

Tomorrow's children

Report of the policy review of welfare of the child
assessments in licensed assisted conception clinics

Chair's foreword

When we launched the welfare of the child consultation, *Tomorrow's Children*, earlier this year, I committed the HFEA to developing a reasonable, proportionate, fair and practical system for clinics to conduct welfare of the child assessments, which is a legal requirement under the Human Fertilisation and Embryology (HFE) Act. Our research during the consultation, the written responses sent to us and the detailed discussions that took place at our four consultative meetings around the country have all given us valuable insights into how to achieve this goal.

A strong message that came across during the consultation was a desire for clearer guidance on how clinics should interpret the welfare of the child provision. Clinics want to know exactly what steps they should take to meet their legal responsibilities. Patients also want clear guidance, to enable them to understand the criteria against which they are being assessed. Having this could reduce the anxiety that such assessments sometime cause and stop patients feeling as if they somehow have to prove themselves in order to qualify for treatment.

In response to this call, we have developed a more focused interpretation of the welfare provision in the Act. The existing guidance interpreted this provision broadly, with the effect almost of requiring patients to demonstrate their suitability for treatment. In our new guidance the burden of proof shifts: there is now a presumption to provide treatment, unless there is evidence that any child born to an individual or couple, or any existing child of their family, would face a risk of serious harm. I believe that this focus upon risk of serious harm clarifies clinics' responsibilities in this area and will help patients to understand and find more acceptable the criteria against which they are assessed.

With the assessment process now more focused upon risk of serious harm, the expectation about the information and support which patients are given in certain circumstances is strengthened. This is particularly important for patients undergoing donor conception treatment. Clinics should encourage and prepare these patients to be open with their children from an early age about the circumstances of their conception.

Stakeholders also wanted a fairer and more proportionate system for assessing the welfare of the child. Most felt that the welfare of the child was an important consideration. However, they argued that the benefit gained from the existing system of assessment was insufficient to justify its level of administrative burden.

We have addressed this issue by deciding to remove the existing requirement for clinics to contact every patient's GP before treatment is provided. Instead, clinics should decide themselves whether there is sufficient concern about risk of harm to warrant making further enquiries. I believe that this approach provides the right level of protection for children without unjustifiably delaying the treatment of people who need medical help to have a baby.



Suzi Leather
Chair, Human Fertilisation and Embryology Authority
November 2005

Contents

Chair's Foreword	1
Summary	3
Introduction	4
The welfare of the child principles	6
Risk factors to be taken	7
Enquiries to be made	10
Donor conception	12
Unlicensed treatments	14
Regulatory impact assessment	15

Summary

In the summer of 2004, the HFEA launched a review of its guidance to clinics on taking into account the welfare of children who may be born as a result of assisted conception treatment. In February 2005, a public consultation document, *Tomorrow's Children*, sought views on a range of options for revising HFEA guidance in this area.

This report gives details of the main changes that have been made to the guidance and the reasons for doing so. Those changes are:

- There should be a presumption to provide treatment to all those who request it, unless there is evidence that the child to be born would face a risk of serious medical, physical or psychological harm.
- When making a welfare of the child risk assessment, clinics should consider factors in the patient's medical or social history or circumstances which are likely to cause serious medical, physical or psychological harm to the child.
- Clinics should collect medical and social information from the patient(s) about the risk factors described above. In cases where clinics think that the child may be at risk of serious harm, they should obtain the patient's consent to make enquiries to other individuals, agencies or authorities in order to gather further factual information.
- Donor conception patients should undergo the same assessment process as other patients, but should be provided with information about the implications of treatment, including preparation for donor-conception parenthood. Clinics should encourage and prepare such patients to be open with their children from an early age about the circumstances of their conception.
- Patients undergoing unlicensed treatment (such as intra-uterine insemination) in HFEA-licensed clinics should undergo the same assessment process as other clinic patients.

1 Introduction

Assisted conception is now a common medical procedure in the United Kingdom, available in nearly 100 clinics around the country. The Human Fertilisation and Embryology Act 1990 sets out the conditions under which assisted conception services should be provided and the standards which should be upheld by clinics. Is there anything which governs who can access those services? Legislators were careful not to lay down any eligibility criteria for patients seeking treatment. However, they did place one responsibility upon clinics:

'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.'

There is nothing in the legislation which describes how clinics should interpret the welfare of the child requirement. 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 account. The existing welfare of the child guidance can be found in the HFEA's 6th *Code of Practice*.

