

<b>Committee:</b>	Compliance Committee
<b>Meeting Date:</b>	2 September 2009
<b>Agenda Item:</b>	7
<b>Paper Number:</b>	CC(09)30
<b>Paper Title:</b>	PGD publication and patient confidentiality
<b>Author:</b>	Danny Edwards, Policy Manager
<b>For Information or Decision?</b>	Decision
<b>Resource Implications:</b>	In business plan
<b>Implementation:</b>	To be published with Choose a fertility clinic – 1 <sup>st</sup> October 2009
<b>Communication:</b>	Communication to be sent to centres licensed for PGD
<b>Organisational Risk:</b>	Medium – <ul style="list-style-type: none"> <li>▪ Perception of heightened risk of identifying patients who have received PGD treatment</li> <li>▪ Risk of public perception of lack of transparency around licensed PGD conditions</li> <li>▪ Risk of patients and centres not being able to access information relevant to treatment</li> </ul>
<b>Recommendation to the Committee:</b>	<ul style="list-style-type: none"> <li>▪ To recommend to the Authority to amend its policy on Publication of Authority and Committee Papers to allow in principle past and future publication of all PGD conditions approved by the Authority for testing</li> <li>▪ That accompanying explanatory information is updated as at 7.2.</li> <li>▪ That OMIM numbers be included where licensed genetic conditions are referred to.</li> <li>▪ To approve the changes on the PGD application form at 7.4.</li> </ul>
<b>Evaluation:</b>	12 months

## 1 A publication policy for PGD

- 1.1 At the March 2009 Authority meeting, the Authority agreed to adopt a revised licensing process for PGD (preimplantation genetic diagnosis). Centres licensed for PGD by the Authority will be able to test for any condition previously licensed for testing by the Authority. This approach will reduce, overall, time and resources invested by licensed centres and the HFEA in licensing of PGD. Alongside this, we seek to increase the transparency and robustness of the process.
- 1.2 As a result of this decision centres will need to access a central ‘in principle’ list of PGD conditions licensed for testing by the Authority which is as accurate, informative and complete as possible.
- 1.3 At the May 2009 meeting the Authority committed to presenting, on ‘Choose a fertility clinic’:
- which centres hold a PGD licence
  - a link to the central ‘in principle’ list of licensed conditions

- which conditions are known to have been tested for at a particular centre

These changes were made in response to feedback from patients and clinicians received during the consultation period.

- 1.4 From 1st October 2009 the Authority will be required by the Human Fertilisation and Embryology Act 1990 (as amended) to have regard to the principles of better regulation, including the principle of transparency (section 8ZA(2)).
- 1.5 As a result of 1.1-1.4, the Executive have looked at the publication policy of conditions licensed for PGD, both on the central list and 'Choose a fertility clinic'. It is timely to ensure that the information we publish about PGD is as accurate, informative and complete as possible, in anticipation of the 1<sup>st</sup> of October.
- 1.6 A change to the publication policy for PGD involves consideration of whether disclosure that a particular condition has been licensed (either on its own or in conjunction with the centre at which it was tested for) risks identification of a particular individual, and thus a breach of section 33A of the Human Fertilisation and Embryology (HFE) Act 1990 (as amended). This section of the Act is included at annex A.

## 2 Background

- 2.1 In December 2003, the Scientific and Clinical advances Advisory Committee (SCAAC) advised that the Authority publish a list of conditions licensed by the Authority to test for in preimplantation genetic diagnosis (PGD). This decision was taken with the view that the publication of a list would be beneficial to patients seeking information about PGD.
- 2.2 A caveat on publication was that conditions which were felt to be so rare that publication risked identification of a particular individual/family (and thus risked breaching the HFE Act) not be published.
- 2.3 The recommendation to publish a list was approved. Subsequently an audit was carried out of licensed PGD conditions, and centres were asked to confirm which conditions they felt bore an increased risk of patient identification. As of 7 August 2009, 16 conditions licensed by the HFEA have a confidential status (out of a total of 126 licensed conditions).
- 2.4 The existing process for the publication of licensed PGD conditions has been:
  - The current PGD application form asks centres to indicate whether they are content for the condition to be included on the HFEA

website, or if publication of the fact that this condition has been licensed would carry a risk of the identification of an individual.

- An HFEA licence committee, when considering the application to licence PGD for that condition, will take this into consideration, and make a judgment whether or not to publish that condition on the public list.

