



Consultation Report

Code of Practice 8th edition and revised consent forms

July 2009

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1 Introduction

- 1.1** Shortly after the Human Fertilisation and Embryology Act received royal assent in November 2008, the HFEA published a revised Code of Practice and consent forms for public consultation.
- 1.2** The new Act meant that we needed to update the Code and consent forms. However, we took the opportunity to review both in order to help clinics, laboratories, patients and donors understand more clearly the law and HFEA guidance. As a result, the Code of Practice was restructured and substantially redrafted and the consent forms were redesigned, reworded and included clear guidance on how to complete them.
- 1.3** We also took the opportunity of the new legislation to introduce some new policies which were not necessitated by the Act, but had been under review following feedback from patients, clinicians and researchers.
- 1.4** Through the consultation, we aimed to gather the views of clinic and laboratory staff, patients and interested groups about the new structure and content of these documents. We did this via an online questionnaire and through three consultation events in London, Bristol and Manchester. We also held a consultation event in London which was focussed specifically on preimplantation genetic diagnosis. The events were attended by clinic and laboratory staff, patients, patient support groups, parliamentarians, disability advocacy groups, academics, policy makers, members of the deaf community and other stakeholders. We also visited clinics in Glasgow and Cardiff and had a stand at the Fertility 2009 conference in Edinburgh. The consultation on the consent forms included a patient and donor focus group and sessions at two clinics where we trialled the draft forms. A total of 85 responses to the online questionnaire were received and 200 people attended the various consultation events.
- 1.5** The views expressed during the consultation were analysed by HFEA staff and presented to the Authority in May. This report summarises the responses to each of the aspects of the Code and consent forms on which we sought views and presents the information gathered about their impact on clinics. It also lays out the decision the Authority took in each instance.

- 1.6** The Code of Practice was approved by the Authority on 13 May 2009. It was awarded the Clear English Standard by the Plain Language Commission and was approved by the Minister for Health. The Code was issued to centres in early July and will come into force, alongside the new legislation, on 1 October 2009. An online version of the Code will be available on time for this commencement.
- 1.7** A guide to the Code is available at www.hfea.gov.uk. This guide identifies and explains the main additions and deletions to the guidance as a result of the new legislation, policy development and production process of the Code.

2 Changes to the structure and format of the Code of Practice

- 2.1 The structure of the Code attempts to make it easier to find and understand the relevant legal requirements and best practice guidance. Guidance is organised into notes on specific subjects, which also include relevant sections of the legislation and, where it's needed, summaries of statutory requirements.
- 2.2 During the consultation views were sought on this new structure. The majority of feedback suggested that centre staff find the Code relatively easy to understand and navigate. Positive comments were received about the separation of mandatory requirements and guidance; interpretation boxes; order of guidance notes and the fact that they are separated into smaller sections than in the 7th Code.
- 2.3 One concern raised at the engagement meetings is that the Code does not indicate which requirements apply to IUI centres. This is addressed in the *'Guide to the changes in the Code of Practice, consent forms and Directions'*.
- 2.4 The consultation questionnaire asked if the new structure of the Code will make it easier to distinguish legal requirements from best practice guidance and if it will be easier for people to find information their looking for. The vast majority of respondents, who expressed a view, answered yes to these questions.
- 2.5 The Code includes 13 Regulatory Principles for licensed centres. The Principles are intended to summarise the key behaviours and outcomes licensed centres are expected to demonstrate. At the two workshops where the Principles were discussed there was general consensus that they are comprehensive, easy to understand and are a helpful summary.
- 2.6 All but one of the questionnaire respondents that gave a view about the Principles felt that the Principles help them understand what the HFEA expects of licensed centres. Reasons given included that the Principles are clear and remove ambiguity, are similar to centres' quality policies and are particularly helpful for new clinic staff and lay people.
- 2.7 There was a majority view that the Principles cover all the behaviours and outcomes that a good licensed centre should demonstrate.

3 Changes to guidance in the Code of Practice

Costed treatment plans

- 3.1** It was proposed that the Code should include a new requirement for clinics to provide each patient with a costed treatment plan. This proposal responded to concerns from patients that costs sometimes increase during treatment without it being clear why this happened. This proposal was one of the main topics of discussion at the workshops and the questionnaire asked whether this guidance would help clinics make costs more transparent for patients, while acknowledging that medical treatments are not entirely predictable.
- 3.2** The majority of workshop attendees felt that this new guidance would be beneficial for patients. Most centres already provide this information to patients, so for many the new requirement would not impose an increased burden. It was suggested that the guidance should specifically require centres to include information about investigations and tests in the costed treatment plan. As well as likely changes to the treatment plan, it was suggested that patients should be informed of possible changes which will have a major impact on cost, eg, changing from IVF to ICSI.
- 3.3** There was discussion about the possibility of including prices of treatments which are not within the Authority's licensing remit, eg, adjuvant therapies. Questions were raised about which members of a clinic's team would give the costed treatment plan to patients and whether it is appropriate for clinicians to discuss prices. It was suggested that the HFEA should provide a template or example costed treatment plan.
- 3.4** The majority of people who expressed a view (42/50) were in support of this new guidance and felt that it would help clinics to make costs more transparent for patients:

“Complaints about hidden, inflated and unclear costs are perhaps the most frequent concerns raised by patients. A carefully compiled check list which is completed with the patient so that they know clearly what may be involved and can return to for reference in the future as plans develop or change is very important.” (The British Infertility Counselling Association (BICA))

“It is important to find a way to help patients to budget for their treatment even if this is issued in the form of a proforma invoice and we can suggest the likely cost if various procedures might be likely for that particular couple. Each procedure or drug cost hundreds of pounds therefore it would be helpful for the patient to plan for the worst case scenario. It would also cover the centre as we are less likely to have disgruntled patients who then refuse to pay their bills.” (A fertility nurse)

- 3.5** A minority of people (5/50) didn't support of this guidance and felt that it would not be helpful for clinics or patients. Reasons given included that drug costs are unpredictable, clinics may quote incomparable costs and that clinics already provide this information.

“This information is already given to patients at our centre including some explanation of any likely additional procedures and their costs and this does not stop complaints entirely! Perhaps a more effective approach would be to provide some additional data on average costs but this varies widely with different patients.” (A person responsible)

The Authority decided that the following guidance should be added to guidance note 4, *Information to be provided prior to consent*.

