

Authority Paper

Committee:	Authority
Meeting date:	18 March 2009
Agenda item:	12
Paper number:	496
Paper title:	Licensing of embryo testing
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For information or decision?	Decision
Resource implications:	The new approach is likely to reduce the time that Compliance staff spend on PGD applications
Implementation	New licensing arrangements to be commenced on 1 October 2009
Communication	Letter to clinics alongside publication of 8th Code of Practice in July
Organisational risk	Medium
Recommendation to the committee:	To adopt the proposed method for licensing PGD from 1 October 2009 and to accept proposals for reviewing: <ul style="list-style-type: none"> genetic conditions considered in the Choices and Boundaries review and preimplantation tissue typing
Evaluation	Review after one year
Annexes	None

1 Introduction

1.1 The Human Fertilisation and Embryology Act 2008 (the 2008 Act) brings the regulation of PGD, HLA tissue typing and PGS (known collectively as embryo testing) onto a statutory footing for the first time. This change in the law requires us to review both the Code of Practice guidance to centres offering such treatments and the HFEA's approach to licensing PGD.

1.2 The Act, in schedule 2, sets out the purposes for which embryo testing can be carried out and, in particular, the circumstances in which preimplantation genetic diagnosis (PGD) and HLA tissue typing can be offered:

(2) A licence under paragraph 1 [PGD] cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the Authority is satisfied—
 (a) in relation to the abnormality of which there is a particular risk, and
 (b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b),
 that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

- 1.3 There is therefore now a new statutory requirement that the HFEA is ‘satisfied’ that PGD is carried out only where there is a significant risk that a child to be born will have or develop a serious condition. In the light of the new legal provisions, the executive reviewed the way that the Authority licenses PGD and set out a possible approach in a document prepared in advance of one of the consultation events held in the New Year.
- 1.4 The method of licensing PGD was that the Authority itself should determine whether each genetic condition that PGD is used to avoid passes the seriousness and significant risk test laid out in the statute. As part of this approach, the executive developed a draft decision-making tool for the Authority to help it determine PGD applications.
- 1.5 At the consultation event, however, and in written responses to the consultation, an alternative method of licensing PGD was presented. External legal advice has since been obtained in order to understand the possible licensing methods that could be operated under the Act. This paper lays out the original PGD licensing system, the one proposed at the consultation event and a summary of the legal advice. It seeks the Authority’s view on its preferred method of licensing PGD from 1 October 2009.

2 Current policy on PGD

- 2.1 HFEA policy on PGD is based upon the work of a joint working party with the Human Genetics Commission which, in November 2001, published recommendations about how the HFEA should regulate this treatment. In determining seriousness and significant risk, the report recommended that the view of the patients should be considered important. However, it also recommended that peer reviewers be asked to comment on the seriousness of the genetic condition which the applying centre wishes to test for.
- 2.2 In summary, the report recommended a balance between respecting the wishes of patients, whilst ensuring that PGD is not available without limits:

In line with the overwhelming weight of responses to the PGD consultation the JWP agreed that the guidance given on the use of PGD should not comprise a prescriptive list of ‘serious conditions’ for which the use of the technique was thought to be appropriate. The JWP agreed the importance of placing greater emphasis on the role of those seeking treatment in reaching the decision about when treatment was appropriate, whilst at the same time maintaining that this should not imply that this treatment should be available on demand. (*Outcome of the public consultation on preimplantation genetic diagnosis*, HFEA/HGC, November 2001)

2.3 With no reference to PGD in the 1990 Act and therefore no statutory guidance about how the procedure should be offered, the HFEA used guidance in the Code of Practice and a clear licensing process to ensure that this balance was appropriately struck.

3 Current PGD licensing arrangements

3.1 At present, any centre wishing to start a PGD service must apply to have its IVF licence varied. The criteria for deciding whether or not a centre may provide PGD are that the embryo biopsy practitioners are sufficiently competent and that the centre is able to comply with the guidance in the Code of Practice.

3.2 When a centre with an existing PGD service wishes to offer PGD for a genetic condition that it has not offered before, it must seek approval from the HFEA. If that approval is given, that genetic condition is added to the centre's licence. If the condition *has not* been offered before at another UK centre, a licence committee considers the application. If the condition *has* been tested for at another centre, the application is considered by the executive and, if approved, the genetic condition is added to the centre's licence.

3.3 At present, a centre cannot apply to have a particular genetic condition added to its licence, unless it has a couple requesting PGD for that genetic condition on whom the application is based. The centre should use the guidance in the Code of Practice, which is based upon the 2001 policy, to establish the appropriateness of the request for PGD:

G.12.3.2 The use of PGD should be considered only where there is a significant risk of a serious genetic condition being present in the embryo. The perception of the level of risk by those seeking treatment is an important factor in the decision making process. The seriousness of the condition should be a matter for discussion between the people seeking treatment and the clinical team.

