

Human Fertilisation and Embryology Authority

Tomorrow's children

A consultation on guidance to licensed fertility clinics
on taking in account the welfare of children to be born
of assisted conception treatment

Chair's foreword

Everyone agrees that the goal of assisted reproduction is to bring about the birth of healthy children. Physical health is easy to measure. But how do we ensure that children born of assisted reproduction are psychologically healthy too? The Human Fertilisation and Embryology Act gives us a steer on this issue, by requiring that treatment services be provided only after the welfare of any child born as a result of treatment has been taken into account. It is the Human Fertilisation and Embryology Authority's job to provide guidance to clinics on how to interpret this requirement. However, the welfare of the child guidance, which is contained in the HFEA's Code of Practice, was drafted more than a decade ago and has not been properly reviewed since. The time to revise this guidance is now long overdue.

In revising our guidance to clinics on how to take into account the welfare of the child, we face a number of challenges. The HFEA must produce guidance which is clear, practical and proportionate and which adequately balances the interests of prospective parents with the needs of the children that we all hope will be born. We must stay faithful to the spirit of the legislation and try to reflect Parliament's intention, whilst providing guidance which is appropriate for today. Ultimately, we need a new steer from Parliament. The Department of Health is carrying out a review of the Human Fertilisation and Embryology Act later this year and a new bill will eventually be put before Parliament. However, a new Act is unlikely to appear on the statute book until 2008.

Last summer, the HFEA launched the Welfare of the Child Review, a piece of work designed to develop new guidance for licensed fertility clinics on how to interpret the statutory requirement to take into account the welfare of any child who might be born as a result of treatment. This consultation document – and the consultative workshops that we have planned – is designed to gather the views of professionals working in clinics (doctors, nurses, embryologists and counsellors), patients and other stakeholders who have experience of child welfare issues or who have suggestions on how we might improve the guidance we provide. Please let us know your views on this important issue.



Suzi Leather
Chair, Human Fertilisation and Embryology Authority

January 2005

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Executive summary

The provision of assisted conception treatment in the United Kingdom is regulated by the Human Fertilisation and Embryology Act 1990. The Act states that, before treatment is offered to a patient, account must be taken of the welfare of any child who may be born as a result of the treatment provided. The Act also requires that the Human Fertilisation and Embryology Authority (HFEA) give, in its Code of Practice, guidance to licensed clinics about the account to be taken of the welfare such children.

The guidance contained within the current HFEA Code of Practice lays out, amongst other things, the factors that clinics are expected to take into account when carrying out a welfare of the child assessment and the steps that clinics are expected to take in order to gather information about the patient(s) relevant to welfare of the child considerations. It also gives guidance on the additional needs of particular groups of patients, such as those having donor conception treatment.

The HFEA is reviewing this section of the Code of Practice, with a view to publishing revised guidance in summer 2005. This consultation document, and the other aspects of the welfare of the child review, is designed to gather the views of clinic staff, patients and other stakeholders on the following policy options:

- Enquiries to be made: should clinics rely upon information gathered from the patients in order to take into account the welfare of the child, or should they approach other parties, such as a general practitioner or social services?
- Factors to be taken into account: when discussing welfare of the child issues with patients, should clinics take into account purely medical or physical risks to the child to be born, or should they consider a broader range of psychological and social factors which could impact upon the welfare of the child?
- Particular groups of patients: should the welfare of the child be carried out in a different way when considering offering treatments such as unlicensed treatment or treatment using donated gametes?

A questionnaire is included in Section 5, asking respondents to opt for a particular policy option and to give reasons for doing so. There is also an opportunity for respondents to provide feedback on the current guidance on welfare of the child, as well as give their views on the welfare of the child principle and its interpretation in clinical practice.

An online version of the questionnaire is available at: <http://www.hfea.gov.uk/AboutHFEA/Consultations>

1. Introduction

The provision of assisted conception treatment in the United Kingdom is regulated by the Human Fertilisation and Embryology Act 1990. The Act does not lay down eligibility criteria for access to treatment, but it does require those providing treatment to consider the child or children who might be born as a result of assisted conception treatment. The section of the Act which describes this requirement, often referred to as the 'welfare section', says:

A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of treatment (including the need of that child for a father), and of any other child who may be affected by the birth¹.

There is no detail in the legislation describing how the welfare section should be interpreted. Instead, the Act requires that the Human Fertilisation and Embryology Authority (HFEA) give guidance in a code of practice to those providing treatment services on how the welfare of the child should be taken into account². The Authority's Code of Practice, currently in its 6th edition, was first published in August 1991. The welfare of the child guidance in the current Code of Practice is reproduced at Appendix 2.

1.1 Purpose of this consultation

Since 1991, when the first Code of Practice was published, staff in licensed fertility clinics have acquired more than ten years' experience of carrying out welfare of the child assessments. The purpose of this consultation is to capture that experience and to gather views both on the limitations of the current guidance and on how it could be improved in the future.

It is not within the powers of the HFEA to amend the welfare section in the Human Fertilisation and Embryology Act. Therefore, whilst we welcome views on the welfare principle itself, the primary purpose of this consultation is not to solicit suggestions on how the Act might be amended. The Department of Health is carrying out its own review of the Act and will be conducting a public consultation during 2005. It is expected that the Department's review will include consideration of the welfare provision in the Act. However, the Department has made clear that changes to the Act are unlikely to happen before 2008 at the earliest.

This consultation is designed to gather views on how the Authority's guidance contained within the Code of Practice could be updated. A questionnaire is included at Section 5 of this document. However, respondents are encouraged to complete the questionnaire online at the HFEA's website. Details of how to respond can be found on page 14.

¹ Human Fertilisation and Embryology Act 1990, section 13(5)

² Human Fertilisation and Embryology Act 1990, section 25(2)

1.2 The welfare of the child review

The HFEA launched its welfare of the child review in April 2004. Since then, preparatory and background work has been carried out in order to inform the development of the policy options discussed in this consultation document. This work has comprised:

- a review of the relevant psychosocial literature;
- a comparative study of legislation in other countries;
- a review of the ethical, social and legal literature;
- a review of other areas of UK law relating to children;
- a small survey of clinics and patients; and
- a review of HFEA inspection reports.