“Before treatment, storage or both are offered, the centre should also give the person seeking treatment or storage and their partner, if applicable, a personalised costed treatment plan. The plan should detail the main elements of the treatment proposed (including investigations and tests), the cost of that treatment and any possible changes to the plan, including their cost implications. The centre should give patients the opportunity to discuss the plan before treatment begins.”

In addition, the HFEA will explore the possibility (in discussion with the British Fertility Society) of providing a costed treatment plan template.

Welfare of the child (supportive parenting)

- 3.6** The Human Fertilisation and Embryology (HFE) Act 2008 removes the requirement to take into account any prospective child's need for a father when considering whether to treat a particular patient and replaces it with the need to take into account a child's need for supporting parenting (as part of the welfare of the child assessment).
- 3.7** In line with parliamentary debates, the proposed guidance in the Code spelt out a presumption that all fertility patients are 'supportive parents', unless there is reasonable cause for concern about significant risk to the prospective child. The questionnaire asked whether the guidance should make this presumption.
- 3.8** The majority of people who expressed a view (51/59) agreed that the guidance should make this presumption. Reasons given included that the right to reproduce should be a basic human right and that people seeking fertility treatment will be committed to becoming parents. There were a few suggestions for rewording this guidance, including removing the word 'sustained' from 'sustained commitment to the health, well being and development of the child' as this could preclude a patient who has a serious medical condition or terminal illness from accessing treatment.
- 3.9** There was also a suggestion that the sentence *'the centre may take account of wider family and social networks within which the child will be raised'*, should be removed as it may enable discrimination against lesbian couples, single women, orphans and recent immigrants, who may not have a wider family or social network:

"It is impossible for the practitioner to be judge and jury in regard to whom fertility treatment should and shouldn't be offered to. I agree that there should be a presumption that all parents are supportive unless there is evidence to the contrary." (A fertility counsellor)

- 3.10** A few respondents, who did not support of this guidance, expressed reservations about whether it would be appropriate to make this presumption for patients who had not been referred from their GP:

"While some of us consider that this presumption is more acceptable where patients have been referred by a GP (on the grounds that GPs are unlikely to refer people where there are doubts about their ability to provide supportive parenting); others strongly believe that such a presumption reduces the likelihood of identifying 'cause for concern' and that centres should routinely and actively seek GP views." (PROGAR)

The Authority decided that there should not be a need for a ‘*sustained*’ commitment to supportive parenting as this may preclude patients who have a serious medical condition or terminal illness from accessing fertility treatment.

The Authority decided that centres should not routinely be required to ‘*take account of wider family and social networks within which the child will be raised*’. This assessment should only be carried out when there are concerns as to whether a commitment to the health, well being and development of the child exists.

The Authority decided that the welfare of the child assessment is sufficient to address concerns regarding self-referred patients. As part of the assessment clinics will verify the identity of the patient by contacting their GP. If a patient does not give consent to contact their GP centre will take this into account as part of the assessment.

Therefore, the following guidance has been added to guidance note 8, *Welfare of the child*:

“When considering a child’s need for supportive parenting, centres should consider the following definition:

‘Supportive parenting is a commitment to the health, well being and development of the child. It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where centres have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised.’”

Storing a child’s gametes

- 3.11** The 2008 Act enables clinics to store a child’s gametes for later use in cases where that child is not able to give informed consent themselves. Proposed guidance in the Code stated that centres should assume it is in the child’s best interests to store gametes unless circumstances suggest otherwise. The questionnaire asked whether the guidance should make this assumption.
- 3.12** The majority of people who expressed a view (48/51) agreed that it is reasonable to make this assumption, providing that consent is obtained from the child when they reach competence. Reasons given included that storing gametes will enable a child to make informed choices later in life

and that it is preferable to using donor gametes. However, a number of responses also highlighted that the majority of centres cannot store testicular or ovarian tissue because their laboratories do not meet Human Tissue Authority standards.

- 3.13** Some responses raised concerns about how clinic staff would judge whether storage of gametes is in a particular child's best interest, especially as technology does not currently provide uses for immature testicular and ovarian tissue. It was suggested that clearer guidance should be provided regarding how to act if parents and clinicians hold conflicting views about what would be in a child's best interest:

"It has long been a concern of PROGAR that some minors may be excluded from fertility preservation services because there has been no 'best interests' consent provision. Centres should be required to have policies and procedures to deal with situations where the views of parents conflict with those of the child and/or centre." (PROGAR)

- 3.14** The BMA was one of the three respondents who are not in support of this guidance:

"Whilst it is important to keep open the future options available to children and young people who are undergoing treatment that might affect their future fertility, there is no need for the HFEA to make any comment about this. Storage of gametes that have been removed is uncontroversial. The controversial aspect is the decision to remove gametes and this is something that is outside the Act and the remit of the HFEA. The current wording implies it is the licensed clinic that will be making the decision about removal which is not the case. Once gametes have been removed, it is appropriate that they should be stored until the young person has the capacity to make a decision about continued storage and/or use. The code of practice should therefore simply state the circumstances in which children's gametes can be stored without written consent." (BMA)

The Authority decided that the following guidance be added to guidance note 5, *Consent to treatment, storage, donation, training and disclosure of information*:

“The centre should presume that it is in the child’s best interests to store gametes unless circumstances suggest otherwise. When assessing whether it is in a child’s best interests to procure and store their gametes, the centre should refer to the General Medical Council guidance ‘0-18 years: guidance for all doctors’ and consider the child’s short- and long-term best interests. Consent should be sought from the child when they reach competence.”