The welfare of the child review

The aim of the welfare of the child review, which began in summer 2004, was 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. The guidance has not been fully reviewed since the first *Code of Practice* was published in 1991, but much has changed in the intervening period.

With one percent of babies born now being the result of licensed assisted conception, the availability and awareness of fertility treatment has grown enormously. The way in which services are provided has changed and, most importantly for this review, those working in clinics now have more than a decade's experience of using the welfare of the child guidance in their day-to-day work. Throughout the consultation period, we aimed to capture that experience and gather views from a wide range of interests about how changes in public awareness and attitudes should shape new guidance on how to interpret the welfare principle in the legislation.

The scope of the review was very clear from the start. Our aim was not to review the section of the Act which refers to the welfare of the child. That is the role of Government, which has recently launched a public consultation seeking views on, amongst many other issues, how the welfare of the child requirement should be recast in new legislation. The HFEA's aim during the welfare of the child review was to work within the existing welfare provision in the Act (which, despite the Government's ongoing review of the legislation, is likely to remain in force until 2008) and to provide licensed clinics with guidance on how the provision should be interpreted in day-to-day clinical practice.

There were two main stages of the welfare of the child review. The first was a period of research, consisting of reviews of the psychosocial, ethical and legal literature, a comparison with regulatory approaches to the welfare of the child in other countries and a review of other areas of law and practice relating to children. During this stage, we also conducted a small survey of clinics and patients and a review of HFEA inspection reports. This work was designed to measure current knowledge and opinion about the welfare of the child and to understand the strengths and weaknesses of the existing guidance.

The second stage of the review involved putting out to public consultation a number of options for revising the guidance. Stakeholders were invited to respond to a written consultation document, *Tomorrow's Children*, giving their views on how the guidance should change in the future. A total of 265 individuals and organisations responded, falling into the following categories:

Stakeholder category	Number	%
Patient	117	44.2
Clinical/scientific	51	19.2
Academic	12	4.5
Adoption/social work organisation	11	4.2
Fertility counsellor	10	3.8
Other	42	15.8
No information	22	8.3
Total	265	100.0

During this consultation stage, we also held four public meetings, in Glasgow, London, Manchester and in Parliament. These meetings were designed to encourage the involvement of people who did not intend to submit a written response to the consultation. They also proved to be a useful forum for discussing various issues in detail and seeking ways of resolving problems.

Stakeholder category	Number	%
Clinical/scientific	61	35.1
Fertility counsellor	35	20.1
Academic	19	10.9
Patient	15	8.6
Adoption/social work organisation	7	4.0
Other	37	21.3
Total	174	100.0

We also commissioned a survey of the views of general practitioners, carried out by Taylor Nelson Sofres (on behalf of MORI), based upon a sample of 210 GPs.

The views of patients, clinic staff, GPs and the other stakeholder groups described above formed an integral part of the evidence base used to inform policy making. The following sections give details about the three main areas of the guidance which were under review and the policy changes which have occurred as a result of the review.

2 The welfare of the child principle

In the *Tomorrow's Children* consultation document, we asked respondents to give general comments about the welfare of the child principle and how it should be interpreted in clinical practice. We used the answers to this open-ended question – as well as discussion at the consultative meetings and findings from our own literature reviews – to help develop a broad interpretation of the welfare of the child principle in the Act. The aim was to address the lack of clarity in the existing guidance about welfare of the child assessments. Having an interpretation of the welfare principle helped the Authority when making the policy decisions discussed in the sections below, thereby maximising consistency across the different elements of the guidance.

The views that were gathered through the written consultation, the consultative meetings and the literature reviews were extremely varied. Some views were based upon personal experience, some upon professional practice and others upon academic knowledge. Some drew from the experience in other areas, such as adoption or natural conception, whilst others explored the unique features of having a child through assisted conception.

Although they were difficult to categorise in a scientific way, four main interpretations of the welfare of the child principle seemed to emerge from the consultation responses. These were:

1. The welfare of the child principle should be removed from the legislation because the autonomy of the prospective parents should always override the ability of third parties to prevent a child from being born.
2. The involvement of a medical team in assisted conception means that certain third parties have some responsibility towards the child to be born. However, the importance of patient autonomy means that clinics should only refuse to provide treatment where there is evidence that the child is likely to suffer serious physical or psychological harm.
3. The involvement of a medical team in assisted conception means that certain third parties have significant responsibility towards the child to be born. Consequently, clinics should not provide treatment unless they are satisfied that the welfare of the child to be born will not be affected negatively.
4. The welfare of the child principle in the legislation should be strengthened so that the child's welfare is the paramount consideration when deciding whether or not to help an individual or couple to become a parent.