This consultation document will remain open for responses until 7 April 2005. It will not, however, be the sole method of consultation used during the HFEA's review of the welfare of the child guidance. In early 2005, a series of consultative workshops will be held in different locations around the United Kingdom, aiming to create the opportunity for dialogue between the HFEA and different stakeholder groups. Those stakeholders include professional societies; individual professionals working in clinics or laboratories; patients and patient representatives; general practitioners; relevant academics and interest groups. A number of in-depth interviews with individual practitioners will also be conducted. The Welfare of the Child Review will culminate in the publication of revised guidance to clinics in summer 2005.

2 Interpreting the welfare of the child section

Many of those working in reproductive medicine, as well as commentators and stakeholders outside the sector, agree that we should have some regard for the welfare of children who might be born as a result of assisted conception treatment. But how should a general principle on the desirability of thinking about the welfare of assisted conception children be applied in the clinic? In short, how should the welfare of the child be taken into account?

The purpose of this section is to consider some of the ways in which the welfare of the child principle in the Human Fertilisation and Embryology (HFE) Act can be interpreted, in order to inform our thinking about how the welfare of the child assessment should be carried out in the clinic.

2.1 Parliament's intention

The route by which the welfare of the child section came to be included in the Human Fertilisation and Embryology Act may provide some clues as to Parliament's thinking at the time. The Government's first step towards regulating assisted conception was to set up the Committee of Inquiry into Human Fertilisation and Embryology, commonly known as the Warnock Committee, which, in July 1984, made a number of legislative recommendations on human embryo research and assisted conception treatments. During its deliberations, the committee considered the issue of access to infertility treatment and concluded that services should not be restricted to married couples. However, the committee was divided about allowing access to single women or lesbian couples and was only able to agree that 'where consultants decline to provide treatment they should always give the patient a full explanation of the reasons.'³

The vast majority of the recommendations which emerged from the Warnock Committee found their way into a 1987 white paper on human fertilisation and embryology and the subsequent Human Fertilisation and Embryology Bill, published in 1989. However, despite the Warnock Committee's deliberations on the welfare of children born of assisted conception, there was no mention of welfare in the White Paper or in the Bill.

The welfare issue in relation to single women re-emerged during the committee stages of the Bill in the House of Lords when various amendments were tabled. One amendment, which sought to make unlawful the transfer of an embryo to the womb of an unmarried woman, fell by just one vote. Following the debate on this amendment, a number of other amendments were discussed in both Houses of Parliament on the welfare of the child issue. The views of parliamentarians on the issue were very mixed, with some insisting that only married couples should gain access and others arguing that any kind of social screening of prospective parents was inappropriate. Despite this wide range of views, the majority of parliamentarians were able to agree on what is generally regarded as a compromise position: that a concern for the welfare of the child to be born as a result of the treatment should be one, but not the paramount, consideration to be taken into account before treatment is offered.

Parliament finally agreed that a child's welfare should be taken into account before treatment is offered. But what does it mean to 'take into account'? The idea of the child's welfare as the paramount consideration was rejected by MPs and Peers during the passage of the HFE Bill through Parliament. This welfare as paramount approach comes from the Adoption and Children Act 2002, in which the welfare of the child is considered to be the 'paramount consideration of

³ Report of the Committee of Inquiry into Human Fertilisation and Embryology 1984 HMSO Cmnd. 9314, recommendation 24

the court or adoption agency⁴ when making decisions about the care of a child. Describing welfare as paramount means that all other considerations are of secondary importance to the best interests of the child concerned.

2.2 The status of assisted conception children

One explanation for the preference for the 'taking into account' approach in the HFE Bill might be the differences between the status of the potential child in assisted conception on the one hand and its status in areas of practice relating to actual children on the other. When a local authority considers whether or not to remove a child from its family and take it into care, the authority must take into account several factors including the wishes of the parents and the child and decide where the best interests of a living child lie. In order to inform this decision, the authority must assess the level of harm that the child is likely to face if it stays in the family home, based upon current family circumstances. In assisted conception, by contrast, the treating clinician must balance the wishes of the prospective parents against the interests of a child who does not yet exist. The clinician must assess the harm that the child is likely to face if it is born to those patients, based upon what the family circumstances might be once the family is created.

How do assisted conception children compare with their naturally-conceived counterparts? When children are conceived naturally, the parents of the child usually make a private decision between themselves to proceed (unless the pregnancy is unplanned). No child exists prior to the decision to have it and no other parties or agencies are involved in the decision. Parents seeking to adopt a child also make a private decision to proceed, but the decision about whether their desire to become adoptive parents will be realised is made by an adoption agency. In this situation, the agencies involved must make a judgement about the suitability of the prospective adopters to parent an adopted child.

How should assisted conception children be regarded in the light of these examples? For couples needing assisted conception treatment, the initial decision to have a child is also a private one. But, as with adoptive parents, the realisation of the desire to have a child is achieved with the involvement of third parties: in this case, the medical and laboratory staff in an assisted conception clinic. Using their combined expertise, this team must assess an individual's or couple's medical suitability for treatment: how likely they are to succeed and whether the woman is healthy enough to carry a pregnancy. But besides having a duty of care towards their patient(s), do the clinic staff have a responsibility to the child they are helping to create? Most would agree that they have a responsibility to protect a child from any significant medical risks associated with a particular procedure. But do they also have a responsibility to protect the child from any physical, psychological or social harm which might befall them after they are born?

2.3 Possible harms to children born of assisted conception

Whatever level of risk to the prospective child we are prepared to tolerate, it is important to have a clear understanding of the harms that children born of assisted conception might face. Those harms are medical, physical, psychological or social.

Medical harms

Some children face the risk of being born with a genetic or an infectious disease. If a couple know that they are carriers of a serious genetic condition, or one of them is affected by one,

⁴ Adoption and Children Act 2002, section 1(2)

they will know before a child is conceived that it has either a 50% or a 25% chance of inheriting that condition. The chance that an infectious disease such as HIV is transmitted to a child depends upon a number of factors, such as which parent is affected and whether steps are taken to limit the chance of transmission, either through sperm washing (if the male partner is affected) or through obstetric management (when the female partner is affected).

Physical harms

A child could be at risk of physical harm from their parents if either parent has a history of child abuse or neglect. They may have been convicted of a child-related offence or they may have had a child or children taken into the care of a local authority. A child may also be at risk of physical harm from a drug or alcohol addicted parent, either during pregnancy or once the child is born.

