

9. Preimplantation genetic screening (PGS)

This guidance note contains:

 Refer to principles 5, 7 and 9

Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

HFEA guidance

- The use of PGS ■
- Prohibitions on embryo selection ■

■ Section includes interpretation of mandatory requirements

Other legislation, professional guidelines and information



Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

Schedule 2

Licences for treatment

- 1 (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services –
- ...(b) procuring, keeping, testing, processing or distributing embryos...

Embryo testing

- 1ZA (1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes –
- (a) establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,
 - (b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,

Licence conditions

- T88 With respect to any embryo testing programme involving biopsy the centre must ensure that:
- a. no embryo is transferred to a woman where that embryo or any material removed from it or from the gametes that produced it, has been subject to a test that supplies genetic information about the embryo, unless the test has been expressly authorised by the Authority, and
 - b. any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, is not used to select embryos of a particular sex for social reasons.
- T89 With respect to any embryo testing programme the centre must ensure that embryo testing is only being carried out for those genetic conditions that are expressly authorised by the Authority.



The use of PGS



Interpretation of mandatory requirements

9A

An embryo may be tested to establish whether it has a particular chromosomal abnormality only if:

- (a) that abnormality may affect its capacity to result in a live birth, or
- (b) there is a particular risk that it has that abnormality, and where the Authority is satisfied that there is a significant risk that a person with that abnormality will have or develop a serious medical condition.

9.1 The centre should ensure that before people seeking treatment give consent to PGS for aneuploidy, they are given information explaining:

- (a) the risks associated with the procedure
- (b) the unproven nature of the procedure, in particular that:
 - (i) more robust clinical and laboratory trials are needed to assess whether or not PGS can significantly increase live birth rates
 - (ii) the method of fluorescent in situ hybridisation (FISH) on embryos, using a limited number of chromosomes, is not effective at increasing live birth rates
- (c) that embryos biopsied may not be available for cryopreservation and for use in subsequent treatment cycles
- (d) the misdiagnosis rates associated with PGS for aneuploidy, including the fact that false results can be positive or negative
- (e) that the more chromosome tests are carried out the higher the possibility of the test not working, and the lower the chance of finding suitable embryos for transfer
- (f) that there is no guarantee against a miscarriage occurring, despite PGS for aneuploidy being performed, and
- (g) the financial and emotional costs where treatment fails and there is no live birth following PGS for aneuploidy.

9.2 Embryos from which biopsies have been taken, or resulting from gametes from which biopsies have been taken, should not be transferred with any other (non-biopsied) embryos in the same treatment cycle.

9.3 Centres should ensure that they keep up to date with relevant literature and professional guidance in order to validate the use of PGS for each category of patient to which they offer it. Validation should also be based on data from previously published studies and retrospective evaluation of the clinic's own data.

Prohibitions on embryo selection



Interpretation of mandatory requirements

9B

The law requires that the centre should not select embryos of a particular sex for social reasons.

NOTE: Guidance note 10 (Embryo testing and sex selection) contains all the guidance and mandatory requirements relevant to embryo testing in general. Centres offering PGS should familiarise themselves with this guidance note as well.



HFEA guidance (cont)

See also guidance note:

- [10 – Embryo testing and sex selection](#)



Other legislation, professional guidelines and information

- British Fertility Society guidelines on PGS: Anderson, R A and Pickering, S (2008). – www.britishfertilitysociety.org.uk/public/factsheets/PGS.html