In order to implement either one of them, interpretations 1 and 4 would require an amendment to the welfare of the child principle in the legislation. Therefore, despite any merits that these interpretations might have, the HFEA is unable to develop guidance to reflect them.

Our conclusions

The Authority considered approaches 2 and 3 and concluded that Approach 3, which is the approach most like that of the existing guidance, placed too much emphasis upon the interests of the prospective child at the expense of patient choice. Although this may have been the most appropriate interpretation to take of the welfare principle in the early 1990s, the experience of the past 14 years suggests that, as a group, children born of assisted conception are no more likely to be disadvantaged than their naturally conceived counterparts.

This led the Authority to conclude that Approach 2 is the preferred interpretation of the welfare of the child principle in the Act. Whilst the involvement of a medical team in conception brings some responsibility towards the child who may be born as a result of their assistance, this responsibility should not outweigh the important responsibility that clinicians have towards respecting patient choice. It is the Authority's view that there should be a presumption towards providing treatment to those who request it, but that treatment should be refused in cases where clinics conclude that the child to be born, or any existing child of the family, is likely to suffer serious harm.

3 Risk factors to be taken into account

The first area of the guidance under review was the section outlining the risk factors that clinics should be expected to consider during a welfare of the child assessment. These factors help clinics to determine which questions to ask people seeking treatment in order to determine what risks the child to be born as a result of treatment might face.

Existing guidance

The existing guidance listed a number of factors that clinics should consider:

- The commitment to raise children
- The ability to provide a stable and supportive environment for a child/children
- Immediate and family medical histories
- The age, health and ability to provide for the needs of a child/children
- The risk of harm to children, including inherited disorders or transmissible disease; multiple births; problems arising during pregnancy; neglect or abuse; and the effect of a new baby/babies on any existing child of the family.

During the research stage of the review, clinic staff and patients identified this aspect of the guidance as being difficult to implement because of the different interpretations that could be made of the risk factors, particularly those relating to the patient's social circumstances. This variation in interpretations often leads to very different decisions being made from one clinics to the next.

Options presented during the consultation

During the consultation period, we presented three options for revising this aspect of the guidance, each focusing upon different risk factors. Option A entailed consideration of risk factors for medical harm only; option B focused upon medical, physical and psychological harm and option C added to that list consideration of social circumstances.

Most stakeholders giving their views either through the consultative meetings or the written consultation favoured either option B or C. Most argued that a proper understanding of welfare, being more than physical health, should mean that clinics consider more than just medical risk factors. However, opinion was divided over whether, besides medical harms and serious psychological risk to the child, clinics should go further and also focus upon the patient's social circumstances. Part of the disagreement was due to a lack of agreed definition of 'psychological' and 'social', with some arguing that the former was just a more serious form of the latter. Some said that social factors were important, but only where they are likely to impact seriously upon the child. Others suggested that only some social factors should be considered. For example, there was little appetite for clinics to continue to consider an individual's or couple's commitment to having children (most considered the decision to embark upon fertility was commitment enough). However, some felt that the age of the prospective parents was an important social factor and should therefore be considered.

Our conclusions

The Authority decided that, in order to take into account the welfare of the child, centres should consider factors which may pose a risk of serious medical, physical or psychological harm, either to the child to be born or to any existing child of the family. Although social circumstances have been removed from the guidance as factors to consider, we expect that where adverse social circumstances are severe enough either to be likely to pose a risk of serious psychological harm to the child or to make the parents unable to care for a child, they will be caught by this new policy.

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. Risk factors to be taken into account should include:

- Any aspect of the patient's past or current circumstances which means that either the child to be born or any existing child of the family are likely to face serious physical or psychological harm or neglect. Such aspects might include:
 - (a) previous convictions relating to harming children;
 - (b) child protection measures taken regarding existing children; or
 - (c) serious violence or discord within the family environment.
- Any aspect of the patient's past or current circumstances which is likely to lead to an inability to care for the child to be born or which is already seriously impairing the care of any existing child of the family. Such aspects might include:
 - (a) mental or physical conditions; or
 - (b) drug or alcohol abuse.
- Any aspect of the patient's medical history which means that the child to be born is likely to suffer from a serious medical condition.
- Any other aspects of the patient's circumstances which centres consider to be appropriate.