Psychological harms

The psychological harms that a child might face are of two main types. The first type of psychological harms are those which might be associated with growing up in a particular family structure. Such structures include single parent families, those with same sex parents, those with older parents, those in which one or both parents are not genetically related to their children or those created through surrogacy arrangements.

There is growing body of research on the psychological welfare of children born to a number of different types of assisted conception families. This research is beginning to show that many early concerns about psychological harm to children were unfounded. Instead, studies suggest that where there are problems, they relate to factors such as poor family relationships or low household income, rather than to the structure of the family. What seems to count is the quality of family life.

One important area of research is on the psychological welfare of children born to lesbian mother families. Studies conducted over the past decade suggest that, despite initial concerns, children born to lesbian couples compare well with other assisted conception children in terms of emotional, behavioural and gender development. There is less information about other types of assisted conception families such as solo mother families, surrogacy families and those in which the child was born to a postmenopausal mothers. More research is needed in these areas.

Another important area of psychological research is into the welfare of children created through donated eggs, sperm or embryos. A number of studies on donor conception families in different countries have been carried out over the past decade or more. These studies show that the psychological wellbeing of children who are not genetically related to one or both of their parents compares well with that of their naturally-conceived counterparts. However, despite the growing tendency towards openness, the majority of parents in these studies have not told their children about their donor origins. Qualitative studies of smaller groups of donor-conceived people who are aware of their donor origins are beginning to emerge. Initial findings suggest that family secrets about donor conception which are revealed later in life, perhaps in an unplanned way, can be damaging for offspring. Donor-conceived people who have known about their origins from an early age, and whose parents are able to discuss the issue in an open and honest way, tend to fare well psychologically.

The second type of psychological harms are those which are caused by the circumstances of a particular family, regardless of the family form. Such circumstances might include families in which a parent has a drug or alcohol problem or mental health problems, or families in which violence or verbal abuse is taking place. Such circumstances can have serious psychological implications for the children.

Social harms

A child could be considered to be at risk of social harms when the care they receive from their parents is compromised. This might be because the parents are older, their health is impaired or the parents' relationship is unstable. Where there will be no legal father, a social harm could also be a lack of contact with male adult role models.

2.4 Different approaches to taking into account the child's welfare

There is a wealth of philosophical, legal and social literature on our responsibilities to future generations in general and on the welfare of the child in assisted conception in particular. Limited space does not permit a full exploration of the views expressed in the literature. However, for the sake of brevity, we have identified three main approaches which capture most of the opinions on this issue. They can be summarised as the maximum welfare principle, the reasonable welfare principle and the minimum threshold principle.

Maximum welfare principle

This approach to considering a future child's welfare is based upon the idea that one should not knowingly and intentionally bring a child into the world in less than ideal circumstances. The maximum welfare principle places a significant responsibility on those who assist in the creation of children to ensure that any child born has a good chance of a living a happy and fulfilled life and is not disadvantaged in any foreseeable way. This approach considers a child's welfare to be of paramount importance and, borrowing from the approach taken in adoption, places the burden of proof upon the prospective parents to demonstrate their competence.

Reasonable welfare principle

The reasonable welfare approach says that the provision of assisted conception treatment is acceptable when the child born as a result of the treatment will have a reasonably happy life. This approach requires those providing assisted conception services to satisfy themselves that any child born of treatment that they provide will have at least an adequate future, cared for by a 'good enough' family. The reasonable welfare principle takes a relatively thorough approach to the welfare of the child, whilst also attaching some importance to the autonomy of the prospective parents. Although it is difficult to determine exactly what this approach might mean in practice, it would require clinicians to consider a patient's or couple's social circumstances, but would only prevent treatment from going ahead if those circumstances meant that the couple were unable to provide a satisfactory level of parenting.

Minimum threshold principle

In the minimum threshold approach to considering a future child's welfare, the emphasis is upon protecting the child from serious harm. Doctors should withhold treatment, thereby preventing a child from coming into existence, only where the quality of the child's life would fall below a minimum threshold of acceptability. This approach places great importance upon the autonomy of the prospective parents and seeks to override their wishes only when their child would be at high risk of serious harm.

In this section, we have attempted to explore the different possible ways of interpreting the welfare of the child requirement under the Human Fertilisation and Embryology Act 1990. Whilst we recognise that the approaches outlined above may not correspond to the views of all respondents, their inclusion is offered as a framework within which the more concrete task of taking the welfare of the child into account in the clinic can be carried out in a manner which is ethically consistent and well-reasoned.

3 Options for revising the welfare of the child guidance

In Section 2, we laid out a number of different ways of interpreting the welfare of the child requirement in the Human Fertilisation and Embryology Act. In this section, we consider how those interpretations might be applied in the clinic. Below are a range of options for revising the guidance in the HFEA's Code of Practice, separated into three main areas:

- the enquiries that clinics are expected to make to the patients themselves and to other agencies in order to gather relevant information;
- the factors that are expected to be considered when taking into account the welfare of the child; and
- the specific requirements of those patients using either unlicensed treatments or donor gametes or embryos.

The options that we lay out in this section aim to reflect the views on the welfare of the child (within the framework set by the 1990 Act) that we have identified so far. A table showing the benefits and costs of each option is included on page 25. Section 5 reproduces these options in the form of a questionnaire which invites you to identify a preferred option and your reasons for choosing it. If none of the options posed corresponds to your view about the welfare of the child principle, we would welcome your suggestions for a different approach and your reasons for proposing it.

3.1 Limitations of the current guidance

Part of the background work carried out in the first stage of the welfare of the child review was designed to develop an understanding of the strengths and weaknesses of the current guidance in the Code of Practice.

The first step in gathering this information was to carry out a review of the findings of the HFEA's inspections of licensed clinics. One recurrent finding was that each clinic has a different approach to the welfare of the child assessment. Although most clinics have a team meeting or an ethics committee to which they refer difficult cases, the protocols for handling welfare of the child assessments vary enormously from one clinic to the next. When, occasionally, problems relating to the welfare of the child assessment arise, they most often occur during the clinic's contact with the patient's GP.

