Reason for referral *State why the case is being referred to the panel for discussion*	
Does the couple meet all the access criteria? *If 'No' please provide details*	***Yes / No***
Background information *Provide pertinent background information relating to the case e.g.:* • *Genetic disorder* • *Suspected gene(s)/chromosome(s) involved* • *Any previous relevant tests/investigations performed*	
Details of the proposed treatment provider *(including ISO accreditation) if not routinely provided by the Scottish PGT service*	
Has the NHS Board of Residence been notified of this referral?	***Yes / No***
NHS Board of Residence Approval *Has this referral been approved by the patient's NHS Board of residence:*	***Yes / No***
Assessment and recommendation (if any) *Assessment of the situation and proposed recommendations*	

Once completed – please return to: nss.sglc@nhs.scot

Annex 2: Panel Membership

Name	Role	Organisation
Chair		
Professor Al Dowie	Professor of Medical Ethics and Law	University of Glasgow
ACS Clinicians		
Dr Helen Lyall	Consultant Gynaecologist, Lead Clinician – Assisted Conception Unit	NHS Greater Glasgow & Clyde
Dr Joo Thong	Consultant Gynaecologist Assisted Conception Unit, Edinburgh Fertility Reproductive Centre (EFREC)	NHS Lothian
Professor Abha Maheshwari	Fertility Consultant	NHS Grampian
Associate Programme Director		
Mr Peter Croan	Associate Programme Director	National Services Division (NSD)
Consultant in Clinical Genetics (x4 – 1 from each Scottish Genetics Laboratories Consortium (SGLC) centre)		
Dr Rosemarie Davidson	Lead Clinician for Cancer Genetics	NHS Greater Glasgow and Clyde
Dr David Goudie	Consultant Clinical Geneticist	NHS Tayside
Professor Zosia Miedzybrodzka	Consultant Clinical Geneticist & Service Clinical Director- Genetics	NHS Grampian
Professor Mary Porteous	Consultant Clinical Geneticist, Service Lead	NHS Lothian SE Scotland Genetic Service
Consultant Clinical Scientist		
Dr Jon Warner	Consultant Clinical Scientist, Director Molecular Genetics Laboratory	NHS Lothian
Mrs Nicola Williams	Consultant Clinical Scientist, Head of Service (Laboratory Genetics)	NHS Greater Glasgow and Clyde
Consultant in Public Health Medicine		
Dr Emilia Crighton	Consultant in Public Health Medicine	NHS Greater Glasgow & Clyde

Embryology Representatives		
Ms Joanne Leitch	Senior Embryologist	NHS Greater Glasgow and Clyde
Genetic Counsellor		
Ms Elspeth Graham	Genetic Counsellor	NHS Grampian
Mark Longmuir	Consultant Genetic Counsellor	NHS Greater Glasgow & Clyde
Mrs Sally Morton	PGT Genetic Counsellor	NHS Lothian
Hospital Management		
Ms Michelle McLauchlan	General Manager	NHS Greater Glasgow and Clyde
NSD Secretariat		
Ms Karina O'Rourke	Programme Manager	National Services Division (NSD)
Ms Joanne Milne-Toner	Programme Manager	National Services Division (NSD)
Ms Ashley Galloway	Programme Support Officer	National Services Division (NSD)
Patient Representative		
Ms Natalie Frankish	Development Policy and Engagement Manager for Scotland	Genetics Alliance UK
Professional in Medical Ethics		
Dr Donald Bruce	Member of various government committees concerned with ethics. Scientist by background.	
Specialist Nurse		
Ms Ciara Heatherwick	Specialist Nurse, Assisted Conception Services	NHS Greater Glasgow and Clyde

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