Where centres identify cases in which there is a risk of serious harm in one of these areas, they should obtain the consent of the patient to contact any individuals, agencies or authorities for further factual information. The aim of collecting further information is to establish whether such serious harm is likely to occur. Treatment should be refused if the centre concludes that either the child to be born or any existing child of the family is likely to face a risk of serious medical, physical or psychological harm.

The Authority concluded that broader social factors such as the stability of the relationship, the commitment to having children and the age of the prospective parents, are unlikely to pose a risk of serious harm to the child. However, although the Authority decided to remove age from the risk factors, there may be instances in which the age of one of the prospective parents means that the child is likely to face medical harm or that the parents are unlikely to be able to care for the child. In this case, it is the problems associated with a person's age (such as ill health) rather than a particular age itself that should be the determining factor in the decision to refuse treatment. Such associated problems should be given proper consideration.

Guidance on how to take risk factors into account

During the consultation, we asked stakeholders whether they would welcome guidance from the HFEA not just on which risk factors to take into account, but also on how to take them into account. For example, the *Code of Practice* might require a centre to consider the implications for the child to be born of a history of mental illness in the patient. But should the guidance also help the centre to make a judgement about the relevance of particular aspects of a patient's case? Should the guidance, for example, include reference to the relevance of how long ago a period of mental illness occurred or how well managed an ongoing mental illness is? A number of stakeholders attending the consultative meetings or responding to the written consultation said that such guidance would be very useful for clinics. Some stakeholders working in clinics said that they found making welfare of the child assessments so difficult, that they would welcome any help in making decisions that the HFEA could provide.

We are acutely aware of the difficulty of making decisions about whether or not to provide treatment to those requesting assistance to conceive. We want to find ways of helping clinic staff with these decisions wherever possible. However, as many stakeholders pointed out, HFEA guidance in this area should not be prescriptive or seek to anticipate the very particular circumstances of each individual or couple seeking treatment. Decisions about whether or not individual patients or couples should be offered treatment must be a matter for clinical discretion. The Authority decided not to provide detailed guidance to clinics about how they should take the risk factors into account. However, the decision to focus welfare of the child assessments upon identifying those patients who are likely to pose a risk of serious harm to the prospective child will, we hope, provide greater clarity and give clinics more confidence about deciding whether or not treatment is appropriate. The situation will be monitored and if, in future, the demand for detailed guidance increases the decision will be reviewed.

4 Enquiries to be made

In order to make a proper assessment of the welfare of the child to be born, clinics need to collect information about each patient requesting treatment.

Existing guidance

In the existing guidance, clinics were expected to make enquiries about each patient in order to collect information on which to base an assessment of the welfare of the child. They were first expected to take a medical and social history from each patient and then to seek consent to contact each patient's general practitioner. They then asked each patient's GP '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'. If unsatisfactory information or no information at all was forthcoming, consent could also be sought to contact any other individuals, agencies or authorities that the clinic thought appropriate to gather additional information.

During the research stage of the review, staff working in clinics and patients identified this area of the guidance as being either very difficult to implement or unnecessary. Some clinics found it difficult to obtain useful information from a patient's GP, either because the GP was uncooperative or because they didn't know the patient well enough to provide the kind of information sought. Many clinics complained of a heavy administrative burden associated with routine contact with GPs. This lack of information, combined with the administrative burden of making contact with GPs led some to conclude that the cost of routine GP enquiries is disproportionate to the benefit gained by doing so. The small number of patients who responded to the initial survey reported feeling nervous about the GP enquiries or felt that it was unfair for them to have to undergo such checks.

Options presented during the consultation

With a general picture of the limitations of the existing guidance emerging, we presented those attending the consultative meetings and respondents to the written consultation with a number of options for revising this section of the guidance. We also asked a panel of GPs about their role in welfare of the child assessments.

