

The Scottish Pre-Implantation Genetic Diagnosis and Screening Service

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

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Executive Summary

An Expert Panel for Pre-Implantation Genetic Diagnosis (PGD) 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 Diagnosis Service in Scotland are reasonable, transparent and justifiable.

The Panel included 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 were central principals 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 or should not be offered access to the PGD service include:

- Predisposed risk of genetic condition
- Availability of an accurate test for which a license has been obtained from the Human Fertilisation and Embryology Authority (or its replacement, if applicable)
- Referrals to be made before woman's 39th birthday
- Woman to have a BMI between 19 and 35
- Woman to have Anti-Müllerian Hormone levels greater than 6.0pmol/l
- Both individuals should be negative for HIV, Hepatitis B and C
- The couple should be in a stable relationship
- No previous unaffected genetic children born to the couple
- Couples are eligible for 2 cycles of PGD. [*Previous NHS IVF/ICSI treatment will be subtracted from this*].
- Both partners must be Scottish residents

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 through the existing Exceptions Panel arrangements within NHS Greater Glasgow and Clyde.

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 justifiable¹. This document provides a framework for ensuring that decisions made relating to access to and prioritisation of patients in the Pre-implantation Genetic Diagnosis 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 top-sliced ring-fenced 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 Scotland².

The Scottish Pre-implantation Genetic Diagnosis 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 Diagnosis (PGD) service

The Scottish Pre-implantation Genetic Diagnosis (PGD) service was designated as a national service in 2005. Cytogenetic testing for fetal chromosome abnormalities is offered at the Glasgow Royal Infirmary, NHS Greater Glasgow and Clyde. On 1st April 2010, the nationally designated PGD service was expanded to provide molecular single gene testing for PGD at The Royal Infirmary of Edinburgh, Edinburgh, NHS Lothian.

4. Pre-Implantation Genetic Diagnosis

4.1 What is Pre-Implantation Genetic Diagnosis?

Pre-implantation genetic diagnosis (PGD or PIGD) refers to procedures that are performed on embryos prior to implantation or oocytes prior to fertilisation. PGD 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. It can also be used to determine the sex of the embryo where there is a risk of an X-linked disorder.

¹ Making Difficult Decisions in NHS Boards in Scotland (2010) Report of the Short Life Working Group, available at http://www.nhs.uk/nhsifedifficultdecisions/Difficult_Decisions_Mar_2010.pdf, last accessed February 2011

² The Healthcare Quality Strategy for NHS Scotland (2010) The Scottish Government, available at <http://www.scotland.gov.uk/Resource/Doc/311667/0098354.pdf>, last accessed February 2011

Couples undergo a standard in-vitro fertilisation (IVF) or intra-cytoplasmic sperm injection (ICSI) procedure with PGD 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. PGD 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 PGD 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 diagnosis can only be offered to couples where the genetic change responsible for the disease that their baby is at risk of has been able to be identified.

4.2.1 Chromosomal Abnormalities

In the case of chromosomal abnormalities, PGD 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

PGD 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 PGD 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 Diagnosis service, an Expert Panel on PGD was established. The Panel, which 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, was tasked with advising on the criteria that should be applied in deciding which individuals should or should not be offered access to the PGD service.

Reasonableness, transparency, justifiability and equitability were central principles adopted by the Panel to ensure **procedural fairness** and **accountability in the decision making processes**.

5.1 Remit of the PGD Expert Panel

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

- Develop a framework for decision making, including agreeing access criteria to be used by the PGD 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 Appendix 1.

6. How were the criteria for access to the PGD 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 PGD*

The primary ethical justification for the offer of PGD is that it 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 PGD with pre-implantation tissue typing

The perception of the seriousness of the condition by those seeking treatment is an important factor in determining the conditions for which PGD should be licensed.

6.1.2 *Some Ethical Issues in the Running of the PGD Service*

Consent

The woman always has the final say on whether or not to establish a pregnancy and to continue with the pregnancy. This is on the grounds that the woman has the right to control what happens to her own body.

Equity

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

Realism

The service must be careful not to raise expectations in patients referred into the service above the realistic expectations of what PGD can 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 Embryology Authority (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 PGD should be licensed. Moreover, a recent paper observes that 'staff find it hard to argue against women's/couple's own conclusions about what constitutes seriousness in the context of supporting individual autonomy and choice'.³

³ Ehrich K, Williams C. (2010) A 'healthy baby': The double imperative of preimplantation genetic diagnosis. *Health* vol. 14(1) pg. 41-56

The HFEA is currently the UK licensing authority and the Expert Panel concluded that only those conditions licensed by HFEA can be offered. In determining the conditions for which PGD 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

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 based on a couple's own conclusions about what constitutes seriousness in the context of supporting individual autonomy and choice. 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 accommodate these 'special reasons'.