### 3 Consultation

#### *Consultation on the presentation of clinic data*

- 3.1 As part of the consultation on the presentation of clinic data over the winter, centres, patient groups and other affected stakeholders commented about how they felt information about PGD should be published on the 'Choose a fertility clinic' pages of the HFEA website.
- 3.2 There was strong feedback throughout the consultation and at the specific PGD event (26 January) that the HFEA should provide more complete information about PGD. Patients, clinicians and the Human Genetics Commission repeatedly stressed that we should clearly state which conditions had been licensed for PGD at each centre. Patients find it frustrating and time-consuming to be directed by the HFEA to PGD licensed centres, and then to have to ask each centre individually whether they offer PGD for a specific condition.

#### *Human Genetics Commission consultative panel*

- 3.3 In May 2009 members of the Executive attended the HGC consultative panel meeting, attended by people with direct experience of living with genetic disorders. Feedback from this meeting echoed the presentation of clinic data consultation, in that people living with genetic conditions found it difficult to access information about which conditions were licensed for PGD by the HFEA (most notably in those cases where publication was withheld where the disease was thought to be so rare as to risk patient identification.)

#### *Genetic Interest Group*

- 3.4 In the development of this publication policy, we also consulted with the Genetic Interest Group (GIG). GIG's position was that:
  - They strongly supported a move towards increased transparency around which conditions were licensed for PGD.
  - They also supported publishing which centres had tested for which condition, thus bringing PGD into line with other services on the NHS. They felt this would be particularly beneficial to patients seeking treatment.

- GIG felt that we should remain mindful of situations where we might provide information that would potentially reveal the identity of patients that have received treatment due to the rarity of the condition concerned. In such cases GIG advised that we should limit the amount of information published to ensure the patient's privacy.

### *Licensed PGD centre*

- 3.5 In the development of this publication policy for PGD we discussed the risk of patient identification with a centre licensed for PGD. This centre expressed the view that we should be able to publish both a complete list of conditions licensed by the HFEA, and which centres had carried out those tests. Their view was that it would not be possible to positively identify any patient from either the fact that a condition had been licensed by the HFEA, or indeed the fact that it had been tested for at a specific centre.
- 3.6 The centre provided an example of the rarest condition they had tested for (recorded prevalence in Europe of 1/400000), in this example they had already treated 3 families –thus their feeling was that it would not be possible to automatically identify an individual who had had treatment using PGD.
- 3.7 The centre expressed the view that excluding conditions from the list creates uncertainty over how many conditions are not included on the list. This leads to centres needing to check with the HFEA, and patients needing to ring around all licensed PGD centres trying to secure information which the HFEA does not provide. From 1<sup>st</sup> October, this centre felt it becomes more important for both patients and centres to have a central reference point where they can see whether a condition has been licensed 'in principle' for use in the UK by licensed PGD centres.

## **4 Preliminary privacy impact assessment, legal opinion**

- 4.1 We have carried out a preliminary privacy impact assessment on the risk of identifying patients through the publication of which conditions are licensed for PGD, and which centres have tested for those conditions. The impact assessment indicated that there is a negligible risk of breaching section 33A of the HFE Act 1990 (as amended) or of breaching data protection principles.
- 4.2 We do not link individual treatment cycles to a particular condition. Additionally, we take great care that any patient identifying information associated with a licensing decision (papers, minutes) is not published. Risk of patient identification is reduced to negligible levels.

4.3 Positive identification of an individual/family having received PGD treatment only seems possible with the provision of additional evidence, perhaps from external sources, linking that family or individual with the fact of licensing. This is something which is outside of the control of the Authority.

4.4 Legal advice was received from Counsel on the publication of PGD conditions. This advice made three key points regarding confidentiality:

- Publication of full information as to the abnormalities or gender-related conditions approved in principle for PGD may encourage wider and more consistent provision of such services and would promote transparency, a principle to which the Authority will be statutorily required to have regard with effect from 1<sup>st</sup> October 2009.
- The Authority may not defer to centres when deciding whether an individual would be identified, but must satisfy itself in each case on the basis of material provided to it.
- The Authority should only refuse to publish where there is a real risk that a particular patient would be identifiable, even after of anonymisation of material associated with the decision.

## 5 Proposed publication policy

5.1 On the basis of the consultation and internal investigations carried out, factors have been identified in PGD licensing which reduce to negligible levels the possibility of identification, most notably:

- We do not link individual treatment cycles to a test for a particular condition, and do not publish information identifying an individual/family in a licensing decision
- People travel from overseas to receive PGD treatment at UK centres, meaning it is never a certainty that a person in the UK has been tested for a published condition
- People within the UK often travel domestically for treatment. Many PGD centres are located in London. Knowledge that a test has been carried out at a particular centre could not positively identify an individual on the basis of the region the person lives in
- The fact of a pregnancy (and the birth of an unaffected child) would not lead someone to conclusively identify that a person had had PGD to avoid a particular condition. It is always a possibility that the family may have elected to:
  - use prenatal genetic screening
  - conceive without a PGD cycle
  - use donor gametes.