The views of clinic staff, patients and GPs were evenly balanced. Some argued that it would be better to stick to the existing guidance because it provided a safeguard against any patients who are dishonest about their circumstances. However, others pointed out that because GPs often know little about the non-medical aspects of their patients' lives, such dishonesty is already a possibility. Those favouring the option of relying upon information from the patient and making enquiries to other agencies or authorities where necessary argued that this was the most practical and proportionate way to proceed. They said that clinic staff are more experienced at spotting problems and discussing them than are busy GPs. Others argued that the only way to gather reliable information on the very few patients who may present a risk to their prospective child would be to routinely make enquiries to agencies such as social services or even the Criminal Records Bureau. However, most (particularly patients) argued that such an approach would be costly and labour-intensive and would represent unjustified scrutiny of a patient's circumstances. With the views on this issue being evenly spread, we had to come to a decision which balanced a range of competing interests.

Our conclusions

The Authority decided that clinics should no longer be expected to make enquiries to patients' GPs on a routine basis. However, they should collect detailed medical and social information from the patients themselves and they should make enquires to any individual, agency or authority (such as a GP, social services or the probation service) if the clinic has concerns about information provided by the patient.

In cases where clinics want to make enquiries to third parties, they must obtain the patient's consent to do so. The Authority decided that refusal by the patients to give such consent is a factor which should be taken into consideration in the decision to provide treatment. However the refusal should not by itself be grounds for denying treatment.

5 Donor conception

Some treatments provided in an assisted conception clinic involve the use of donated eggs, sperm or embryos, which may have particular implications for the welfare of the child to be born.

Existing guidance

Under the existing guidance, clinics were expected to take into account an additional set of factors for those people undergoing donor conception treatment. Those factors were:

- 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
- Family attitudes towards such a child
- Implications which may arise if the donor is known within the child's family or social circle
- The possibility of disputed fatherhood

It is not clear from the drafting whether the additional factors to be taken into account represent a list of issues which should be discussed with prospective donor conception patients, or a list of issues which should be considered when deciding whether or not to offer treatment. This apparent blurring of assessment and information needed to be clarified in the revised guidance.

Options presented during the consultation

During the consultation period, we presented three options for revising this aspect of the guidance. Option A allowed respondents to say that patients undergoing donor conception treatment should be treated in exactly the same way as those undergoing treatment using their own gametes and embryos. This meant that they should have both the same assessment and be given the same information. Option B entailed having the same assessment, but identified a need for donor conception patients to be given additional information and preparation for becoming a donor conception parent. Option C allowed respondents to opt for a system in which donor conception patients received a more thorough assessment and additional information and preparation.

The majority of stakeholders giving their views either through the consultative meetings or the written consultation favoured option B. They felt that there was no reason why donor conception patients should undergo a more thorough assessment because, as a group, they pose no greater risk of harm to their prospective children than do those patients using their own gametes. This view concurred with information gathered from literature reviews. However many argued that, because of the particular issues associated with having a child who is genetically unrelated to one or both parents, donor conception patients do need particular information and preparation that other patients do not need.

Our conclusions

The Authority found these arguments persuasive and concluded that, as far as the welfare of the child assessment goes, there were no grounds for differentiating between donor conception and other patients. Clinics should use the same risk factors and make the same enquiries as they do for patients undergoing treatment with their own gametes.

We also concluded that donor conception patients need specific information and preparation before they embark upon treatment. However, in order to overcome the lack of clarity in the existing guidance, the assessment and information requirements have been separated.

The *Code of Practice* already specifies that in order to ensure that patients undergoing any kind of licensed treatment have given effective consent, they must be given information about the nature, purpose and implications of the treatment. In the context of donor conception, giving information about the implications of treatment should be understood to include preparation for donor-conception parenthood, including the importance of sharing information with the child about their donor origins at an early stage.

6 Unlicensed treatments

The Human Fertilisation and Embryology Act established a licensing and inspection regime over a number of assisted conception treatments. These treatments, known in the Act as 'licensed treatments', include those in which an embryo is created in the laboratory (IVF and variants such as intracytoplasmic sperm injection (ICSI) and those which involve the use of donated eggs, sperm or embryos.

Unlicensed treatments are those in which a medical practitioner assists conception, but does so by using eggs and sperm which are not fertilised in the laboratory. Such treatments include intrauterine insemination (IUI) and gamete intrafallopian transfer (GIFT) without donor eggs or sperm.

Existing guidance

Unlicensed treatments, as their name suggests, are not normally subject to licensing and inspection by the HFEA. However, where they take place in a clinic licensed to carry out IVF and other treatments, certain provisions in the Act apply to them. One such provision is the requirement for welfare of the child assessments. This section requires welfare of the child assessments to be carried out on all 'treatment services', which are defined in the Act as:

'Medical, surgical or obstetric services provided to the public for the purpose of assisting a woman to carry a child.'