Authority members felt that although the decision making process for procurement was not strictly within the HFEA's remit, this would be integral for the decision as to whether to store a child's gametes as it

Disputes about using embryos

- 3.15** The 2008 Act will introduce a one-year cooling-off period that will allow clinics to continue storing embryos for a year after one partner withdraws their consent to store them, in order to give both parties time to reach an agreement.
- 3.16** It was proposed that guidance in the Code should require clinics to have procedures in place for dealing with disputes when one gametes provider withdraws their consent to the use or storage of gametes or embryos in treatment. The guidance stated that in this situation the centre should stop treatment and notify all relevant parties. Centres should also provide information about counselling and refer patients to mediation as appropriate. The consultation questionnaire asked whether this guidance will help clinics deal with these disputes.
- 3.17** The majority of people who expressed a view (48/55) felt this guidance would be helpful. It was suggested that it would be important for counsellors to receive additional training on how to deal with these issues:

“This is a welcome development for those rare but very emotional situations where such disagreements occur. There will be a need for additional training for counsellors and other staff on this if it is anticipated that LTC staff should provide the mediation, or LTCs should be required to know how they would guide patients to such services if required. Currently it is unlikely that many staff have any working knowledge of mediation services. The ‘cooling off’ period is a welcome way for approaching disputes at a heated time.” (BICA)

3.18 However, a minority (7/55) said that it is not the role of clinics to refer couples to mediation or deal with counselling issues in these situations:

“The guidance implies that it is for licensed clinics to mediate between couples who are in dispute about the future use of their embryos. Clinics should fulfil their legal obligation to notify those who have embryos in storage about the withdrawal of consent and inform them of their options – including the fact that embryos may be kept in storage for up to 12 months to give time for both parties to reach agreement. Clinics may wish to suggest counselling or mediation services but it should not be seen as their responsibility to try to broker an agreement. Ultimately the decision rests with the gamete donors.” (BMA)

In response to concerns that referring patients to mediation services should not be a clinic’s responsibility, the Authority decided that, instead, it would be good practice for clinics to provide patients with information about mediation services (where appropriate). Therefore, the following guidance has been added to guidance note 5, *Consent*:

“The centre should have procedures for dealing with disputes that may arise when one gamete provider withdraws their consent to the use or storage of gametes or embryos in treatment. In this situation the centre should stop treatment and notify all relevant parties. Centres should provide information about counselling or mediation services as appropriate.”

Choosing an affected donor and choosing an affected embryo

3.19 Section 13(9) of the Human Fertilisation and Embryology Act 1990 (as amended) prohibits clinics from preferring a donor or an embryo known to be affected by a serious genetic condition over a donor or an embryo not known to have that condition.

3.20 The use of affected donors was not completely ruled out in the draft Code of Practice. Clinics and patients could still choose an affected donor if this wasn’t done *exclusively* because the donor was affected by a known genetic condition (for example because the couple might want to use a known donor who is affected). Similarly, the use of affected embryos in treatment is not ruled out in cases where there might be a good clinical reason for replacing an affected embryo, and where there is no other embryo ‘suitable for transfer.’

- 3.21** In drafting the Code of Practice the Authority felt that the spirit of any guidance ought to make clear that there is scope for clinical judgment as to the most suitable embryos to transfer, even where those embryos may have tested positive for an abnormality. Similarly the Authority felt that guidance regarding the suitability of donors known to be affected by a genetic condition should have a similar level of flexibility.
- 3.22** The consultation on these issues fell into two parts: questions in the online questionnaire, and workshops focusing on these questions held at a public consultation event on 26 January 2009. The consultation questionnaire asked whether or not our interpretation of this statutory requirement was reasonable – both for the use of affected donors and affected embryos.
- 3.23** With respect to the question on the selection of affected embryos, 50 respondents expressed a view. Of these, 74.5% (38/51) agreed that the approach taken by the guidance was reasonable, with 25.5% (13/51) feeling that the approach was not reasonable.
- 3.24** With respect to the question on the selection of affected donors, 48 respondents expressed a view. Of these, 75.5% (37/49) agreed that the approach taken by the guidance was reasonable, with 24.5% (12/49) feeling that the approach was not reasonable.
- 3.25** Of those who felt that the interpretation regarding donors was reasonable, two felt that such a decision should only be made with appropriate counselling, and with the assistance of the clinic’s clinical ethics committee. Several felt that where the use of an affected donor was proposed, this should be included as part of the welfare of the child assessment. Several respondents felt comfortable with our interpretation as they felt it would be inappropriate to make presumptions about the quality of a life lived with a particular condition in a particular family, and that some families would not consider their condition a ‘serious disability’ or even a disability. Some felt that clinicians would be put in the undesirable position of requiring proof of the reasons why the affected donor was selected. Following from this, some felt that there ought to be more guidance for clinics for these difficult situations.

“Yes, the decision not to completely rule out the use of affected donors is reasonable.... Such situations need to be handled on a case-by-case basis, under regulatory guidance from the HFEA, and with due regard for the welfare of the future child...” (Progress Educational Trust)

3.26 Of those who felt our interpretation regarding donors was not reasonable, many thought it would fall foul of the welfare of the child requirements. Similarly, others felt it was inappropriate to knowingly increase the risk of a child inheriting a particular serious condition and that a child needs to be given the best chance of a ‘good life’ from the outset.

“The welfare of the child should always come first and I struggle to come to terms with using a donor with a possible detrimental genetic condition for any reason....” (An embryologist)

3.27 Of those who felt our interpretation regarding embryos was reasonable, many felt it was the best possible interpretation, given that clinical choice should not be completely restricted. Some felt, however, that more guidance was required to make it clear in which situations this might be appropriate, as they found it difficult to imagine a scenario in which this might be the favoured option. Two accepted the guidance with the proviso that appropriate counselling is given to the patient, and use is made of a clinical ethics committee. Again, several felt that the decision to replace an embryo known to be affected by a serious condition ought to form part of the welfare of the child assessment.

“The proposed guidance makes clear that the reason for testing must be to avoid the transmission of a serious genetic condition and that affected embryos may only be replaced if there are no suitable unaffected embryos available.... It is worth noting that in such cases the welfare of the child provision will be engaged...” (British Medical Association)

3.28 Of those who felt our interpretation regarding embryos was not reasonable, many felt that the welfare of any potential child ought to be weighed over the desire of a person to become pregnant at any cost. Others felt that replacing a lower grade embryo rather than an affected embryo would be the preferable alternative. A clinician felt that if a person was prepared to replace an affected embryo, then that is a good indicator that the condition was not serious enough to be screened for in the first place.

3.29 We also held a consultative event at which workshops were held focusing on these questions. These people were from a range of backgrounds: patient support groups, clinicians, parliamentarians, disability advocacy groups, academics and policy makers. We also welcomed attendees from the deaf community who had concerns about this area of HFEA guidance. In particular, they were concerned that the legislation may prevent deaf people from having deaf children.

