

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY
ETHICS & LAW ADVISORY COMMITTEE

Committee:	Ethics & Law Advisory Committee
Meeting Date:	15 December 2009
Agenda Item:	7
Paper Number:	ELAC (12-09)2
Paper Title:	Non-disclosure of genetic test results – proposed guidance
Author:	Joanne Anton, Policy Officer
For Information or Decision?	For Decision
Resource Implications:	None
Recommendation to the Committee:	Members are asked to agree the proposed guidance on the non-disclosure of genetic test results for recommendation to the Authority at its January 2010 meeting.

1. Introduction

1.1 The following paper sets out proposed guidance on the non-disclosure of genetic test results, for recommendation to the Authority. The guidance is based on previous discussions by the Ethics and Law Advisory Committee (ELAC) on the regulation of exclusion testing and PGD with non-disclosure. In addition, the proposed guidance reflects the feedback that was received from the consultation event on PGD licensing on 1 December 2009.

2. ELAC Recommendations

2.1 At the October 2009 meeting ELAC discussed a paper on the ethical issues pertaining to exclusion testing and PGD with non-disclosure. Members were asked to provide recommendations to the Authority.

2.2 In light of the discussion on the ethical and legal issues pertaining to the tests, the Committee recommended:

1. that exclusion testing is acceptable.
2. to issue strong guidance on PGD with non-disclosure, including:
 - that exclusion testing is preferable to PGD with non-disclosure

- that PGD with non-disclosure is acceptable only in exceptional circumstances
- a list of stringent conditions which a clinic must meet if they choose to offer PGD with non-disclosure. This should include information regarding consent which illustrates that the patient understands all of the possible implications, and including the risks of inadvertent disclosure

3. Consultation event

- 3.1 A consultation event was held on 1 December, with PGD clinic staff, professional and patient organisations, to seek views on PGD licensing. The event included a session on exclusion testing and PGD with non-disclosure, in which participant's views were sought on ELAC's recommendations (see section 4).
- 3.2 In particular, participants were asked whether they agree that non-disclosure should only be offered in exceptional circumstances and, if so, what conditions should be in place before offering PGD with non-disclosure.

4. Feedback

- 4.1 There was broad consensus that exclusion testing is preferable to non-disclosure and that non-disclosure should only be offered in exceptional circumstances. It was felt, however, that to ban the option of non-disclosure would be unreasonably limiting patients for whom exclusion testing was not a feasible option.
- 4.2 A minority view was expressed, however, that non-disclosure could be seen as a better or equal alternative to exclusion testing, as the former method does not involve discarding unaffected embryos. In addition, it was highlighted that there may be a clinical case to perform non-disclosure for patients with sub-fertility, because non-disclosure testing is likely to produce more viable embryos than exclusion testing.
- 4.3 It was agreed that, when non-disclosure is offered, the following conditions should apply:
- Dummy or pretend treatment rounds should not be performed. Patients should be informed prior to treatment that there may be no embryos to transfer and this does not mean that the patient has the condition.
 - Patients should be offered information and counselling on the implications of PGD with non-disclosure, including the risks of inadvertent disclosure.
 - Patients should be informed that they are free to change their mind about knowing their status at any time, both before and after treatment.

- Steps should be taken to minimise the risks of inadvertent disclosure including the requirement that staff who have direct contact with patients should not have access to the patient's laboratory tests.
- Staff should be entitled to conscientiously object to work on non-disclosure cases.

5. Proposed Guidance

- 5.1 The Committee is asked to discuss and agree the proposed guidance for recommendation to the January 2010 Authority meeting. If the guidance is agreed by the Authority at its January meeting, it will be included in the update to the 8th edition of the Code of Practice in April 2010.

Non-disclosure of genetic test results

Concerns have been raised about the ethical implications of directly testing embryos for a genetic condition without disclosing the test results to the patients (PGD with non-disclosure).

Where patients seek PGD, but do not wish to discover their own genetic status, centres should, where possible, only offer PGD with exclusion testing.

In exceptional circumstances the centre may offer PGD, but withhold the patient's test results (PGD with non-disclosure). However, this should only be offered under the following conditions:

- (a) that patients are given the opportunity to receive genetic counselling on the implications prior to giving consent,
- (b) that protocols are established to limit, as far as possible, the risk of unwanted disclosure to the patients. Centres may wish to consider using a different embryology laboratory from their own, in order to minimise the number of centre staff who know the patient's genetic status,
- (c) that no dummy embryo transfers or other forms of pretend treatments are to be performed, and
- (d) that the centre documents its reasons for offering PGD with non-disclosure to a patient. This record needs to include a statement from the people seeking treatment confirming that they have been given the opportunity to receive genetic counselling and that they have, prior to giving consent, received information:
 - (i) on the risks of inadvertent disclosure,

- (ii) that where no embryos are suitable for transfer this is not evidence of the patient's genetic status,
- (iii) that therefore dummy embryo transfers are not necessary or permissible, and
- (iv) that treatment may go ahead which is not medically necessary in cases where the patient (or partner) does not have the genetic condition. This includes information about the potential costs and risks of any medically unnecessary treatments.

When deciding if it is appropriate to provide non-disclosure PGD, the centre should consider the views of the staff to whom the information is to be disclosed.

6. Recommendations to the Committee

- 6.1 Members are asked to discuss and agree proposed guidance on the non-disclosure of genetic test results for recommendation to the January 2010 Authority meeting.

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