

The draft 8th Code of Practice and consent forms: An overview on administrative burdens and equality impacts

1 Introduction

1.1 When developing new guidance for licensed centres, we measure the likely impact that those proposals will have upon centres and patients. Patients and clinical practitioners legitimately expect to be able to use and provide fertility services without being burdened by excessive levels of administrative and regulatory intervention. Also, the impact of any guidance change on different groups needs to be monitored to ensure that no group is discriminated against in their access to fertility services. We therefore measure the impact of the various options, in order to assess which is the most effective and least burdensome approach, bearing in mind the purpose of the proposed policy change.

What are the different types of impact we are assessing?

1.2 New guidance can have an impact on the **administrative burden** on clinics. We therefore ask ourselves how much staff time it might take to comply with the guidance or what additional procedures might be required. In order to help assess the administrative costs associated with particular policies, we recruited a reference group of seven licensed clinics and laboratories. Each centre provided an estimate of the impact of the proposed changes on their administrative burden, calculated in terms of staff time needed to comply with regulation, from which we were able to estimate the impact on the sector as a whole.

1.3 We also need to understand the impact of new policies on patients and the wider community. These **equalities impacts** are concerned with any unfair or disproportionate impact that a new policy has in the following areas:

- Age
- Disability
- Ethnicity or race
- Religion
- Gender
- Sexual orientation and identity
- Human rights

1.4 There are a number of other impacts which government and regulators should assess. These relate to the environment, public health and rural communities and are usually not relevant to HFEA policies. However, we highlight them where they are relevant.

1.5 We have undertaken detailed impact assessments for each of the significant changes to the Code of Practice and consent forms. Upon request, we are happy to share with you our assessment of all those changes where we concluded impacts were not significant enough to merit detailed discussion and consultation.

Which elements of Code and consent forms are we considering?

1.6 When the amended Human Fertilisation and Embryology Act 1990 comes into force on 1 October 2009, licensed clinics and laboratories will have a new set of statutory requirements placed upon them. Some of these legal requirements will apply directly to centres. The new embryo research provisions, for example, define the types of embryos which can be created and used in research and the purposes for which the research can take place. It is the Department of Health's responsibility to assess the impact of these legal requirements which apply directly to centres¹. However, it is our responsibility to assess the impact of guidance in the Code of Practice and consent forms which either interprets the Act or goes beyond its requirements. The changes to the Code we introduced in this draft eighth edition fall into three categories: those necessitated by the new legislation, those that were not necessitated by legislation but that conclude a HFEA policy review, and finally changes to the structure and style of the Code.

1.7 The following significant changes to the Code and consent forms were necessitated by the new HFE Act:

- Welfare of the child (supportive parenting) guidance
- Embryo testing guidance
- Consent guidance
- Revised consent forms

1.8 The following areas of guidance were introduced into the Code not because of the new Act, but in response to patient and professional concerns:

- Counselling (recording the offering of counselling) guidance
- Costed treatment plans
- Preimplantation genetic screening

1.9 Besides revising some of the guidance in the Code of Practice, we have also taken the opportunity to change the structure and format of the Code, with the aim of making it more user-friendly. The Code now consists of 32 guidance notes, each covering a particular clinical situation or activity. We have also introduced a clearer distinction between mandatory requirements and HFEA guidance, and have sought to simplify the Code's language and organisation wherever possible.

What feedback are we seeking?

1.10 We are actively seeking feedback on both the administrative costs, and equalities impacts, of the changes highlighted in this paper. Although the cost impacts identified are based on feedback from a representative sample of clinics, we recognise the limitations of using a small sample (for example, none of the centres in the reference group offers PGD as a service). We will get a better feel for the projected costs and savings from a wider range of respondents. Similarly, we are

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http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Regulatoryimpactassessment/DH_080209

keen to hear from anyone with a particular perspective on any equalities issues raised by our proposed policies.

1.11 You can provide feedback on these issues using the consultation questionnaire, which can be found at <http://cop.hfea.gov.uk/cop/consultation/>

2 The structure and format of the Code

Background

2.1 The HFEA has radically restructured the Code of Practice in order to improve its usability. Initial user testing and feedback from the reference group seems to suggest that the changes introduced to the overall structure of the Code will make the document easier to use. These improvements can be divided in two categories:

- Style: clearly distinguishing between legal requirements and best practice guidance, removing duplication and putting guidance into plain English, and
- Structure: grouping legal requirements and guidance by subject area, improving navigation and cross-referencing.

