BFS response to HFEA consultation on revision of the Code of Practice 2018

Qualifications for the role of the Person Responsible
Q2: Do you think these new requirements clearly set out the expectations of a person responsible?

Unsure

Q3: Any comments:

We have 2 suggestions
1. The wording in points 1.3 and 1.4 is non-specific and open to interpretation. We accept that it is in the nature of such descriptions that precision is difficult to achieve. It is difficult to quantify ‘integrity’ and ‘leadership quality’. The HFEA should consider whether to ask that there should be ‘evidence’ of ‘integrity’ and ‘leadership quality’ in the professional record of the PR. This could be from their appraisals, CV and other sources.

2. The guidance concerning ‘managerial authority and capability’ appears to apply only to new Persons Responsible. For equity, should this not also be a condition for existing PRs to fulfil? Also, the HFEA should consider asking for evidence of managerial authority and competence, for instance from CV, job plan and a description of where the centre’s leadership sits in the wider organisation of which it is a part (if applicable).

We suggest that the Code should require documented evidence of the requirements laid out in 1.7, 1.8 and 2.3. This will help the PR demonstrate that the centre meets these requirements.

Patient support
Q4: Is the proposed guidance clear about what should be included in the patient support policy?

YES, but we would ask for clarification of the term ‘customised support intervention’

Q5. Can you foresee any difficulties in implementing a patient support policy in your clinic?

Many clinics will not be able to set up their own support groups or forums, but we are relieved to note that it is not a requirement to provide these. It may be argued that
support groups should be separate to the influence of any one clinic and best originating from patient-led organisations, eg FNUK. Support groups come and go depending on their members and the clinics can’t be held responsible for their demise. We suggest that in 3.18d it is made clear that a centre may signpost to these where available rather than describing what they may “provide”. We suggest that open evenings which are centre run fall under information provision not support and shouldn’t be in this grouping

**Quality Policy and Quality Objectives**

**Q6: Any comments:** None

**Information specific to the centre**

**Q7: Do you think that guidance in 4.2 includes all the relevant information that should be provided to patients about the centre?**

**NO**

We consider that this section is unclear. The section describes information that should be given to patients before treatment is ‘offered’. We suggest that the HFEA should consider whether this should be changed to before treatment is ‘provided’. Centres may be deemed to ‘offer’ treatment by the fact that they exist.

Further, Sections 4.2 (b), 4.2 (f) and 4.2 (g) are not specific to any centre, rather they apply to all centres. Conflating them with centre-specific requirements makes this section confusing.

We suggest that this section be revised with these comments in mind.

Irrespective of where it is placed in the final version, 4.2 (f) "information about future use" should specifically include information about the "duration of storage".

**Information about the treatment**

**Q8: Do you think that the requirements set out above in 4.3 (b) will be effective in ensuring that patients receive sufficient unbiased, evidence-based information about the nature and effectiveness of any treatment add on which they may be offered?**

**Yes,** However, the wording should be amended to state that the information should be both verbal and written (‘written’ may including online information to which the patient has been directed).
Information about the risks of treatment
Q9: Do you think the requirements set out in 4.4 (d) will be effective in ensuring that patients are informed of what to do and who they should contact if experiencing symptoms of OHSS?

NO. Information regarding OHSS should be re-iterated during treatment, whereas this section only refers to information before treatment. Of course, the information should also be provided prior to treatment.

Information about success rates
Q10: Do you think that the guidance provided in section 4.5 is sufficiently clear that clinics can understand what is expected of them in terms of success rates displayed on their website or any other material they produce?

YES but see below

Q11: Any comments

Why state that centres "are encouraged", and "may be displayed" at point (b), rather than "should" or "must" as written at each other point? Perhaps the HFEA should create a paragraph with hyperlinks and require that this is included on the clinic website. This would ensure that the requirement is met and would be easy to inspect against.

Extension of storage of gametes and embryos
Q12: Do you think that the changes to guidance note 17 are sufficient to provide clarity about these legal obligations?