- 3.30** The views expressed at the event were broadly similar to the responses from the online questionnaire. Clinicians felt there was a need for more guidance in these situations to help them, and there were concerns that the possibility of patients lying to clinicians about the reasons for their donor choice could undermine the patient-clinician relationship. Clinicians felt that they needed the flexibility of not completely ruling out the use of affected embryos, but would benefit from more guidance to ensure they were acting within the law. Others felt that in some circumstances embryos should never be replaced, due to the suffering associated with the conditions.
- 3.31** Finally, we sought advice from legal counsel on the application of Section 13(9) in order to ensure that the draft guidance was adequately supported by the legislation. The legal advice we received agreed that the guidance provided on this clause in the draft Code of Practice, both with respect to embryo and donor selection, was acceptable. The legal advice agreed that the inclusion of the word 'preferred' in the Section inferred that the section *'applied to situations where there is a choice or selection to be made between more than one embryo or donor.'*
- 3.32** With respect to donor selection, the legal advice agreed that the guidance was largely appropriate, but that the word 'exclusively' should be removed. The reason for this was that the word 'exclusively' does not exclude the possibility of there being multiple reasons for the choice of a donor, one of which may still be because that donor had a serious condition. Counsel advised that to be faithful to 13(9) the fact that a donor had a serious condition could not form any contributing factor to the decision.
- 3.33** With respect to embryo selection, Counsel agreed that the approach taken in the guidance was appropriate, with minor amendments. Counsel also advised that it was important that Section 13(9) ought not be read in isolation, and consideration of the welfare of any child to be born resulting from treatment (Section 13(5)) also needed to be considered. Counsel advised that inclusion of this was appropriate.
- 3.34** In addition, Counsel advised that the reason for the choice of an affected donor or embryo should be documented, in order that the Authority could properly scrutinize the operation of this Section.

The Authority decided that the following interpretation of the law and guidance, regarding choosing an affected embryo, should be included in guidance note 10, *Embryo testing and sex selection*:

“Interpretation of mandatory requirements

The law prohibits the selection of an embryo for treatment if it is known to:

- a) have a gene, chromosome or mitochondrial abnormality involving a significant risk that the person with the abnormality will develop a serious physical or mental disability, a serious illness, or a serious medical condition, or*
- b) be of a sex that carries a particular risk that any resulting child will have or develop a gender-related serious physical or mental disability, serious illness, or serious medical condition*

This applies only where there is at least one other embryo suitable for transfer that is not known to have the characteristics. Where there is no other embryo suitable for transfer, an embryo with these characteristics may be transferred.

Guidance

10.13 The use of an embryo known to have an abnormality as described above should be subject to consideration of the welfare of any resulting child and should normally have approval from a clinical ethics committee.

10.14 If a centre decides that it is appropriate to provide treatment services to a woman using an embryo known to have an abnormality as described above, it should document the reason for the use of that embryo.

NOTE: An example of an embryo not suitable for transfer in this context is one that has no realistic prospect of resulting in a live birth.”

The Authority decided that the following interpretation of the law and guidance, regarding choosing an affected donor, should be included in guidance note 11, *Donor recruitment, Assessment and Screening*:

“Interpretation of mandatory requirements

A donor must not be selected because they are known to have a particular gene, chromosome or mitochondrial abnormality that, if inherited by any child born as a result of the donation, may result in that child having or developing:

- a) a serious physical or mental disability*
- b) a serious illness, or*
- c) any other serious medical condition.*

Guidance

11.11 The use of gametes from a donor known to have an abnormality as described above, should be subject to consideration of the welfare of any resulting child and should normally have approval from a clinical ethics committee.

11.12 If a centre determines that it is appropriate to provide treatment services for a woman using a donor known to have an abnormality as described above, it should document the reason for the use of that donor.”

Criteria used by clinics to decide the appropriateness of the offer of PGD

3.35 The HFEA Executive received advice in April 2008 from the Department of Health that there were subjective elements in the Code of Practice guidance about the offer of PGD that they felt needed to be removed, or replaced with more objective criteria. These were:

G12.3.3 a) the view of the people seeking treatment of the condition to be avoided, and

G.12.3.3 h) the family circumstances of the people seeking treatment.

3.36 The Ethics and Law Advisory Committee (then the Ethics and Law Advisory Group) considered this request at its meeting on 8 May 2008. ELAC agreed that the criteria in the Code of Practice were for use by clinics, on a case-by-case basis, and thus it was wholly appropriate that there be an element of subjectivity in their application. A member suggested at this point

however that the criteria could be made *less* subjective if the word ‘views’ were substituted for ‘experience.’

- 3.37** In response to the changes regarding embryo testing in the 2008 Act, the phrase *‘the seriousness of the condition should be a matter for discussion between the people seeking treatment and the clinical team’* was removed from the draft Code of Practice. This was because the legislation establishes that the Authority must be satisfied of the seriousness of the condition to be avoided, rather than the clinics.
- 3.38** These changes were consulted on at the PGD consultative event on 26 January 2008. People in all workshops where this question was asked felt that a move to greater emphasis in guidance on the *experience* of the patient and away from the patient’s *views* was not appropriate. Reasons for this included that if both couples are aware they have a recessive gene, they may have no experience of that condition. The word ‘view’ was broadly preferred by most people who expressed an opinion, though ‘understanding’ was suggested by one as a more appropriate alternative. Some people felt better information about the experience of a genetic condition be made available to patients making this decision to better inform their views.
- 3.39** In addition, some attendees at this consultative event said that thought it inappropriate to remove the fact that clinics would need to satisfy themselves of the seriousness of a particular condition:

“...these statements are a reflection of the Joint Working Party’s¹ work on this issue, work that has highlighted that, at least to a certain extent, that there are some deeply personal parental issues involved in the quest for PGD. In a similar vein I think the phrase ‘the view of those seeking treatment of the condition’ should be retained...” (A lawyer and academic)

- 3.40** On a separate issue, concerns were raised about the length of time it takes the Authority to process and decide on the PGD licence applications (particularly for tissue typing cases). The Chair and Chief Executive committed to reducing these delays.
- 3.41** In March 2009, following the receipt of advice from legal counsel that the Authority would indeed need to satisfy itself of the seriousness of a particular condition before a licence could be granted, the Authority agreed that, from October 1, the licensing of PGD would change. Following October 1, the Authority will need to be satisfied of the seriousness of a particular condition in general (in the absence of a specific case). Once this was established, clinicians would then apply the criteria in the Code of Practice to individual situations to decide whether or not PGD is appropriate. Thus a general decision is made at the level of the Authority, leaving clinicians, in

consultation with their patients, the freedom to make particular decisions based on the situation of those patients.