Administrative burden

2.2 The restructuring of the Code is expected to reduce the time spent by clinic employees looking up guidance and using external legal advisers to interpret the Code. Based on the reference group's feedback, we estimate this positive impact to amount to a saving of around £410,000 per year for the whole sector.

2.3 We acknowledge that the cost impact in the first year is likely to be greater as centre staff familiarise themselves with the new guidance.

Equalities impact

2.4 We have not identified any equalities impacts of the restructuring of the Code of Practice.

3 Revised guidance: Costed treatment plans

Background

3.1 New guidance in guidance note 4, Information: general, requires clinics to provide patients with a personalised and costed treatment plan. This new guidance responds to concerns from patients that costs sometimes increase during treatment without it being clear why this happened.

Administrative burden

3.2 Based on feedback from our reference group of centres, we estimate that the administrative burden on clinics for complying with this guidance will be a cost of around £97,000 per year across the sector.

Equalities impact

3.3 We have not identified any equalities impacts of the costed treatment plans guidance in the Code of Practice, according to the categories listed in paragraph 1.3. However, those patients on a low income are likely to benefit from costed treatment plans because they will be able to better plan the expenditure.

4 Revised guidance: Welfare of the child (supportive parenting)

Background

4.1 New guidance in guidance note 8, Welfare of the child, gives advice to centres on how to comply with the new requirement in the Act to take into account a child's need for supportive parenting before treatment is offered (which replaces the previous one to take into account the child's need for a father). The guidance states that all prospective parents should be presumed to be supportive, unless there is cause for concern to the contrary.

Administrative burden

4.2 The feedback we received from our reference group of centres showed that the introduction of this guidance would create an estimated saving for the sector of around £10,000 per year. This is based upon the response from only one centre, which calculated the impact compared to the previous guidance on how centres should take into account the child's need for a father. The other centres estimated that there would be no cost impact of the new guidance.

Equalities impact

4.3 We estimate that there are no negative equalities impacts upon the different categories of individuals. However, some groups, such as lesbians and single women, may notice an improvement in comparison to the previous guidance regarding the need for a father. The new guidance applies to all prospective patients and does not differentially impact upon those in same-sex relationships.

5 Revised guidance: Counselling

Background

5.1 Following advice from key professionals and associations, we have removed the requirement for centres to record the offer of counselling in the patient's health records, including whether or not the offer was taken up. The new policy responds to concerns expressed by key stakeholders that recording the uptake or otherwise of counselling serves no obvious purpose and infringes the privacy of patients.

Administrative burden

5.2 Following feedback from the reference group, we estimate that the removal of this requirement will have a broadly neutral effect on the sector (a modest saving of around £4,600 per year to the sector as a whole).

Equalities impact

5.3 We have not identified any equalities impacts of the removal of this guidance.

6 Revised guidance: Embryo testing

Background

6.1 Besides the new requirements regarding embryo testing in the amended Act, we have changed three aspects of the guidance to centres on this topic:

- Centres are no longer required to offer implications counselling for embryo testing to all members of the family. The requirement to make genetic counselling available is retained.
- Centres may now, as an alternative to providing patients with information from other families about the particular condition in question, provide information about that condition from a patient organisation instead.
- When offering sperm sorting for medical reasons, centres are now required to provide information to patients about 'the process, procedures, possible risks and the experience of the centre in carrying out the procedure'.

Administrative burden

6.2 None of the centres in the reference group offers PGD as a service. We are therefore unable to estimate the administrative burden of this new guidance on the sector.

Equalities impact

6.3 Guidance on embryo testing has an impact on patients with disabilities who might access PGD techniques because their disability is caused by a genetic variation that PGD aims to circumvent. All the guidance changes listed above aim to improve the experience of people who need PGD. Arguably, the guidance changes have a positive impact on people affected by a disability who choose to use PGD.

7 Revised guidance: PGS

Background

7.1 In response to feedback from professional organisations and new evidence in the scientific literature, we have changed our guidance regarding preimplantation genetic screening. The new guidance is as follows:

7.2 Centres are now required,

- To give PGS patients information about 'the experimental nature of this procedure, in particular that more robust randomised controlled trials are needed to assess whether or not PGS can significantly increase live birth rates for all indications';
- To 'monitor the latest literature and professional guidance including the BFS policy and practice guidelines on PGS';
- To 'validate the use of PGS for each category of patients/indication they offer it for based on data from previously published studies and retrospective evaluation of the centre's own data'.
- Centres are no longer required to restrict PGS to certain categories of patients.