This difficulty in the clinic's contact with GPs was echoed in the responses to a clinic survey which was carried out during summer 2004, the main findings of which were as follows:

- Most respondents from staff working in clinics regard the welfare of the child assessment as an important part of clinical practice. Just over half found contact with the patient's GP a useful aid in the assessment.
- However, some clinics find it difficult to get GPs to respond to the welfare of the child assessment form, either because the GP does not fully understand what is being asked of them or because they are unwilling to complete the welfare of the child questionnaire. Lack of familiarity with the patient, particularly in busy urban surgeries, means that GPs often don't have enough information to give a full assessment.

- Clinics sometimes make further enquiries to other agencies, but very rarely turn patients down for treatment. When this happens, the most common reasons are medical (because the patient has an infectious disease or they are being treated for cancer), psychiatric (because the patient has a mental illness or a drug or alcohol problem) or, occasionally, social (because the couple lives apart).
- The fact that patients are rarely refused treatment led a number of respondents to suggest that the time and cost of carrying out the welfare of the child assessment is disproportionate to the benefit gained.
- When asked how the welfare of the child assessment could be improved, suggestions included standardised forms for gathering information from patients or GPs, more detailed guidance or an expansion of assessments to include unlicensed treatments such as ovulation induction. Some said that the requirement to take account of the welfare of the child should be removed altogether.
- Clinic staff reported that patient attitudes towards the welfare of the child assessment vary. Some view the assessment with 'neutral acceptance'; others feel unfairly treated compared with those who conceive naturally.

A small number of patients responded to a questionnaire displayed in clinic waiting rooms. Some respondents questioned the fairness of the welfare of the child assessment, particularly when couples who conceive naturally are not subject to such checks. Others saw the importance of the welfare of the child assessment in principle, but reported feeling very nervous about the outcome.

These initial insights into the limitations of the current guidance were used to draw up the following options for revising the guidance to clinics on how to take into account the welfare of the child in assisted conception.

3.2 Enquiries to be made

The 'Enquiries to be made' section of the Code of Practice sets out the steps that clinics are expected to take in order to gather information to be taken into account when carrying out the welfare of the child assessment. In Section 3.1, we outlined some of the problems that clinics are currently experiencing in fulfilling these requirements. Not all of the problems stem from the guidance itself. Sometimes, GPs don't fully understand what is being asked of them. Other problems, however, could be addressed through a review of the guidance itself. Views are sought on the following options for the 'Enquiries to be made' section of the guidance.

Policy options for 'Enquiries to be made'

a) No social enquiries

This approach would interpret taking account of the welfare of the child as primarily a question of medical risk to the child to be born. Treatment could be offered within the terms of the Human Fertilisation and Embryology Act if, after asking the patient about their medical history, the clinician is content that that the procedure used does not pose a significant medical risk to the child.

b) Medical and social enquiries to be made of the patient(s)

This approach would require clinicians to ask the patients themselves about medical and social issues relating to the welfare of the child by asking them to complete a questionnaire. Any problems identified would be discussed and resolved within the clinic, without seeking information from the GP or other agency.

c) Medical and social enquiries to be made of the patient(s), with enquiries to a third party if a problem is identified

Modelled upon b), this approach would also involve gathering medical and social information through a patient questionnaire. However, there would be an additional requirement to contact the GP or other agency if a problem is identified.

d) Medical and social enquiries to be made of the patient(s), with enquiries to the GP routinely

Reflecting existing guidance, this approach to making enquiries would require clinicians to contact the patient's GP routinely in order to satisfy themselves that there is no foreseeable medical or social risk to the child.

e) Medical and social enquiries to be made of the patient(s), with enquiries to the GP and other agencies routinely

Modelled upon d), this approach would require clinicians to contact the patient's GP and other agencies, such as social services, routinely.

3.3 Factors to be taken into account

Paragraph 3.12 of the Code of Practice lays out the factors which clinics should take into account when carrying out a welfare of the child assessment. They are:

- (i) The commitment to raise children
- (ii) The ability to provide a stable and supportive environment for a child/children
- (iii) Immediate and family medical histories
- (iv) The age, health and ability to provide for the needs of a child/children
- (v) The risk of harm to the children including:
 - (a) inherited disorders or transmissible disease
 - (b) multiple births
 - (c) problems arising during pregnancy
 - (d) neglect or abuse
 - (e) the effect of a new baby or babies upon any existing child of the family.

The factors in this list could be organised into three main groups: medical risks to the child; social factors which might cause the child physical or psychological harm and social factors which might affect the child's quality of life. The following options for revising the 'Factors to be taken into account' section, for which views are sought, are arranged into those groupings.

Policy options for 'Factors to be taken into account'

a) Risk factors for medical harm only

This approach would focus solely upon medical risks to the child who might be born. Those risk factors might include the possibility of inherited or transmissible diseases or problems arising during pregnancy which could affect the health of the baby.

b) Risk factors for medical, physical and psychological harm

This approach would broaden the scope of the first option by focusing not only upon medical risks to the child, but also upon aspects of the individual's or couple's social and medical history which are likely to cause physical or psychological harm to the child. These additional factors might include previous convictions relating to children, any child protection measures taken regarding existing children, drug or alcohol abuse and a history of mental illness.

c) Risk factors for medical, physical and psychological harm and social factors

Preserving the existing guidance, this approach would require clinics to take into account any risk of medical, physical or psychological harm, as well as a range of social factors which might affect a child's quality of life. These social factors might include the age and health of the prospective parent(s), the stability of the family environment and, where there will be no legal father, the mother's ability to meet the child's needs.

It should be remembered that, whichever approach is taken, none of the risk factors mentioned above should necessarily preclude patients from being offered licensed treatment. Rather, the questions asked of the patients and/or the contact made with a GP or agency are designed to gather information which can trigger the need for further investigation and/or help the treating clinician make an assessment of the patient's suitability for treatment.

3.4 Welfare of the child assessments for particular treatments

Patients undergoing donor conception treatment

Paragraph 3.13 of the Code of Practice considers treatment with donor eggs and sperm (gametes) and embryos and requires clinics to take into account the 'following additional factors':

- (i) A child's potential need to know about their origins and whether or not the prospective parents are prepared for the questions which may arise while the child is growing up
- (ii) Family attitudes towards the child
- (iii) Implications which may arise if the donor is known within the child's family or social circle
- (iv) The possibility of disputed fatherhood.