Consequently, in the existing guidance, licensed clinics are required to carry out a welfare of the child assessment before offering any treatment, whether or not they are licensed.

Options presented during the consultation

During the consultation, stakeholders were asked whether the welfare of the child assessments carried out for unlicensed treatment should be the same as, or different from, those carried out for licensed treatments such as IVF.

There was overwhelming support for carrying out exactly the same assessment for unlicensed treatments. Most people attending the consultative meetings or responding to the written consultation argued that this should be the case because the relevant aspects of unlicensed treatments are just the same as they are in licensed treatments. In both types of treatment, a medical team is involved in assisting conception; the patients, although they may have different causes of infertility, are therefore no different from one another and, in general, pose no greater or lesser risk to their prospective child. Most stakeholders felt that just because unlicensed treatments tend to be more 'low tech', this made no difference to the potential outcome for the child to be born.

Our conclusions

We were persuaded by the arguments given by many stakeholders and decided that there will continue to be no difference between welfare of the child assessments for patients undergoing treatments like IVF and those undergoing unlicensed treatments in licensed centres. We also decided that the placing of eggs or sperm into frozen storage should not be regarded as a medical, surgical or obstetric service provided for the purpose of assisting a woman to carry a child. People storing gametes, perhaps because they are about to undergo chemotherapy treatment, will not be required to undergo a welfare of the child assessment.

Regulatory impact assessment

This regulatory impact assessment (RIA) is designed to consider the likely impact upon centres, patients and other parties of the policies contained within this report. 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 outcome of the welfare of the child policy review is new guidance which aims to achieve an appropriate balance between respecting patient autonomy and protecting the interests of the child. This will enhance uniformity of practice in all centres and increase the effectiveness of inspections. New guidance applies 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.

Benefits and costs

Benefits and costs associated with the policy options identified in the consultation document are set out in the summary table on page 17.

Equity and fairness

The equity and fairness of treatment provision is unaffected by the policies in this report because all patients, regardless of the type of treatment they undergo, will be subject to the same welfare of the child assessments.

Consultation with small businesses

A small business is defined as having fewer than 50 employees. None of the policies presented in the report will have a disproportionate impact on small businesses.

Competition assessment

None of the policies presented in the report 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 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 licence.

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

During the early stages of the welfare of the child review, 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 the consultation document, *Tomorrow's Children*, published in February 2005. During the consultation period, four public consultative meetings were held around the United Kingdom. Together, the consultation document and the consultative meetings meant that the HFEA was able to gather a wide range of views from a number of different key groups.

October
05

Benefits, costs and net impacts of policy options

This benefits and costs table aims to consider each of the welfare of the child policy decisions. The table considers how the adoption of a particular option might impact upon centres, understood as a change from the current situation.

Policy Amendment	Benefits	Costs	Net impact
When making a welfare of the child risk assessment, clinics should consider factors in the patient's medical or social history or circumstances which are likely to cause serious medical, physical or psychological harm to the child.	<p>More proportionate response to welfare of the child assessments</p> <p>Ability to make further enquiries if there are concerns</p>	Cost to clinics of updating protocols and producing patient questionnaires and administering further enquiries, where they are needed	Saving on administrative costs for centres
Clinics should collect medical and social information from the patient(s) about the risk factors described above. In cases where clinics think that the child may be at risk of serious harm, they should obtain the patient's consent to make enquiries to other individuals, agencies or authorities in order to gather further factual information.	<p>More risk-based approach to assessments, focusing upon more objective and less speculative judgements</p>	No financial costs	No financial impact
Donor conception patients should undergo same assessment process as other patients, but should be provided with information about the implications of treatment, including preparation for donor-conception parenthood, including the importance of sharing information with the child about their donor origins at an early stage.	Proper recognition of the information and preparation needs of donor conception patients	Cost to clinics of updating information	Increased information costs
Patients undergoing unlicensed treatment (such as intra-uterine insemination) in HFEA-licensed clinics should undergo the same assessment process as other patients.	No change from previous policy	No financial costs	No financial impact



Human Fertilisation and Embryology Authority
21 Bloomsbury Street
London WC1B 3HF
Telephone: 020 7291 8200
Website: www.hfea.gov.uk
Email: welfaremeetings@hfea.gov.uk

05/31467

Publication date: 03.11.05