Administrative burden

7.3 Based on feedback from our reference group, we acknowledge that this new guidance is likely to increase the administrative burden on centres and estimate that this amounts to approximately £40,000 additional costs per year across the whole sector.

Equalities impact

7.4 The new guidance no longer restricts the use of PGS to any given categories of patients, particularly regarding the patient's age. Arguably, this has an equalising impact on patients of all age groups.

8 Revised guidance: Consent

Background

8.1 Following changes to the consent provisions in the Act and learning from best practice in other areas of regulation, we have introduced the following new guidance on consent:

- Centres are now required to 'give consideration to the needs of individuals whose first language is not English. Where consent is obtained, any difficulties in communicating the implications of giving consent and providing other information to the person (eg, language, hearing) and an explanation of how these difficulties were overcome (eg, where there are language difficulties the use of an independent translator), should be recorded.'
- Centres are now required to 'presume that it is in the best interests of a child to store gametes unless circumstances suggest otherwise. When assessing whether procurement and storage of gametes is in a child's best interests the centre should refer to the General Medical Council guidance "*0-18 years: guidance for all doctors*".
- Centres are now required to 'have procedures in place for how they will deal with disputes that may arise when one gamete provider withdraws their consent to the use or storage of gametes or embryos in treatment services. In this situation the centre should halt treatment procedures and notify the relevant people. Centres should provide information about counselling and refer patients to mediation as appropriate.'

Administrative burden

8.2 Based on our reference group, we acknowledge that this new guidance will increase the administrative burden on centres. We estimate this impact to amount to around £132,000 across the whole sector.

Equalities impact

8.3 The first guidance change listed above aims to address the needs of those affected by communication barriers, including the hearing impaired and those whose first language is not English. It therefore has a possible positive impact on those groups. The second guidance change has a positive impact on children, where previously it was uncertain whether gametes could be stored when a child was unable to give consent due to young age. This new guidance enables clinicians to preserve a child's chances to have a family in later life if a child has to undergo medical treatment that will damage their fertility.

9 The revised consent forms

Background

9.1 We have reviewed all the HFEA consent forms in order to make them more user friendly. New legislation introduces new requirements and types of consent, but the biggest changes concern the forms' design and wording. The main changes introduced are:

- Because forms have been redesigned to be more situation specific, there are now more of them (14). They are also longer, which reflects a desire to include more explanations and to make them more accessible.
- There is a new form for patients to consent to the use of their gametes or embryos in surrogacy arrangements
- There is a new form for changes to consent
- The 'Consent to the treatment involving egg retrieval and/or egg or embryo replacement' form will not be issued in the new Code of Practice.
- The forms have been designed and worded to make them comprehensible and user friendly.
- Amendments to the CD form (consent to disclosure) will allow patients, partners and donors to consent to disclosure to all categories of people with one tick, plus the categories will be broader.

Administrative burden

9.2 Overall, the reference group found that some of the changes were beneficial, whereas some would increase the administrative burden on centres. The net impact of the revised consent forms is expected to be marginally negative (a cost of around £3100 per year for the whole sector), which is unsurprising, given the new law requires the taking and recording of additional consents.

9.3 We acknowledge that the cost impact in the first year is likely to be greater as centre staff familiarise themselves with the new forms. More detail can be found in section 10.

Equalities impact

9.4 We have not identified any negative impacts on equalities from the redesign of the consent forms. Arguably, our attempts to make them easier to read by increasing the font size of all the questions might have a positive impact on people with visual impairments. We are consulting on how to make the forms generally more user friendly.

10 Summary of administrative burden

10.1 We have added together the costs and benefits of the Code of Practice restructuring, the revised guidance and the new consent forms. This enables us to show the total benefit or cost to the sector of implementing the new provisions in Human Fertilisation and Embryology Act.

10.2 The costs to clinics are expressed here in monetary terms. The time spent by clinic staff carrying out tasks required by regulation has been multiplied by the wages of the staff to obtain the monetary value of the cost to the clinic. The aggregated results are set out in the table below. Cost to clinics is shown as negative while benefits are shown as positive.

10.3 The aggregate effect on the Administrative Burden of the sector is estimated at around £132,000 per year over the whole sector. While these figures are estimates calculated from the responses of a small sample of centres, they give an idea of the likely direction and order of magnitude of the impact.