The HFEA recognises that patients undergoing donor conception treatment need to be adequately prepared for the potential challenges of having a child who is not genetically related to one or both of their parents. This preparation might include information about the legal parentage of children born of donor conception, advice on telling the child or children about their origins and the attitudes of family members towards the child or children.

However, besides the issue of preparation, the question remains as to whether there should be a different kind of welfare assessment when patients are using donated gametes from when they are using their own gametes. One argument in favour of a more thorough assessment for donor conception treatment is that clinics have a responsibility to donors (in the same way that adoption agencies have a responsibility to birth parents), who might be concerned about the family environment of a child born from their gametes or embryos. A counter-argument is that, because research to date shows that the psychological outcome for children born of donor gametes is as good as the outcome for standard IVF children, there is no evidence for distinguishing between these two groups of patients.

Patients undergoing unlicensed treatments

Other groups of patients who might warrant a different approach to the welfare of the child assessment are those who undergo unlicensed treatments, such as intrauterine insemination (IUI) or ovulation induction, in licensed clinics. The current guidance says that centres are expected to carry out a welfare of the child assessment when patients are being treated in licensed clinics, regardless of whether the treatment itself requires an HFEA licence. When IUI or ovulation induction are provided on unlicensed premises (in a hospital gynaecology department, for instance), there is no expectation that the welfare of the child will be taken into account. Some respondents to our survey suggested that licensed clinics should not be expected to carry out a welfare of the child assessment when patients are undergoing unlicensed treatments.

Policy options for patients undergoing donor conception treatment

a) The same assessment and preparation for all patients

This approach would not distinguish between standard IVF patients and donor conception patients and would involve the provision of generic information for all patients to prepare them for having a child through assisted conception.

b) The same assessment for all, but extra preparation for donor conception patients

This approach would expect clinics to conduct the same welfare of the child assessment for all patients, with a requirement to help patients undergoing donor conception treatment prepare for having a donor-conceived child.

c) Extra assessment of, and extra information for, donor conception patients

Using an adoption approach, this option would require clinics to carry out a more thorough assessment when patients are using donated gametes or embryos. It could, for instance, mean routine contact with the GP or social services for donor conception patients, whilst the information about IVF patients using their own gametes is gathered from the patients themselves.

4. How to respond

The consultation is open to any organisation or member of the public in the United Kingdom. The consultation will run from 13 January until 7 April 2005.

Via the internet

We would prefer to receive your response via the HFEA website. Please go to <http://www.hfea.gov.uk/AboutHFEA/Consultations> to complete the online questionnaire.

By email

Please follow the format of the questionnaire beginning on page 15. For each question, please indicate which of the options presented in the document you prefer and give your reasons. Please email your response to Welfare@hfea.gov.uk.

By post

Please use the questionnaire beginning at page 15. We welcome as much information as you would like to provide. If there is insufficient space in the questionnaire for your comments, please continue on a separate sheet of paper, indicating to which question your comments relate. Written responses should be sent to:

Kerri Treston
Consultation Co-ordinator
Human Fertilisation and Embryology Authority
21 Bloomsbury Street
London WC1B 3HF

Further information

Further information about the Welfare of the Child Review is available on the HFEA website at:

<http://www.hfea.gov.uk/AboutHFEA/HFEAPolicy>

Telephone: 020 7291 8200

Email: Welfare@hfea.gov.uk

If you have any questions regarding the content of this document, or any other aspect of the welfare of the child review, please contact Juliet Tizzard, Policy Manager, using the contact details above.

If you have any complaints regarding this consultation, please contact Charles Lister, Head of Policy, using the contact details above.

5. Questionnaire

Name: _____

Organisation (if applicable): _____

Address: _____

Position in organisation (if applicable): _____

Please indicate the nature of your interest in the Welfare of the Child Review: _____

In line with the Cabinet Office Code of Practice on Written Consultation, responses to this consultation may be made public unless confidentiality is specifically requested. Do you agree to the HFEA making your response publicly available?

Yes

No

General

- 1 Please give any general comments you might have about the current guidance in the code of practice regarding welfare of the child assessment.

Reason

Enquiries to be made

- 2 Which of the following options best reflects your view on the enquiries that clinics should be expected to make in order to gather relevant information for the welfare of the child assessment?

- a) No welfare of the child enquiries should be made

Reason

- b) Information about risk factors should be provided by the patient(s) themselves

Reason

- c) Information about risk factors provided by the patient, plus follow-up to a third party if a problem is identified

Reason _____

- d) Information about risk factors provided by the patient, plus follow-up to the GP routinely

Reason _____

- e) Information about risk factors provided by the patient, plus follow-up to the GP and other agencies routinely

Reason _____

- f) None of the above

Reason _____

3 Do you think that refusal by a patient to give consent for a centre to contact their GP should be taken into account when deciding whether or not to provide treatment?

a) Yes

Reason

b) No

Reason

Factors to be taken into account

4 Which of the following options best reflects your view on the factors that should be taken into account during the welfare of the child assessment?

a) Only risk factors for medical harm should be taken into account.

Reason

- b) Risk factors for medical, physical and psychological harm should be taken into account.

Reason

- c) Risk factors for medical, physical and psychological harm and social circumstances should be taken into account.

Reason

5 Would you welcome guidance from the HFEA on how to take into account the factors mentioned above?

- a) Yes

Reason

- b) No

Reason

Welfare of the child assessments for particular treatments

6 Which of the following options best reflects your view on the assessment that should be carried out during donor conception treatment?

- a) When patients are having donor conception treatment, the same welfare of the child assessment as patients using their own gametes should be used and no extra information should be provided.

Reason

- b) When patients are having donor conception treatment, the same welfare of the child assessment as patients using their own gametes should be used. However, donor conception patients should receive extra information and preparation for becoming the parent(s) of a donor conceived child.

Reason

- c) When patients are having donor conception treatment, a more thorough welfare of the child assessment should be made and patients should receive extra information and preparation for becoming the parent(s) of a donor conceived child.

Reason

7 If you opted for either 6 b) or c), what kind of assessment and/or preparation for donor conception patients is desirable?

8 Which of the following options best reflects your view on the assessment that should be carried out for patients undergoing unlicensed treatments in licensed clinics?

a) When patients are undergoing unlicensed treatments, the same welfare of the child assessment as those undergoing licensed treatments should be used.