The Authority decided that the guidance should be reverted back to the guidance used in the 7th Code of Practice.

“10.4 When deciding if it is appropriate to provide PGD in particular cases, the centre should consider the circumstances of those seeking treatment rather than the particular heritable condition.

10.5 The use of PGD should be considered only where there is a significant risk of a serious genetic condition being present in the embryo. When deciding if it is appropriate to provide PGD in particular cases, the seriousness of the condition in that case should be discussed between the people seeking treatment and the clinical team. The perception of the level of risk for those seeking treatment will also be an important factor for the centre to consider.

10.6 The centre should consider the following factors when deciding if PGD is appropriate in particular cases:

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

Preimplantation genetic screening (PGS)

3.42 Guidance on PGS has been changed in light of a number of recent publications about the effectiveness of PGS. The proposed new guidance and licence conditions no longer require centres to restrict PGS to certain categories of patients. However, they require centres to:

- give PGS patients information about the experimental nature of this procedure
- monitor the latest literature and professional guidance on PGS

- validate the use of PGS for each category of patients/indication they offer it for.
- 3.43** The consultation questionnaire asked if this strikes the right balance between clinical freedom and uncertainties about whether PGS leads to better overall pregnancy rates.
- 3.44** About half of respondents did not express a view on this question. Of those that did express a view 31 answered 'yes' and 9 answered 'no'. Reasons given in support of the new guidance included that patients should be able to make informed choices about their treatment, that treatments should be evidenced based and that it is positive that the HFEA have allowed clinics to further explore the benefits of this technique. Of those that answered 'no' reasons given included that embryo testing should only be used for serious medical conditions, studies show that PGS does not increase live birth rates, that it is an expensive technique and cycle numbers will be too low for centres to build up a significant evidence base.
- 3.45** One respondent expressed the view that current reservations around PGS arise from widespread and indiscriminate use and limitations of current methods (fluorescence in situ hybridisation). A number of superior technologies are being developed including array comparative genome hybridisation and others which allow testing for all 24 chromosomes in polar bodies, blastomeres or trophectoderm cells biopsied from blastocysts.
- 3.46** Progress Educational Trust (PET) suggested that the reference to the British Fertility Society policy and practice guidelines on PGS should be removed from the guidance. Their reason was that it has already been superseded, and if any equivalent reference were to be added to the Code of Practice in its place, then these too would likely be superseded before long. They suggest that by removing this specific reference and refraining from adding another in its place, the HFEA would more clearly make it incumbent upon providers of fertility services to 'monitor the latest literature and professional guidance' in this area.
- 3.47** PET also suggest that the word 'experimental' in licence condition 13.9 (ii) should be replaced with the word 'unproven'. They believe that using the word 'experimental' to describe PGS is potentially misleading - it may result in the patient forming an impression that they are participating in a formal scientific experiment rather than undergoing treatment, and it fails to convey adequately the fact that the efficacy of this technique is unproven. They also believe that more distinction is needed in the guidance between currently used techniques and potential future techniques - for example stating that blastomere biopsy using FISH with embryos has been shown to be damaging/not effective at increasing live birth rates.

3.48 A couple of responses to the PGS question in the Code consultation have suggested that the following line in the PGS/multiple birth guidance should be removed, as it is not certain that PGS increases live birth rates and any theoretical increase in multiple births will be dealt with by the multiple birth strategy:

"9.2 If a woman is to receive treatment using her own eggs or embryos that have been screened for aneuploidy, the centre should not transfer more than two embryos in any treatment cycle, regardless of her age at the time of transfer."

The Authority decided that the guidance should not specify the categories of patients which PGS can be offered to. It should be up to centres to validate the use of PGS. The following licence conditions have been included in guidance note 9,

"With respect to any preimplantation genetic screening (PGS) programme the centre must ensure that: ...

c. before the people seeking treatment give consent to preimplantation screening of embryos for aneuploidy they must be given an oral explanation supported by relevant written material:

...

ii. of the unproven nature of the procedure, in particular that more robust clinical and laboratory trials are needed to assess whether or not PGS can significantly increase live birth rates for different specific indicators and it is likely that the method of fluorescent in situ hybridisation (FISH) on embryos, using a limited number of chromosomes, is not effective at increasing live birth rates

d. they monitor the latest literature and professional guidance in order to validate the use of PGS for each category of patients to which they offer it. Validation should also be based on data from previously published studies and retrospective evaluation of their own data."

The Authority decided to remove the restriction on the number of embryos which can be transferred following aneuploidy screening, as this will be addressed by centres' multiple birth strategies.

Information about the donor for patients undergoing donor conception treatment

3.49 As well as basic information, such as ethnic origin and eye colour, donors are given the option of providing a more detailed description of themselves

(pen portrait) and a goodwill message for children born as a result of their donation. Views were sought on how much of this information should be shared with patients undergoing donor conception treatment when they select the donor.

- 3.50** Mixed views were expressed on this issue. About half of respondents to the questionnaire felt that patients seeking treatment with donor gametes should be able to access all non-identifying information including the goodwill message. Of these, 46 percent were fertility patients (past or present) and 19 percent were fertility counsellors. A third of respondents thought that patients should be entitled to basic information plus the pen portrait; of these, 24 percent were fertility nurses, 18 percent were fertility doctors and 18 percent were embryologists. 22 percent of respondents said that only basic information should be available.
- 3.51** Of those who felt that patients should have access to all non-identifying information, the prevailing view was that patients are entitled to as much information as possible when choosing a donor. It was felt that there should be no surprises about the donor after conception has taken place. There was a strong view that sharing donor information with patients encourages openness in informing children of their donor-conceived origins from the offset. Many respondents emphasised the importance of ensuring donors understand how their information will be shared.