	Total annual benefit	Total annual cost	Total annual net impact	Total year 1 benefit	Total year 1 cost	Total year 1 net impact
Consent forms	£73,954	-£77,061	-£3,106	£73,954	-£77,061	-£3,106
Code restructuring	£411,244	£0	£411,244	£192,682	-£149,159	£43,522
Revised guidance	£15,068	-£290,963	-£275,895	£4,603	-£301,428	-£296,825
Costed treatment plans	£0	-£96,619	-£96,619	£0	-£96,619	-£96,619
Welfare of the child	£10,465	£0	£10,465	£0	-£10,465	-£10,465
Counselling	£4,603	£0	£4,603	£4,603	£0	£4,603
Embryo testing	£0	£0	£0	£0	£0	£0
Preimplantation genetic screening	£0	-£39,945	-£39,945	£0	-£39,945	-£39,945
Consent	£0	-£154,399	-£154,399	£0	-£154,399	-£154,399
Total	£500,266	-£368,024	£132,242	£271,239	-£527,648	-£256,409

Note: Code restructuring and Welfare of the child will have additional costs in the first year whilst clinics become familiarized with the new guidance. The benefits to clinics of these policies are expected to be fully realized after the first year

Impact on small clinics

10.4 The burden in regulation can tend to fall disproportionately on small firms. Small firms tend to have less capital and fewer employees to use to comply with mandatory requirements and guidance. Therefore, compliance costs per employee can be higher for small businesses.

10.5 Most of the clinics and research laboratories that we regulate can be defined as small or micro, using the European Commission's definitions for firm size². We are

therefore very aware of the impact of our policies on small and micro clinics. Smaller clinics are well represented in the Reference group, ensuring that their concerns are taken into account. Due to the very small sample for each type of clinic, the results should be seen as broad estimates.

10.6 The figures summarised in the table below seem to suggest that micro and small clinics do not suffer more than larger centres as a result of the new measures.

	MICRO clinics: average annual net impact	SMALL clinics: average annual net impact	MEDIUM clinics: average annual net impact
Consent forms	-£52	£53	-£238
Code restructuring	£4,307	£734	£0
Revised guidance	-£1,856	-£793	-£2,311
Costed treatment plans	£0	-£490	-£2,235
Welfare of the child	£0	£0	£354
Counselling	£0	£0	£156
Embryo testing	£0	£0	£0
Preimplantation genetic screening	-£265	£0	-£586
Consent	-£1,591	-£303	£0

10.7 In order to obtain more data on this issue, small and micro clinics will be asked for their input during consultation. This will be fed into the decision-making process and we will consider whether any changes should be made to any policy in light of those responses.

² According to the European Commission definition, large firms = 250 staff or more, medium firms = 50 to 250 staff, small firms = 10 to 50 staff and micro firms = 1 to 10 staff.

11 Technical Annex: Methodology

11.1 The calculation of the administrative burden follows the methodology outlined in the Standard Cost Model. In order to obtain first-hand information about the impact of the options, a reference group of clinics and laboratories was established.

11.2 The seven centres in the reference group were chosen to represent the different types of centres regulated by the HFEA. The different characteristics of the centres include:

- size (micro; small; medium)
- public/private
- type of centre (fertility clinic; research laboratory; storage centre)
- type of treatments performed (IVF; donor insemination; other)

11.3 The reference group was asked how each proposed change would affect them, in particular:

- whether the proposed change would have any impact on their centre and whether the net effect would be positive or negative
- how much time per week would be spent/saved due to the change
- the type of employees who would spend/save time
- whether the change would have any other effects on their centre, including non-financial effects.

11.4 The additional time per week spent or saved by employees was multiplied by the average weekly wage for that type of employee. Average wages were obtained from the Office of National Statistics' Annual Survey of Hours and Earnings (ASHE), plus other sources where necessary.

11.5 This calculation was used to obtain the cost for each type of centre, using the assumption that each centre in the reference group was representative of the type of centres that it belonged to. Finally, the results were weighted and added up to obtain the total impact on the sector.

11.6 This type of estimation should be unbiased (that is, unlikely to systematically over- or under-estimate the administrative burden) but will inevitably be subject to a degree of uncertainty.

11.7 During the public consultation, centres will be able to comment on the accuracy of the estimated costing. This additional input will be taken into account when the Impact Assessment is amended after the consultation period.