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. Readily intelligible 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 PGD 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 the framework is sufficiently 'realistic'. The Framework that has been designed, acknowledges that 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 loosened as appropriate by the Expert Panel, depending on the resources at the service's disposal.

6.3 Justiciability and Legal Challenges

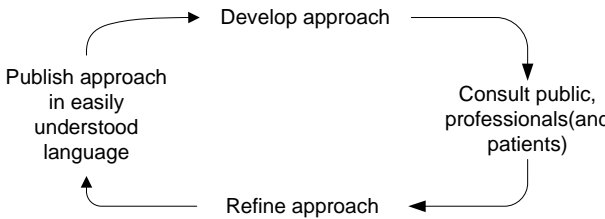
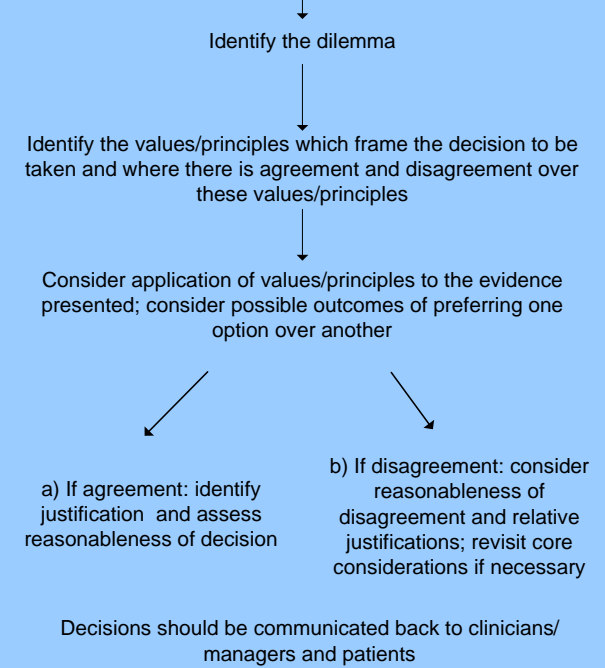
The Expert Panel on PGD has considered a range of legal cases which highlight the importance of due process in decision-making. Any challenge to clinical decisions will concentrate on the reasonableness of the decision taken. It is, therefore, important that health professionals are aware of, and routinely use, the criteria developed. This is similarly advised in the Making Difficult Decisions in NHS Boards in Scotland, referred to in section 7.

The Expert Panel on PGD has, therefore, developed a framework for decision making in PGD which is documented below. This identifies the processes and roles and responsibilities of those involved in the decision making process, including the involvement of the Expert Panel and also those of individual clinicians in the service.

As the Panel will have an oversight role in the future the considerations raised in previous cases may prove helpful should the Panel be required to make decisions or advise on particularly complex cases.

7. The Framework for making decisions in the PGD service in NHS Scotland

The Panel agreed to adopt the generic framework developed by the National Planning Forum as a basis for decision making with regard to access to, and receiving treatment from, the PGD service. This will help to ensure that the decisions reached when discussing individual cases are reasonable, transparent and justifiable. By introducing the approach described here, the NHS Board will be able to build reasonableness, transparency, procedural fairness and accountability into its decision-making process. It is emphasised, however, that good communication is essential at all stages of the process.

Requirements	Approach	As applied to PGD
<p>Communication and Involvement</p> <p>Publicise, consult and involve professionals, patients and public in the development of approaches to be used in difficult decisions</p> <p>Ensure clear communication of decisions</p>		<p>The Expert Panel met to agree the approach, and to develop the framework including the criteria and process for decision making.</p> <p>The Expert Panel to publish the framework document.</p>
<p>Making difficult decisions</p> <p>Identify and clearly define:</p> <ul style="list-style-type: none"> - 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 		<p>The PGD service in partnership with patient representatives to develop the patient information leaflet.</p> <p>Clinical geneticists and the clinicians involved in the running of the PGD service use the framework to decide who has access to the service.</p> <p>a) apply framework</p> <p>b) Where there are difficulties in applying the framework, the Expert Panel will convene to discuss individual cases.</p>
<p>Ensure the ability to appeal decisions with clearly defined referral criteria and process</p>	<p>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</p>	<p>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 PGD service).</p>
<p>Enforcement</p> <p>Ensure accountability and responsibility at NHS Board level</p>	<p>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</p>	