“As long as the donor is aware that the recipient parents are going to read the pen portrait or goodwill message. Up to now the pen portrait has been written to the children born so it changes it psychologically if it is available to the prospective parents. If I had a donor conceived child I would want to know what the donor had written about themselves and I would feel it was my responsibility to check it out, before my child has access to it.” (A fertility counsellor)

“The BMA believes that the maximum amount of information should be available both to those choosing a donor and to the parents of children conceived by donor conception. Care should be taken, however, not to reveal anything that might inadvertently identify the donor. It should also not include information that might allow parents to compare information in an attempt to informally identify genetic half-siblings, so donor numbers should not be provided for example.” (BMA)

“BICA welcomes the emphasis being placed on ‘telling the child’ and the impetus it gives licensed treatment centres to support patients in this.” (BICA)

3.52 Of those who felt that basic information plus the pen portrait should be shared, it was felt that parents needed this information to assist them in choosing a donor, but did not need the goodwill message, which was personal to the child. It was also felt that too much information would be unhelpful in facilitating decision-making and that to reveal more information before pregnancy may discourage donors from providing information.

“It does not seem appropriate to give all information to patients when choosing a donor. In fact in our clinic the goodwill message is not always available at the time of donor selection. However giving the pen-portrait would help recipients to understand the process they are undertaking. We feel that patients would find it reassuring to know something of the character of the donor and this information will help their thinking processes later if treatment is successful. Therefore it may make it more likely that the patients would tell their child/children about donor conception.” (Licensed clinic)

“The additional information is too personal to read when you are choosing a donor and would make the decision harder to choose one. I think that information should become accessible to the parents of a donor conceived child after the child is born to assist with educating the child regarding his/her conception.” (A patient)

“We feel that this strikes a good balance for the patients choosing the donor and the donor themselves.” (ACE)

3.53 Of those who felt that only basic information should be available to patients, concern was raised that divulging more information may discourage donors from being candid and open in the information they provide. Some felt that providing more information would be inappropriate.

“To make other information more widely available would be likely to have an inhibiting impact on donors; if they knew it would be more available to a wider audience.” (Centre for Law, Gender and Sexuality)

“At this stage we feel that this is all that prospective parents need to know.” (Anonymous)

3.54 Common to many of the responses was an emphasis on the importance of being clear with donors about how their information will be used and to whom it will be disclosed. During its discussion of the Opening the Register policy in January 2009, the Authority decided to amend the donor

information forms, to include a signed declaration of understanding from the donor of how the information provided will be used.

- 3.55** Mixed views were expressed on this topic at the three workshops. About half of the participants felt that people choosing a donor should only be given very basic information (and that the HFEA should be very clear and prescriptive about what this information should be). They thought people should only be able to access all of the non-identifying information (including pen portrait and goodwill message) once they conceive. It was argued that this would avoid 'shopping' for the donor with the best information and potentially discriminatory practices.
- 3.56** The other half of workshop participants thought that both people choosing a donor and parents of donor conceived children should be given all the non-identifying information about donors whenever they request it. They argued that there were no convincing reasons for withholding such information and that being open about all the information was in the best interest of patients and children, plus was the best way to avoid inconsistent practice between centres.
- 3.57** In summary, views on the amount of donor information that patients seeking treatment with donor gametes and embryos should be able to access at the time of treatment were finely balanced. No clear consensus emerged from the consultation feedback, although it is clear that the majority of respondents are in favour of providing more than basic donor information to patients. It is also clear that a key concern of respondents is transparency and communication with donors as to how their information will be used. Given that the Authority has committed to the latter, this may mitigate some of the concerns around providing personal donor information to patients at the time of treatment.
- 3.58** At the route of the different views as to how much donor information patients are entitled to at the time of treatment, seems to be a tension between respect for donors and the needs of patients. On the one hand there is a concern that the information donors provide in the goodwill message is too personal to be accessed by patients before treatment as has taken place – the message is intended for any resultant children. There is also some concern that sharing this information with parents may deter donors from providing it in the first place. Conversely, the majority view of both patients and counsellors is that patients seeking treatment with donor gametes should have all available information on the donor; this is both because of the gravity of the decision being taken and the fact that it encourages openness with donor-conceived children at an early stage.

Information about the donor for parents of donor conceived children

- 3.59** As well as basic information, such as ethnic origin and eye colour, donors are given the option of providing a more detailed description of themselves (pen portrait) and a goodwill message for children born as a result of their donation. Views were sought on how much of this information should be shared with parents of donor-conceived children.
- 3.60** A majority view was expressed that parents of donor conceived children should be able to access all of the non-identifying information, including the goodwill message (44 out of 55 people that gave a view). 9 respondents thought that parents should be entitled to basic information plus the pen portrait. 2 respondents said that only basic information should be available.
- 3.61** Of those who felt all non-identifying information should be made available to patients, the most salient view was that there is a potential benefit to donor-conceived people in doing so. It was felt that this information is best assimilated as children are growing up, with the help of their parents. It was also felt that access to such information would encourage parents to be open with children.

“This information can then be given to offspring by the parents so that children have information about their origins as they are growing up. May help to influence people towards being more open with their children.”
(Licensed clinic)

“This would then allow the parent the time to consider the best way to share this information. For instance our child has a book clearly telling him how he was created, it would be nice to have all information, rather than the rough notes I made in the car on my mobile, when I was confirmed pregnant and the pen portrait was read out to me. This information could be significantly important and I want to be ready to support my child if and when this information is shared.” (A fertility patient)

“We favour the goodwill message being made available to parents of donor conceived children if they choose to have it. Donors should be encouraged to think about the possible ages at which they intend their message to be received. Parents should then use their discretion in how to use the message in conveying information to their children about the donor.” (Donor Conception Network)

3.62 Several respondents also emphasised the importance of continuing to provide donor codes to parents to enable them to trace their children's donor-conceived genetic siblings. However, one organisation emphasised that no information should be disclosed to parents which would facilitate sibling tracing.

3.63 Of those who stated that only basic information plus the pen-portrait should be given to parents, it was felt that the donor-conceived person should retain the choice over if and when the goodwill message is accessed.