Reason

b) When patients are undergoing unlicensed treatments, a less thorough welfare of the child assessment than those undergoing licensed treatments should be used.

Reason

Appendix 1: Partial regulatory impact assessment

This partial regulatory impact assessment (RIA) is designed to consider the likely impact upon centres, patients and other parties of the options contained within this consultation document. Most RIAs consider the financial impact of new policies, particularly upon small businesses. However, because of the nature of the welfare of the child issue, this RIA considers the impact upon other aspects such as the doctor-patient relationship, compliance with the Human Fertilisation and Embryology Act and the protection of children to be born.

Title of proposal

An assessment of the regulatory impact of policy options suggested in the HFEA's review of the welfare of children guidance to licensed assisted conception centres.

Purpose and intended effect of measure

i) The objective

The aim of this policy review is to reconsider the HFEA's guidance relating to centres' taking to account the welfare of any child who might be born as a result of treatment, before that treatment is offered. The intended outcome is new guidance which achieves an appropriate balance between respecting patient autonomy and protecting the interests of the child, enhances uniformity of practice in all centres and increases the effectiveness of inspection. New guidance will apply to licensed centres throughout the UK.

ii) The background

The provision of assisted conception treatment in the United Kingdom is regulated by the Human Fertilisation and Embryology Act 1990. The Act requires those providing treatment to consider the child or children who might be born as a result of assisted conception treatment. Section 13(5) of the Act says: 'A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of treatment (including the need of that child for a father), and of any other child who may be affected by the birth'. The Act also requires that the Human Fertilisation and Embryology Authority (HFEA) should give guidance in a code of practice to those providing treatment services on how the welfare of the child should be taken into account.

The current guidance on welfare of the child assessments is, in places, unclear. This means that practice varies from centre to centre and compliance with the guidance is a frequently raised issue at inspection. The review aims to produce clearer guidance, leading to more uniform practice in centres.

Benefits and Costs

Benefits and costs associated with the policy options identified in the consultation document are set out in the summary table at the end of this document.

Equity and Fairness

The equity and fairness of regulation or treatment provision may be affected if the policy option requiring particular groups of patients to be subject to more assessment than other patients were adopted. However, equity and fairness would only be affected if a differential approach to assessment for these patients was not based upon evidence and therefore imposed an unreasonable level of assessment upon those groups of patients.

Consultation with small businesses

A small business is defined as having fewer than 50 employees. It is not anticipated that any of the options presented in the consultation will have a disproportionate impact on small businesses.

Competition assessment

It is not anticipated that any of the options presented in the consultation will affect competition between licensed centres in the private sector.

Enforcement and sanctions

Compliance with guidance contained within the HFEA's Code of Practice is achieved through the HFEA's own licensing and inspection system. Non-compliance with guidance in the Code of Practice may or, in some circumstances must, be taken into account by a licence committee when it is considering whether to issue, renew, vary or revoke a license.

Monitoring and review

New guidance contained within the HFEA Code of Practice will be monitored through the existing inspection process and reviewed in the light of emerging evidence. All guidance is reviewed prior to publication of each edition of the Code of Practice.

Consultation

Prior to publication of this consultation document, the views of licensed centre staff and patients were gathered by means of a questionnaire sent to centres in summer 2004. The responses to this questionnaire were used to inform the development of the policy options contained within this consultation.

Benefits, costs and net impacts of policy options

This benefits and costs table aims to consider each of the policy options contained within this consultation document on its own merits. It considers any transfer of responsibility or cost from centres to parties outside assisted conception (such as social services), should a particular option be adopted. Finally, the table considers the how the adoption of a particular option might impact upon centres, understood as a change from the current situation.

Enquiries to be made

Option 1: No social enquiries to be made about patients

Benefits	Costs	Transfers	Net impact
Respect for patient autonomy Limited administrative burdens for centres and GPs	Possible contravention of the Human Fertilisation and Embryology Act 1990	Possible increased burden upon social services if more at-risk children are born	Significant saving on administrative costs for centres

Option 2: Medical and social enquiries to be made of the patient(s) themselves

Benefits	Costs	Transfers	Net impact
Respect for patient autonomy Limited administrative burdens for centres and GPs	Small cost to centres of producing patient questionnaires Potential for patients to deceive centres	Possible increased burden upon social services if more at-risk children are born Increased burden of responsibility and decision-making upon centres to assure themselves that patients are suitable	Saving on administrative costs for centres where no further enquiries are necessary

Option 3: Medical and social enquiries to be made of the patient(s) themselves, with enquiries to a third party if a problem is identified

Benefits	Costs	Transfers	Net impact
Ability to make further enquiries if there are concerns Protection of children to be born	Cost to centres of producing patient questionnaires and administering further enquiries Potential for patients to deceive centres		Small saving on administrative costs for centres where further enquiries are minimal

Option 4: Medical and social enquiries to be made of the patient(s) themselves, with enquiries to the GP routinely

Benefits	Costs	Transfers	Net impact
Protection of children to be born	Cost to centres of producing patient questionnaires and administering further enquiries		None: status quo

Enquiries to be made (continued)

Option 5: Medical and social enquiries to be made of the patient(s) themselves, with enquiries to the GP and other agencies (e.g. Criminal Records Bureau, social services) routinely

Benefits	Costs	Transfers	Net impact
Protection of children to be born	Cost to centres of producing patient questionnaires and administrating further enquiries Could undermine doctor-patient relationship if patient regards questions as inappropriate Waiting times for patients while enquiries to other agencies are made	Increased cost and administrative burden for social services in responding to requests for information	Increased administrative burden through routine further enquiries Increased waiting times for patients Possible associated loss of business for small units which are not able to absorb administrative overheads

Factors to be taken into account

Option 1: Discussion to focus upon risk factors for medical harm only

Benefits	Costs	Transfers	Net impact
Respect for patient autonomy	No financial costs Approach could be regarded as failing children to be born	Possible increased burden upon social services if more at-risk children are born	None

Option 2: Discussion to focus upon risk factors for medical, physical and psychological harm

Benefits	Costs	Transfers	Net impact
Protection of children to be born/opportunity to discuss problems with patients	No financial costs		None

Option 3: Discussion to focus upon risk factors for medical, physical and psychological harm and social factors