G.12.3.3 In any particular situation the following factors should be considered when deciding the appropriateness of PGD:

- (a) the view of the people seeking treatment of the condition to be avoided; and
- (b) their previous reproductive experience; and
- (c) the likely degree of suffering associated with the condition; and
- (d) the availability of effective therapy, now and in the future; and
- (e) the speed of degeneration in progressive disorders; and
- (f) the extent of any intellectual impairment; and
- (g) the extent of social support available; and
- (h) the family circumstances of the people seeking treatment.

3.4 Once the application is made, the Authority uses the same criteria to decide whether or not to approve the centre to offer PGD for that genetic condition. If permission is given, the centre may offer PGD for that condition to any other patients it sees fit, subject to the criteria in the Code.

3.5 Under the current PGD licensing system, the licence committee places significant emphasis on the experience and views of patients, although licence

committee reserves the power to refuse applications from PGD centres to have particular genetic conditions added to their licence.

4 Alternative method of licensing PGD

4.1 The method of licensing PGD which was suggested by some participants at the PGD consultation event and in a number of written responses to consultation is that the PGD centres themselves (already licensed by HFEA to provide a PGD service) determine seriousness and significant risk on a case-by-case basis in the clinic, subject to assessment criteria in the Code of Practice and a revised approach to inspection. The system would involve the following stages:

1. Centres must be licensed to provide a PGD service and must have appropriate decision-making processes in place (an ethics committee or multi-disciplinary meeting, for instance).
2. Where centres are considering offering PGD for a genetic condition that they have not offered before, they must use the decision-making criteria in the Code of Practice to determine seriousness and significant risk and document the reasons for the decision. We may wish to require them to notify the HFEA in these circumstances, so that we have an up-to-date record of the genetic conditions for which PGD has been offered. Centres may then offer PGD for that genetic condition to individual couples, using the criteria in the Code of Practice to assess the appropriateness in each case.
3. HFEA will inspect the centres at least every two years and assess the extent to which they are complying with the Act and the Code of Practice.

Consequences for the Code of Practice and for inspection

- 4.2 If this approach to licensing were adopted, the guidance in the Code of Practice would need to be changed to reflect the additional requirements mentioned above. This would include decision-making criteria designed to help centres decide about the appropriateness of individual requests for PGD and guidance on the decision-making process itself.
- 4.3 We would also need to add to licence new licence conditions providing for the manner in which PGD may be carried out. Compliance with the licence conditions and the guidance would be checked during the inspection process. This would include examining patient records in order to determine how the decision to offer treatment was made and that this process fulfilled the requirements of the Act and adhered to the guidance in the Code of Practice.

Advantages and disadvantage of this option

- 4.4 The principal advantage of this approach is that it retains – and builds on – the current emphasis on the views and experience of those seeking PGD in the determination of seriousness and significant risk. It trusts PGD practitioners, in consultation with patients, to interpret the requirements in the Act appropriately

and to restrict the use of PGD to cases where the patients are at significant risk of passing on serious genetic risk to their children.

- 4.5 Devolving the determination of significant risk and seriousness to clinics would also reduce the time and administrative overhead required to approve PGD, thereby lightening the regulatory burden upon PGD centres.
- 4.6 However, this method of licensing may not satisfy the concerns of those who fear that PGD will be used for less serious genetic conditions in the future. It may also fail to satisfy the wishes of Parliament. It may also expose centres to public scrutiny.

5 Legal advice

- 5.1 The executive has sought external legal advice on the possibilities for licensing PGD under the 2008 Act. In particular, we sought advice on whether the proposed alternative method of licensing PGD would be lawful.
- 5.2 Counsel's opinion is that it would *not* be sufficient for the Authority to license a centre to offer a PGD service and then to leave it to the centre to determine seriousness and significant risk according to the Act itself, with the Authority determining retrospectively through inspection whether the centre's decisions were legitimate.
- 5.3 Counsel's view was that whilst the statute does not require the Authority to satisfy itself as to the risk and seriousness of genetic conditions in every *individual* case, it does require the Authority to determine significant risk and seriousness, in general, for each genetic condition for which PGD is offered. There is no need for the Authority to base this decision on the facts of an individual case, even for the first use of PGD for that condition. The Authority could, therefore, agree in principle that PGD could be used for a particular genetic condition, based upon 'the nature of the disability, illness or medical condition which is likely to result from that abnormality *in general*.'
- 5.4 This means that, whilst the Authority needs to approve the use of PGD for genetic conditions that have not previously been tested for in the UK, it could take a different approach when centres seek to offer PGD for a genetic condition that the Authority has already approved another centre to test for.