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

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

Criteria	Type of decision	Evidence
Predisposed risk of genetic condition	Clinical	<p>PGD can prevent harm to babies who are predisposed to a risk of a genetic condition.</p> <p>The harm which can be prevented may be to:</p> <ul style="list-style-type: none"> • 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 PGD with pre-implantation tissue typing • cross contamination of siblings with compromised immunity e.g. cystic fibrosis <p>The perception of the seriousness of the condition by those seeking treatment is an important factor in determining the conditions for which PGD should be licensed. Human Fertilisation and Embryology Authority (HFEA) website, last accessed February 2010.</p>
An accurate test is available and a licence has been obtained from Human Fertilisation and Embryology Authority	Clinical safety	<p>A full list of tests is available from the Human Fertilisation and Embryology Authority (HFEA) website.</p>
Referral to be made before woman's 39th birthday	Clinical	<p>Referrals to be made before the woman's 39th birthday with a realistic prospect of completion of treatment by the age of 42 years and 364 days.</p> <p>HFEA data shows a success rate of 11.8% live birth rate with fresh treatment and a 17.4% live birth rate with frozen embryo transfer is achieved up to and including 42 years of age.</p> <p>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.</p> <p>The Expert Advisory Group on Infertility Services In Scotland (EAGISS) (1999) Evidence & Equity: A National Service Framework For The Care of Infertile Couples In Scotland last accessed February 2011</p>

Criteria	Type of decision	Evidence
<p>BMI between 19 -35 Patients should only be placed on a waiting list if their body mass index is ≥ 19 and ≤ 35.</p> <p>Women should be offered support to assist them to achieve a BMI within the normal range prior to referring for any investigations or treatment</p>	Clinical	<p>Obesity and being overweight are associated with decreased pregnancy rates, increased requirement for gonadotrophins and a higher miscarriage rate. The Expert Panel agreed that while these differences are evident at a BMI of 25, they were markedly so at a BMI of 35. 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.</p> <p>Norman J. E (2010) The Adverse Effects of Obesity on Reproduction (2010) Society for Reproduction & Fertility, Vol. 130, (3).</p> <p>British Fertility Society Guidelines on the effect of obesity on female reproductive health.</p> <p>Maheshwari. A, Stofberg. L, and Bhattacharya. S, (2007) <i>Effect of overweight and obesity on assisted reproductive technology - a systematic review</i>, Human Reproduction Update Vol. 13. (5) 433-444.</p>
<p>Individuals or both partners should be negative for HIV, Hepatitis B and C</p>	Clinical	<p>The service is unable to provide the PGD service to people who test positive for Hepatitis B, C and HIV due to risk of cross contamination and risk to staff. This is inline with Clinical Pathology Accreditation requirements.</p>