"I think it's fair enough that after conception the child is given some info about the donor, if that's what the parents want. The personal message to the child should stay personal. Again what counts is clarity. The donor needs to know before filling the forms in." (A potential sperm donor)

"The basic information should be available as it would enable social parents to answer questions, but would reserve some information which the child could choose to access himself or herself at a later stage." (Centre for Law, Gender and Sexuality)

3.64 The majority of workshop participants felt that all non-identifying information should be made available to parents of donor conceived children (reasoning as above). There was consensus that guidance for donors should be improved to ensure it is clear how their information will be used.

The Authority decided that all information about donors (basic characteristics, pen portrait and goodwill message) should be available to people at all stages from the point of choosing a donor. This is subject to clear information being given to donors about how their details will be used.

The Authority felt that it is important for patients to know as much information as possible about a donor in order to make a suitable choice and to prepare for informing their children. The Authority will review this policy if evidence emerges that it deters donors from providing detailed goodwill messages.

Therefore, the following guidance has been included in guidance note 20, *Donor Assisted Conception*:

“The centre should give anyone seeking treatment with donated gametes or embryos:

(a) relevant non-identifying information about donors whose gametes are available to them, This includes any goodwill message and pen-portrait (if available).”

And

“The centre should inform people seeking treatment with donated gametes or embryos that, once they give birth to a child as a result of that donation, they will be entitled to access all non-identifying information about the donor. It is recommended that this information is shared with the child born as a result of donation. If the centre is unable to provide this information, the centre should direct parents to the HFEA.”

4 Consent forms

- 4.1** Feedback about the consent forms from the patient and donor focus group and trials with patients at clinics was generally positive. Accompanying guidance was found to be very helpful and that the signposting on the forms made navigation easier. It was suggested that an overarching short guidance document, including a glossary, be produced to accompany all forms. During trialling of the consent forms at clinics, patients expressed a preference for consent to specific research projects involving their embryos and gametes rather than giving generic consent as previously offered on HFEA forms.
- 4.2** Responses to the online consultation were also positive. The following questions were asked:
- Given the legally complex issue of consent and the various scenarios that can arise, are the new consent forms easy to understand and use?
 - Do you think that the form (CD) reflects the right balance between information sharing for better patient care and the patient's right to privacy?
- 4.3** Most of the respondents who expressed a view stated that despite the legally complex issue of consent and the various scenarios that can arise, the new consent forms were easy to understand and use (23/30). About two-thirds believed that the Consent to Disclosure form reflected the right balance between information sharing for better patient care and the patient's right to privacy (20/31). Comments from the other third included that there was too much of an emphasis on patient confidentiality in the Act and that this may hinder the administration of clinics.
- 4.4** People obtaining consent (clinic staff) suggested that the HFEA consider how, if possible, the forms could be made shorter and more specific. They were concerned that the increased length of the forms and the colour design would increase the costs for clinics. Some clinic staff suggested that the HFEA should produce back and white versions of the forms with less shading. It was also suggested that the forms be more tailored to specific treatments, so that clinic staff obtaining consent would not have to spend time explaining options irrelevant to the majority of patients.

Consent to the use of gametes and embryos for research and training purposes

- 4.5** The set of draft consent forms contained a form for consent to the use of gametes and embryos in research and training. Those in the research sector who responded to the consultation considered the generic consent to research in the form to be insufficient to meet ethic committees' standards of informed consent. Centres currently use project-specific, ethics committee approved consent forms when obtaining consent to the use of gametes and embryos in research.
- 4.6** Some respondents suggested that the HFEA consent forms ask whether the patient or donor would be willing to be approached about using their gametes or embryos in research projects. Researchers could use this indication to identify possible research candidates and then obtain consent using research project specific forms
- 4.7** Centre staff responding to the consultation also commented that having consent to the use of gametes or embryos for training purposes in the research and training form, separate from the main treatment forms, would make patients and donors less likely to consider this option.

The Authority decided that questions about research and training should be incorporated into the treatment, donation, storage and surrogacy forms (MD, MT, MGI, WD, WT, WGI, MSG, WSG and GS). The proposed research and training consent form was therefore no longer needed.

Consent to donating gametes and embryos for the treatment of others

- 4.8** At the Authority meeting in September 2008 members suggested investigating the possibility of creating a separate form to cover the donation of embryos for the treatment of others. This was intended for couples who have embryos in storage which were created for their own treatment.

The Authority decided that references to donation of existing embryos should be transferred from the proposed HFEA donation forms (WD and MD) to a new embryo donation form (ED).

Consent to storage of gametes and embryos

- 4.9** The HFEA consent forms for the storage of gametes and embryos have been updated in accordance with the HFE (Statutory Storage Period for Embryos and Gametes) Regulations 2009.
- 4.10** Comments from clinicians indicated that the average IVF treatment pathway does not involve storage of sperm or eggs. Therefore, questions regarding storage of gametes should be removed from the main treatment consent forms (MT and WT) and moved to the specific gamete storage consent form (GS).

The Authority decided that questions regarding consent to the storage of gametes should be removed from the main treatment forms (MT and WT). Following feedback from the sector during the HFEA consultation, people giving consent using the gamete (GS) and embryo (ES) storage forms are now asked to specify their sex to make sure the forms are easier for centres to use.

The new HFEA forms have been adjusted in line with the HFE (Statutory Storage Period for Embryos and Gametes) Regulations 2009.

Consent to the use of gametes with or without the creation of embryos *in vitro*

- 4.11** Staff at centres suggested that consent to the use of gametes without the creation of embryos *in vitro* (ie, for intrauterine insemination (IUI)/gamete intra-fallopian transfer (GIFT) and with the creation of embryos *in vitro* (ie, *in vitro* fertilisation) should be sought on separate forms.

The Authority decided that new consent forms for the use of gametes in treatment, without the creation of an embryo *in vitro*, should be created (MGI and WGI).

Consent to disclosure of identifying information

- 4.12** The online consultation questionnaire asked whether the consent to disclosure of identifying information form reflects the right balance between information sharing for better patient care and the patient's right to privacy.

- 4.13** During the consultation it was recommended that the form for these disclosures should include a better explanation of to whom and for what purposes people can consent to identifying information being disclosed.
- 4.14** Further consultation was carried out with regards to consent to the disclosure of identifying information to researchers. This involved consulting our Opening the Register Expert Group; National Information Governance Board for Health and Social Care; the Medical Research Council; the Wellcome Trust and various researchers. It was decided that consent should only be sought for disclosing data held on the HFEA register, about patients and their partners. It will not cover consent to disclosure of any additional data held by clinics (such as data held on patient health records). It was also decided that the form should allow for people either to give generic or specific consent for disclosure of the individual's own data for non-contact and contact research.