6 Proposed new method for licensing PGD

- 6.1 Bearing in mind the views about PGD expressed during the consultation of the Code of Practice and legal advice summarised above, we propose that the Authority licenses PGD for 'new' genetic conditions (ie, those not tested for at another other UK centre) on a condition-by-condition basis before PGD is offered. 'Existing' genetic conditions (ie, those that the Authority has already approved another UK PGD centre to offer) can be offered by any PGD centre,

provided that the centre notifies the Authority that it has done so. The system would involve the following stages:

- An IVF centre wishing to set up a PGD service should apply to the HFEA to have this activity added to its licence. The criteria for assessing the application will continue to be whether the centre has competent embryo biopsy practitioners and has the necessary procedures and facilities in place, as laid out in the Code of Practice.
- A PGD centre wishing to offer PGD for a new genetic condition must apply to the Authority to do so, setting out how it considers the genetic condition in question meets both the significant risk and seriousness requirements in the Act. The centre will not need to have a couple requesting PGD for this condition on whom to base the application.
- The Authority will determine whether the genetic condition in question meets requirements in the Act, using the criteria in the decision-making tool to help it to make a judgement based on information provided by the applicant centre and advice from peer reviewers and, where necessary, other organisations or groups.
- If the genetic condition in question is approved, all PGD centres will be notified of the decision and will be able, from then on, to offer PGD for that condition.
- When considering whether to offer PGD to a particular couple, the centre should use guidance in the Code of Practice to determine the appropriateness of PGD in that case.

Guidance in the Code of Practice

- 6.2 Once a PGD centre has been given approval by the HFEA to test for a particular genetic condition, it should use the guidance in the Code of Practice to assess the appropriateness of individual requests for PGD for that genetic condition. Centres may be able to offer PGD for a particular condition but, as in the current system, they may choose not to accept all requests from patients wanting to avoid that condition in their prospective child.
- 6.3 Following feedback about our guidance on PGD provided during the Code of Practice consultation, the executive has reconsidered the need to make the guidance more objective than in the 7th Code of Practice. As many respondents observed, it might make sense for the Authority's determination of significant risk and seriousness to be based on more objective criteria. However, it does not follow that the guidance, which is designed to assist decision-making in individual cases, should also be objective – a distinction which was supported by Counsel's opinion. Many PGD centres and patient groups argued that this kind of objectivity is inappropriate in the individual cases, where decisions are made based upon the particular circumstances of the applicant couple and the features of the genetic condition at which they are at risk, which may be different from one family to the next.

- 6.4 We therefore recommend that much of the guidance in the 7th Code of Practice – relating to the perception of the level of risk and the seriousness of the condition – be retained.

Benefits of this method of licensing

- 6.5 One significant advantage of this approach to licensing that it speeds up the approval process whilst retaining control over the new genetic conditions for which PGD is offered. With the removal of the requirement for a couple on whom the application is based, a centre will be able to apply ‘in principle’ to the HFEA to approve PGD for a particular condition, rather than having to wait for a couple to obtain funding and for a laboratory to prepare the test.
- 6.6 Another advantage of this approach to licensing PGD is that it responds to concerns about the potential for PGD to be offered for less serious conditions in the future. With the HFEA determining the appropriateness of PGD for a particular genetic condition, it is able to strike a balance between the interests of prospective patients and the concerns of wider society about the use to which PGD is put.
- 6.7 Finally, this approach would allow the Authority to publish the full range of genetic conditions for which PGD is available and the centres at which treatment might be carried out. Stakeholders at the consultation event in January strongly supported the publication of such information. Counsel’s opinion was that a move to licensing genetic conditions in principle would mean that any concerns about confidentiality were significantly reduced.

7 Other issues

- 7.1 This paper has not sought to distinguish between the different types of genetic conditions which PGD is currently used to avoid. Lower penetrance, late-onset diseases such as familial predispositions to cancer are currently licensed on a patient-by-patient basis. When the results of the Choices and Boundaries consultation were published, the Authority committed to reviewing its decision to license familial predispositions to cancer on a case-by-case basis. The timing of the new Act has meant that a review of these conditions has not been possible. However, once the new licensing system is established, a policy project to review the licensing of these conditions will be commenced.
- 7.2 One message from the consultation event in January is that Authority needs to review its approach to licensing preimplantation tissue typing. Following the review of preimplantation tissue typing that was carried out in 2004, the Authority decided that embryo testing for this purpose should be approved by the Authority on a patient-by-patient basis. However, because of the need for information to be gathered from the clinician responsible for the care of the existing sibling and the current application process, significant delays are often suffered by applicants. Such delays cause distress to applicants, who may witness a deterioration in their child’s condition during that time.

- 7.3 The timing of the new Act has meant that a review of preimplantation tissue typing has not been possible. However, once the new licensing system of PGD is established, a policy project to review the licensing of tissue typing will be commenced.

8 Recommendation to the committee

8.1 The committee is invited to consider the following questions:

- Is the Authority content to adopt the method of licensing PGD as laid out in section 6 of this paper?
- If no, what alternative method would the Authority recommend?
- If yes, is the Authority content to reintroduce some of the more subjective elements of the guidance in the Code of Practice which had been removed?
- Is the Authority content that the genetic conditions discussed in the Choices and Boundaries consultation (lower penetrance, later onset cancer susceptibility conditions) should continue to be licensed on a patient-by-patient for the time being, until a review of this approach is carried out?
- Is the Authority content that preimplantation tissue typing should continue to be licensed on a patient-by-patient basis for the time being, until a review of this approach is carried out?

9 Next steps

- 9.1 If the Authority is content with the proposed approach, the executive will then redraft the guidance for approval at the May meeting as part of the consideration of the 8th Code of Practice. The executive will also refine the decision-making tool, based upon feedback from the consultation and legal advice and present it to the Compliance Committee for approval.

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