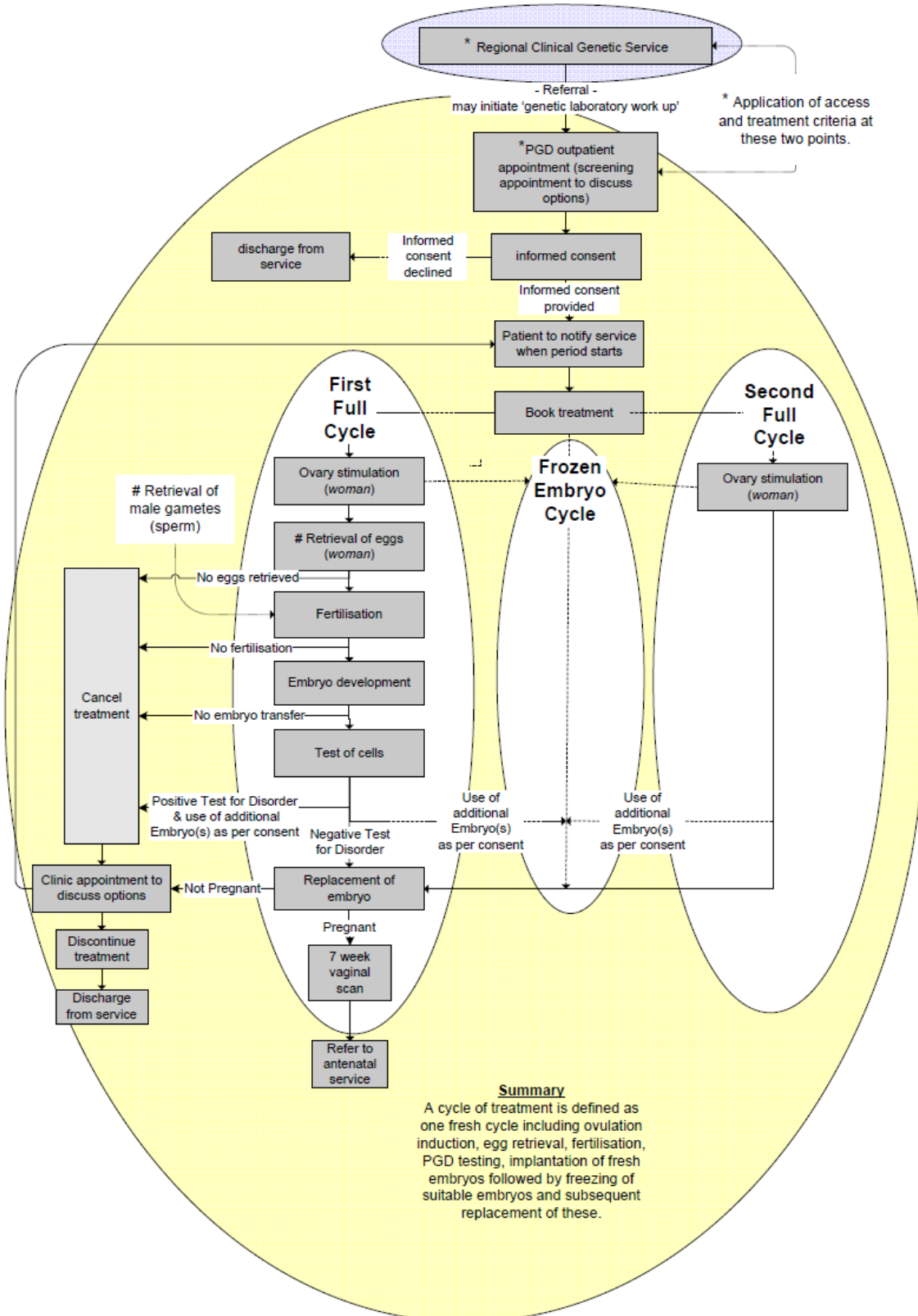
Criteria	Type of decision	Evidence
Anti-Müllerian Hormone (AMH) levels greater than 6.0 pmol/l	Clinical	<p>In recognition of the available assays and evidence, the Expert Panel agreed that an acceptable Anti-Müllerian Hormone (AMH) levels greater than 6.0pmol/l should be considered as the appropriate level.</p> <p>Plasma AMH is a superior predictor of live birth and anticipated oocyte yield compared with FSH and age, facilitating individualization of therapy prior to first assisted reproduction treatment (ART) cycles. The use of circulating Anti-Müllerian Hormone (AMH) to individualize treatment strategies for controlled ovarian stimulation (COS) may result in reduced clinical risk, optimized treatment burden and maintained pregnancy rates.</p> <ul style="list-style-type: none"> • The predicted 'reduced' response category (AMH 1.0 to 5.0 pmol/l). • The predicted 'normal' or 'safe' response category (AMH 5.0 to 15.0 pmol/l). • The 'high' response category (AMH greater than or equal to 15.0 pmol/l). Women with an AMH of ≥ 15 pmol/l were younger, produced high oocyte numbers and higher clinical pregnancy rates than other AMH categories after controlled ovarian stimulation. • Above an AMH concentration of 7.8 pmol/l there was no discrimination in live birth rates. <p>The evidence from a recent publication demonstrate that similar precision and excellent between-assay agreement should be obtained when laboratories change from the DSL to the AMH Gen II ELISA and they should expect an increase in AMH values of approximately 40%.</p> <ul style="list-style-type: none"> • Using the linear regression equation for the full data-set the corresponding cut-offs for the Gen II assay, are 6.4 and 20.4 pmol/L. <p>Nelson SM, Yates RW, Lyall H, Jamieson M, Traynor I, Gaudoin M, Mitchell P, Ambrose P, Fleming R. (2009) <i>Anti-Müllerian hormone-based approach to controlled ovarian stimulation for assisted conception</i>. Hum Reprod. 2009 Apr; 24(4):867-75. Epub 2009 Jan 10.</p> <p>Nelson SM, Yates RW, Fleming R. (2007) <i>Serum anti-Müllerian hormone and FSH: prediction of live birth and extremes of response in stimulated cycles--implications for individualization of therapy</i>. Hum Reprod. 2007 Sep;22(9):2414-21. Epub 2007 Jul 18.</p> <p>Wallace A M, Faye S A, Fleming R and Nelson S M (2011); <i>A multicentre evaluation of the new Beckman Coulter anti- Müllerian hormone immunoassay (AMH Gen II)</i>, Ann Clin Biochem</p>