Benefits	Costs	Transfers	Net impact
Increased protection of prospective children/opportunity to discuss any problem with patients	No financial costs Could undermine doctor-patient relationship if patient regards questions as inappropriate		None

Assessment of patients undergoing particular treatments

Option 1: Discussion to focus upon risk factors for medical, physical and psychological harm and social factors

Benefits	Costs	Transfers	Net impact
Uniform approach to all patients	Failure to recognise donors' anecdotal desire to see adequate protection of children born		None

Option 2: The same assessment for all, but extra preparation for particular groups of patients

Benefits	Costs	Transfers	Net impact
Proper recognition of the particular preparation needs of patients such as those using donor gametes	Cost of producing information for particular groups of patients (donor conception, surrogacy etc)		Increased information costs

Option 3: Extra information for and extra assessment of particular groups of patients

Benefits	Costs	Transfers	Net impact
Proper recognition of the particular preparation needs of patients such as those using donor gametes Recognition of donors' anecdotal desire to see adequate protection of children born	Cost to centres of producing information for particular groups of patients (donor conception, surrogacy etc) Cost to centres of carrying out further enquiries if GP and social are to be involved Possibility of legal challenge if policy is not shown to be evidence-based	Increased costs to GPs or social services if extra assessment includes enquiries to agencies	Increased administrative burden through routine further enquiries Increased waiting times for patients Possible associated loss of business for small units which are not able to absorb administrative overheads

Appendix 2: Current guidance

The HFEA's current welfare of the child guidance, reproduced below, can be found at section 3 of the Code of Practice 6th Edition. A copy of the code is on the HFEA website at: <http://www.hfea.gov.uk/HFEAPublications/CodeofPractice>.

Welfare of the Child and the assessment of those seeking treatment

General obligations

Human Fertilisation and Embryology Act 1990

Section 13

- 1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act...
- 5) A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father) and of any other child who may be affected by the birth.

- 3.1 When considering the treatment of any woman, treatment centres must take into account the welfare of the child that may be born as a result of treatment. Treatment centres are expected to also consider the welfare of any children the woman may already have responsibility for and the effect that treatment could have on these children. Treatment centre staff are expected to be aware of the need to show both care and sensitivity in this decision making process. Consideration is expected to be taken regarding the wishes and needs of those seeking treatment and the needs of any children involved.
- 3.2 Treatment centres are expected to take reasonable steps to ensure:
 - i) The safety of those seeking treatmentand
 - ii) The protection of any resulting or affected child or children
- 3.3 Treatment centres are expected to ensure that they have clear written criteria for assessing the welfare of any child or children which may be born or which may be affected by the birth of such child or children. Those criteria are expected to include the importance of a stable and supportive environment for any and all children who are part of an existing or prospective family group.

- 3.4 Best practice is expected to include an assessment of the welfare of the child upon first contact for licensed treatment with the prospective patients. If there is a delay before treatment takes place, treatment centres are expected to establish that no changes of circumstances have occurred since the original assessment of the welfare of the child before proceeding with treatment.
- 3.5 Treatment centres are expected to repeat the welfare of the child assessment where there has been:
- i) A gap of two years or more in contact between the clinic and the patient(s)
 - or
 - ii) A change of partner
 - or
 - iii) A child born to the patient(s) since the previous assessment
 - or
 - iv) A significant change in the prospective patient's medical or social circumstances
- 3.6 Treatment centres are expected to take all reasonable steps to verify the identity of those seeking treatment. This might be achieved through information from both partners' GP. However, if consent to this disclosure of information from both partners' GP is not given, or the patient(s) are from abroad, the patient is expected to be required to provide additional confirmation of identity e.g. birth certificate, passport.
- 3.7 Women over 35 and men over 45 are expected – like all patients – to be offered clinical advice and counselling at the outset. Advice and counselling is expected to focus on the implications of age for success in treatment. Gametes of patients in these age groups are expected to be used only for their own or their partner's treatment.
- 3.8 Gametes for use in treatment may only be taken from patients under the age of 18 in the following exceptional circumstances:
- i) If it is the intention to use such gametes for the patient's own treatment or for the use of the patient's partner
 - and
 - ii) If the centre is able to satisfy itself that the patient is capable of giving and actually gives effective consent to the use or storage of those gametes
- 3.9 Sperm to be used for the purposes of research may be taken from a male under the age of 18 only if the centre is able to satisfy itself that the donor is capable of giving, and actually gives, effective consent to such use.
- 3.10 It is expected that eggs shall not to be taken from a female under the age of 18 for the purposes of storage or licensed research without informing the HFEA.

Welfare of the Child

- 3.11 Treatment centres are expected to:
- i) Take reasonable steps to determine who will have parental responsibility for the child or children which may be born as a result of treatment and
 - ii) Take reasonable steps to determine the person or persons responsible for raising such child or children and
 - iii) Take particular care where the child is to be raised in another country and where the law may be different from that in this jurisdiction. In such cases patients are expected to have counselling on the implications for the potential child and all others who could be affected (particularly when using donated gametes) especially if the treatment requested is considered illegal in the country of origin
- 3.12 Those seeking treatment are entitled to a fair assessment. Treatment centres are expected to conduct the assessment with skill and care, and have regard to the wishes and sensitivities of all those involved. This assessment is expected to take into account the following factors relating to patients:
- i) The commitment to raise children
 - ii) The ability to provide a stable and supportive environment for a child/children
 - iii) Immediate and family medical histories
 - iv) The age, health and ability to provide for the needs of a child/children
 - v) The risk of harm to children including:
 - (a) inherited disorders or transmissible disease
 - (b) multiple births
 - (c) problems arising during pregnancy
 - (d) neglect or abuse
 - (e) the effect of a new baby or babies upon any existing child of the family
- 3.13 Where donated gametes are used, treatment centres are expected to take into account the following additional factors:
- i) A child's potential need to know about their origins and whether or not the prospective parents are prepared for the questions which may arise while the child is growing up
 - ii) Family attitudes towards such a child
 - iii) Implications which may arise if the donor is known within the child's family or social circle
 - iv) The possibility of disputed fatherhood

Other issues to be taken into account

- 3.14 Where the child will have no legal father the treatment centre is expected to assess the prospective mother's ability to meet the child's/children's needs and the ability of other persons within the family or social circle willing to share responsibility for those needs.
- 3.15 Where the couple are not married couples are expected to be advised that their legal position as parents, whether or not donated gametes are used, may require legal advice in order for full parental responsibility to be achieved.