Changes have been made to the form to ensure it is clear that, following consent, whose information will be disclosed to whom and why. References to donor information have been removed from the forms following legal advice.

Signing at the direction of someone who is unable to do so due to physical illness, injury or disability

- 4.15** Under the HFE Act 1990 (as amended), it is possible for someone to sign at the direction of the person giving consent if it is witnessed and the person giving consent is unable to do so due to physical illness, injury or disability. Responses to the consultation suggested that the witness's name and the representative's name and relationship to the person consenting should be stated as a measure to avoid misuse of the ability for someone to sign on at the direction of the person giving consent.

On all forms where it is possible for someone to sign at the direction of the person giving consent (who is unable to do so due to physical illness, injury or disability), the witness's name and the representative's name and relationship to person consenting must be stated.

Restricting consent

- 4.16** The draft consent forms ask whether the patient or donor wishes to place any restrictions on their consent. This open question confused patients, donors and people obtaining consent (when the forms were trialled at the

focus group and two centres): they found it unclear as to what possible restrictions could be stated. At the same time, feedback from patients, donors and clinic staff was that to give an example on the form would encourage people consenting to place that particular restriction on the use of their gametes or embryos.

The Authority decided that questions about restricting consent should only be included in the donation and surrogacy forms and that the example of a known recipient should be used. This, the Authority felt, was a relatively common restriction and its inclusion would help those completing the form.

The Authority agreed that on other forms, where there was not an obvious, common example restriction, the questions should be removed. The consent guidance document should make patients, donors and centre staff aware that consent can be restricted in notes attached to the relevant consent form and gives an example.

Format of the consent forms

4.17 During the consultation, centre staff that regularly obtain consent recommended that where possible the forms should be made more specific and tailored to individual treatment pathways so that obtaining consent would be quicker, the forms were shorter and printing costs reduced.

4.18 In terms of usability, the consultation responses, especially from patients and donors, suggested that the new consent forms were a significant improvement on the current forms. Both the layout and guidance within the new forms were seen as very helpful changes.

The format of the consent forms has been redesigned to reduce form length. The consent forms have also been made more specific and some sections removed or amalgamated, eg, consent to IUI/GIFT on separate forms to IVF.

Accompanying guidance

4.19 Members, at the Authority meeting in September 2008, recommended that the HFEA produce accompanying guidance to the consent forms. This was also suggested by a number of patients, donors and clinicians during the consultation. Suggested content included a glossary of terms and

information on the following: why consent is needed, examples of research and training, storage, counselling, withdrawal of consent, consent restriction and death/mental incapacity. It was also suggested that the HFEA provide direction to further sources of information on donation and that any guidance document should be provided in multiple languages.

The Authority approved a guidance document outlining why consent is required and including a list of HFEA consent forms, an introduction to donation (treatment, research and training), death and mental incapacity, withdrawal, consent restriction and counselling and links to further information.

Publication and implementation of the forms and guidance will be a priority until October 2009. After October 2009, and pending Authority approval, the guidance document will be produced in different languages eg, Welsh.

5 Impact assessment

- 5.1** The consultation questionnaire asked for views on the impact of the new structure of the Code, and proposed new guidance, in terms of the administrative burden on clinics.
- 5.2** A summary of the estimated costs and benefits associated with the new guidance (plus revised consent forms) was provided alongside the questionnaire. For example, it was estimated that the restructuring of the Code is expected to reduce the time spent by clinic employees looking up guidance and using external legal advisors to interpret the Code. Based on feedback from a reference group of centres, we estimated that this positive impact will amount to a saving of around £410,000 per year for the whole sector. We acknowledged that the cost impact in the first year is likely to be greater as centre staff familiarise themselves with the new guidance.
- 5.3** The majority of people who expressed a view agreed with the potential benefits and costs associated with the structure of the Code (27/31). Reasons given included that the layout of the Code is easier and quicker to follow and it is more user friendly. However, one clinician felt that the Code does not provide clinics with easy "off the shelf" guidance for common scenarios, or simple audit checklists so that clinics can check their compliance with new requirements.
- 5.4** The majority of people who expressed a view agreed with the potential benefits and costs associated with the new guidance (21/27). Reasons given included that the equalities benefits will compensate for any increased administrative burden. However, one clinician felt that:

“The administrative burden will be much higher than estimated. Because the guidance is not easy to follow through, it means that all changes need to be seen through by the most highly qualified staff with large team meetings to ensure the changes are made and understood.”

- 5.5** In relation to the proposed guidance regarding costed treatment plans, a nurse stated that:

“The costed treatment plans will cost patients more - if the Centre aims for a one price fits all to decrease the amount of explanation, paper work, consents and charges for credit card payments, those that require less procedures/time spent during the cycle.”

- 5.6** The new guidance must not unlawfully discriminate on the basis of age, disability, ethnicity or race, sexual orientation, religion or gender, or infringe upon the human rights of any group. The consultation questionnaire asked whether the proposed guidance changes would have a disproportionate effect on any groups. About two thirds of people who expressed a view (19/28) felt that they would not have a disproportionate effect on any group of people. Reasons given included that some of the changes reverse discrimination to lesbian couples:

“The changes reverse discrimination on grounds of sexual orientation which was inherent in the original Act’s assumption of the heterosexual model. It is a great improvement from this point of view. The emphasis on supportive parenting is consistent with this and the role of the second parent is consolidated and advanced by the parenthood conditions and consent forms. The reality of the profile of families being treated at clinics had been out of line with the Act for some years, and these changes support clinics in enabling us to treat lesbian families on an equal basis.” (A fertility counsellor)

- 5.7** Of those who felt the proposed guidance changes would have a disproportionate effect, a nurse highlighted that consideration needs to be given to the fact that patients attending a centre for treatment may be offended by gamete donation, surrogacy and research programmes carried out at the centre. A patient expressed concerns that those who currently have embryos in storage would not benefit from the changes in legislation regarding embryos storage periods. However, this is outside the scope of guidance in the Code of Practice.