Criteria	Type of decision	Evidence
The need for a stable relationship	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.
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 are eligible for 2 cycles of PGD. [Previous NHS IVF/ICIS treatment will be subtracted from this.]	Resource allocation	It was noted that within the existing financial envelope two cycles of fertility treatment per couple were available, and this was likely be the case for access to wider fertility services - In Vitro Fertilisation (IVF). The Panel agreed that couples would be entitled to a total of two cycles funded by the NHS. This meant that couples who have received two previous cycles of NHS funded PGD treatment or who have received two cycles of NHS funded IVF/ intra-cytoplasmic sperm injection (ICSI) would not be entitled to any further NHS PGD cycles in the NHS in Scotland. There may be clinical exceptions to this, which would be referred to, and discussed by, the Expert Panel where a decision will be made.

Criteria	Type of decision	Evidence
Both partners must be Scottish residents	Establishing the Responsible Commissioner	<p>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.</p> <p>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.</p> <p>Department of Health (Sept 2007) <i>Who Pays? - Establishing the Responsible Commissioner</i> http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_079724.pdf last accessed April 2011]</p> <p>Charging for other UK residents</p> <p>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.</p> <p>Other international patients</p> <p>Treatment of European Economic Area (EEA) 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.</p>

9. Pre-implantation Genetic Diagnosis Patient Pathway

Once it has been agreed that individuals meet the criteria, two cycles of treatment should 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, PGD 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 PGD services.



Appendix 1

Membership

The Panel is Chaired by Professor Sheila McLean, International Bar Association Professor of Law and Ethics in Medicine, and membership includes representation from experts in genetics, gynaecology, embryology, service planning, as well as those in the field of medical ethics. The interests of the patient group are represented by the Genetic Alliance UK (formerly Genetics Interest Group (GIG)) and a member of NSD's Public Reference Group.

Professor Sheila McLean, International Bar Association Professor of Law and Ethics in Medicine, University of Glasgow (*Chair*)

Mr Jonathan Best, Regional Services Director, Southern General Hospital, NHS Greater Glasgow & Clyde

Professor Kenneth Boyd, Professor of Medical Ethics, University of Edinburgh

Dr Emilia Crichton, Consultant in Public Health Medicine, NHS Greater Glasgow & Clyde

Professor Robin Downie, Emeritus Professor of Moral Philosophy, University of Glasgow

Ms Natalie Frankish, Patient Engagement Project Officer, Genetics Alliance UK [Ms Claire Cotterill prior to 29th September 2010]

Mr Brian Gorman, Member of NSD's Public Reference Group

Dr David Goudie, Consultant in Clinical Genetics, NHS Tayside

Dr Gordon Lowther, Consultant Clinical Scientist, Cytogenetics, NHS Greater Glasgow & Clyde

Dr Helen Lyall, Consultant Gynaecologist, NHS Greater Glasgow & Clyde

Dr Zosia Miedzybrodzka, Head of Medical Genetics Service & Consultant [Clinical Geneticist](#), NHS Grampian

Dr Sue Pickering, Consultant Embryologist, NHS Lothian

Professor Mary Porteous, Consultant Clinical Geneticist, NHS Lothian

Dr Margo Whiteford, Consultant Clinical Geneticist, NHS Greater Glasgow and Clyde

Sr. Helen Walton, PGD Co-ordinator, NHS Greater Glasgow and Clyde

Dr Jon Warner, Consultant Clinical Scientist, Molecular Genetics, NHS Lothian

Secretariat

Mr James Steven, Programme Manager, NSD

Miss Hannah Cornish, Programme Support Officer, NSD

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Nelson SM, Yates RW, Fleming R. (2007) *Serum anti-Müllerian hormone and FSH: prediction of live birth and extremes of response in stimulated cycles--implications for individualization of therapy*. Hum Reprod. 2007 Sep;22(9):2414-21. Epub 2007 Jul 18.

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The Expert Advisory Group on Infertility Services In Scotland (EAGISS) (1999) *Evidence & Equity: A National Service Framework For The Care of Infertile Couples In Scotland*, available at <http://www.show.scot.nhs.uk/Publications/ME/eagiss.pdf>, last accessed February 2011