Surrogate pregnancy*

- 3.16 Where the child will not be raised by the carrying mother all involved parties are expected to be made aware that the child's legal parent will be the carrying mother (and in certain circumstances could be her husband or partner) unless relevant court proceedings are carried out. Treatment centres are expected to – where possible – assess the possibility of a dispute in such circumstances and the effect upon the child, and the effect of any proposed arrangement upon a child or children of the family of the carrying mother or commissioning parents.
- 3.17 Treatment centres are expected to consider the use of assisted conception techniques to produce a surrogate pregnancy only where the commissioning mother is unable for physical or other medical reasons to carry a child or where her health may be impaired by doing so.

Selection of donated gametes

- 3.18 Where treatment is provided for a man and woman together, treatment centres are expected to strive as far as possible to match the physical characteristics and ethnic background of the donor to those of the infertile partner, or in the case of embryo donation, to both partners, unless there are good reasons for departing from this procedure.
- 3.19 When discussing the selection of potential donors, treatment centres are expected to be sensitive to the wishes of those seeking treatment for information, whilst avoiding the possibility that this information could be used to select a donor possessing certain characteristics for reasons that are incompatible with or not relevant to the welfare of the child. For example, those seeking treatment are expected not to be treated with gametes provided by a donor of different physical characteristics unless there are compelling reasons for doing so. Those seeking treatment with donated gametes (or embryos) are expected to be advised that no guarantees can be given where an attempt is made to match physical characteristics.

Enquiries to be made

- 3.20 In their assessment of prospective patients, treatment centres are expected to:
- i) Take medical and social histories from each prospective parent and see each couple together and separately
 - ii) Obtain the patients' consent to make enquiries of each of their GPs. Refusal by the patients, or either of them, to give such consent is a factor to be taken into consideration in the decision to provide treatment. In such circumstances, the treatment centre is expected to ask the patient's reason for the refusal and record the answer in the patient's medical records. In the absence of such consent, treatment centres are expected to seek to establish the identity of the patient(s) by appropriate evidence e.g. passport, photocard driving licence and birth certificate

* The attention of treatment centres is drawn to the Parental Orders (Human Fertilisation and Embryology) Regulations 1994 and (in Scotland) the Parental Orders (Human Fertilisation and Embryology) (Scotland) Regulations, which provide that parental rights and obligations in respect of surrogacy arrangements may be transferred from the birth parents to the commissioning parents. Appendix D of this Code of Practice sets out the conditions which must be fulfilled before an application may be made, and also contains information about birth registration in these circumstances.

- iii) Once the relevant consents have been received from the prospective patients, ask the GP of both partners if he/she knows of any reason why the patient(s) might not be suitable for treatment and if he/she knows of anything which might adversely affect the welfare of any resulting child
- iv) Where unsatisfactory responses or no responses to enquiries are received, obtain the further consent from the prospective patient(s) to approach any individuals, agencies or authorities for such further information as the centre deems to be required for a satisfactory assessment. (A response may be deemed to be unsatisfactory, for example, where prospective parents have had children removed from their care or committed a relevant criminal offence.) Refusal by the prospective parents or either of them to give such consent is a factor to be taken into consideration in the decision whether or not to provide treatment

Multidisciplinary assessment

- 3.21 In deciding whether to provide treatment, treatment centres are expected to take into account views from the staff who have had involvement with the prospective patients. Those seeking treatment are expected to be given the opportunity to respond to adverse comments and objections before a final decision is made.
- 3.22 Where adverse information has been provided in confidence to a member of staff at the treatment centre, consent is expected to be sought from the information provider to discuss it with other members of staff. Where such consent is refused but the member of staff considers the matter as crucial to the decision to be taken, treatment centres are expected to use their discretion based upon good professional practice before breaking that confidence.
- 3.23 Treatment centres are expected to base their decision to refuse to provide treatment upon all available information. Treatment may be refused if the treatment centre concludes:
 - i) That it would not be in the interests of any resulting child
 - or
 - ii) That it would not be in the interests of any other child
 - or
 - iii) That it is unable to obtain sufficient information or advice upon which to base a proper assessment
 - or
 - iv) That, having regard to all the circumstances, it is inappropriate to offer such treatment
- 3.24 Where treatment is refused treatment centres are expected to:
 - i) Explain the reasons for such refusal to the woman and – where appropriate – her partner, together with any circumstances which may cause the treatment centre to reconsider its decision
 - and
 - ii) Explain any remaining options
 - and
 - iii) Explain opportunities for obtaining appropriate counselling

Written record in respect of the Welfare of the Child

- 3.25 Treatment centres are expected to record in writing information that has been considered in respect of the welfare of the child. This record is expected to reflect the views of those who were consulted in reaching the decision and the views of those seeking treatment.

Additional information for those seeking long term storage of gametes and embryos

- 3.26 Centres are expected to seek to obtain the clients' consent to approach the GPs of each partner. Failure to give such consent is expected to be taken into account in the decision whether or not to store or accept gametes or embryos for treatment or research.
- 3.27 Where such consent is given, centres are expected to ask the GP(s) if they have information relevant to the storage of such gametes or embryos which they are prepared to disclose to the HFEA.

Additional information for those seeking an egg sharing arrangement

- 3.28 In addition to considering the general advice given above (paragraphs 3.1 – 3.10), treatment centres are expected to have clear written procedures for welfare of the child assessments in respect of:
- i) The egg provider
 - ii) The egg recipient(s)
 - iii) The partners of the egg provider and the egg recipient
- 3.29 Treatment centres are expected to ensure that:
- i) Care is taken in the selection of egg providers in egg sharing arrangements
and
 - ii) Egg providers are fully assessed and medically suitable
and
 - iii) The treatment offered is the most suitable available to satisfy the needs of the egg provider and recipient(s)
- 3.30 Treatment centres are expected to offer counselling to egg providers and recipients and to the partners of women donating and receiving eggs and any other individuals directly affected. There is expected to be the opportunity for the donor to receive counselling from a different counsellor from the one providing counselling to the recipient.
- 3.31 Treatment centres are expected to provide any additional impartial support (e.g. a member of the nursing staff not involved in the treatment of either donor or recipient) to all parties during the egg sharing cycle.

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