- 5.2 When thinking about the publication policy post 1<sup>st</sup> October, Compliance committee is asked to consider the following key areas:
1. There is a clear benefit in complete information being disclosed. Limiting transparency around PGD licensing impedes both the ability of people seeking treatment to access information about licensed PGD conditions, and reduces the ability of PGD centres, post 1<sup>st</sup> October, to assess what conditions they are able to test for.
  2. That the HFEA will have, from 1<sup>st</sup> October, included in the HFE Act 1990 (as amended) an additional duty to have regards towards the principle of transparency.
  3. That there is, based on the factors detailed at 5.1, negligible risk that a particular individual or family will be identified as having received PGD treatment either through the publication of their condition on a central list, or by publication that a particular centre has tested for it. Thus there is a negligible risk of a breach of section 33A of the HFE Act.
- 5.3 In any particular case, even where a person might suspect that another individual (known to them, perhaps through a patient group) had used PGD to become pregnant, information that the Authority had published that the condition was licensed for use in the UK (and had been tested for at a particular centre) could not be used to conclusively to identify an individual. The person concerned would have to confirm, if asked, that they had received treatment.
- 5.4 The proposed policy of publication of PGD conditions is thus to publish, in principle, all conditions licensed by the HFEA for use in PGD in the UK, both retrospectively, and for future decisions.
- 5.5 If this publication policy is approved, all PGD centres will be informed. Those centres licensed to carry out conditions currently kept confidential will be informed that these conditions will be published.
- 5.6 While the presumption, is to disclose all conditions in principle, if the licence committee has reason to believe that after considering the factors described at 5.1, that there are exceptional circumstances which render patient identification a likelihood, then the licence committee should notify the Chair of the Authority and the Chief Executive that publication of the decision to licence will not meet the deadline prescribed in the Policy on Publication of Authority and Committee Papers. The decision on whether to publish the licensing of that condition should then be referred to the full Authority for decision.

## 6 Other proposals

- 6.1 In implementing these changes there are several other items that Compliance committee is asked to agree.

### *Presentation of the list*

- 6.2 That the supporting explanatory information presented on the central list is updated to reflect the adopted changes to the licensing process. In particular, to detail that people may travel from overseas for treatment. This will help to alleviate concerns about patient confidentiality, and increase understanding of the licensing process.
- 6.3 Currently, the central PGD list is published without OMIM (Online Mendelian Inheritance of Man) numbers. OMIM numbers classify genetic variants of a condition. We licence conditions (where applicable) by OMIM number. We do not, however, publish the OMIM number on the public list. This leads to confusion in cases such as muscular dystrophy. Muscular dystrophy appears on the public list, but in reality we have only licensed PGD for some variants of this condition. It is recommended that wherever possible, when publishing a condition we also include the OMIM number.

### *PGD Application form*

- 6.4 We recommend, in the light of the revised publication policy, that the application form centres use when applying for a previously unlicensed condition is updated to remove the section asking centres to indicate where they feel that a condition not be included on the public list. We recommend that this be replaced with:

*"Please confirm that you will inform a patient seeking PGD for a condition not yet published on the HFEA website, with information that the condition tested for will be published on the HFEA website, both on the central HFEA list of licensed conditions, and also on 'Choose a fertility clinic' in connection with the centre carrying out the test."*

## 7 Next steps

- 7.1 If Compliance committee and the Authority approve the recommendations in this paper Policy will work with Compliance to ensure that centres are communicated with, the PGD list is accurate and up to date in preparation for the 1<sup>st</sup> of October.
- 7.2 If the proposal in this paper is agreed to, then, from 1<sup>st</sup> October, all new conditions licensed by the Authority will be published. New conditions will communicated by the Licence Committee Secretary to the communications team for addition to the public list. The Licence Committee secretary will still need to be mindful (as with any patient

identifying information) of redacting Licence committee minutes where patient identifying information related to a PGD decision is discussed.

7.3 With respect to 'Choose a fertility clinic' a communication will be sent to centres asking which conditions they have tested for. When a centre tests for condition they have not tested for before, they will notify us. In this way 'Choose a fertility clinic' will be kept updated.

**8 Compliance committee is asked:**

- **to recommend that the Authority amend its policy on Publication of Authority and Committee Papers to allow in principle past and future publication of all PGD conditions approved by the Authority for testing**
- **that explanatory information is updated**
- **that OMIM numbers be included where licensed genetic conditions are referred to.**
- **To approve the change on the PGD application form at 6.4.**

## Control sheet

### Document control

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### Version/revision control

Version	Changes	Updated by:	Release date
1.1	Structural changes	Danny Edwards	
1.2	Changes following meeting with AD/PT	Danny Edwards	

\* Excluding control sheet