NO

Q13: Any comments

1. The lack of definition of ‘Premature Infertility’ remains a potential source of confusion and variation in practice. Section 17.19 states ‘a woman who has reached menopausal age will not however be considered prematurely infertile’. This has the potential to cause confusion and lead to women suffering from premature menopause (which can occur at any age up to 40) being denied long-term storage of eggs or embryos.)
2. Could some guidance be offered on the practice of allowing a ‘cooling-off’ period where the centre is unable to contact the couple or where the couple are unable to come to a decision? If a patient is eligible to store for 55 years and has consented to this, but does not return to the centre for review at the end of 10 years, there is a need for clear guidance on what the centre should do, and how it can avoid breaking the law. Despite the best efforts of licensed centres, patients will sometimes not return for a review for a number of reasons.

3. This part of the Code is specially complex and would lend itself to a flow-chart, which would be very useful to clinic staff faced with these situations. In feedback received by the BFS even experienced clinicians professed themselves confused and unsure about the regulations, section 17.9 especially.

4. We suggest that the HFEA should consider adding in a 10 year review into the GS form, so that it is clear to patients that storage beyond 10 years depends on certain requirements being met.

5. We also suggest a long-term embryo storage form, analogous to GS, with a similar structure. We consider that although we do not wish to increase the number of forms, this may make practice clearer, and may allow the Medical Practitioner's statement to be discontinued.

Q14: Is this addition feasible for clinics to carry out to ensure consent is given by the correct individual?

YES

Q15: Do you think that these additions will be effective in allowing clinics to be given evidence of the legal relationships between patients seeking treatment whether as a couple in a marriage or civil partnership?

NO

This section mixes two separate though related issues – patient and partner identity and the relationship.
Section 5.13 asks centres to ‘take all reasonable steps to verify the identity’ of all patients and partners. One sentence later, it says that if there is a doubt about identity, centres should ‘verify their identity, including examining photographic evidence’. We do not see a difference between ‘reasonable steps to verify the identity’ (which is prescribed for all patients and their partners) and ‘verify their identity’ (which is required in cases where there is a doubt about identity. We suggest that the Code should state that treatment should not be provided if there is a doubt about identity and the centre has been unable to establish identity through reasonable steps (including photographic evidence).

With regard to ‘evidence of legal relationships’, it is not clear that this is a requirement in the wording of 5.13. Does the HFEA require clinics to obtain divorce/marriage/civil partnership certificates in certain circumstances? We do not consider that the proposed additions make it easier for clinics to be given this evidence.

Q16: Do you think that this guidance will be effective in ensuring that the clinic can avoid carrying out potentially unlawful treatment when a partner of a patient no longer consents to treatment?

YES

Q17: Any Comments

We are unclear why the words "in fact" have been used in last sentence of section 5.15

Egg sharing

Q18: Do you think that this deletion is a feasible requirement

NO

Comments:
(i) We do not consider that it is "exceptional" that it may be deemed appropriate to defer treatment to the egg provider. Such a situation may arise in the event of an excessive ovarian response or a hydrosalpinx or endometrial pathology identified during stimulation.

(ii) In such a situation, whilst egg or embryo freezing may be appropriate, it should
be left to the egg donor to decide whether or not she wishes to have either of these options. We recommend that section 12.5 paragraph 2 should be modified to read:

‘In the event that it is appropriate to defer treatment of the egg provider, the centre should offer the egg provider the option of cryopreservation of eggs or embryos’.

Q19: Do you think that this addition is a feasible requirement?

YES

Q20: Do you think that this proposal will be effective in ensuring prospective gamete providers and recipients in kind arrangements receive appropriate information prior to consent?

NO

Q21: Any comments

The wording should be amended to positively recommend counselling in all such cases. We are in sympathy with the stance of the professional counselling organisation (BICA). However, we do not feel that making counselling mandatory would be in keeping with the principle of autonomy. The BFS received a range of views in regard to counselling of gamete providers and recipients. We consider that implications counselling must be provided, by a practitioner sufficiently knowledgeable and experienced in the implications of issues around gamete donation. This is in distinction to therapeutic counselling, which is not required for all gamete providers and recipients and must only be delivered by a qualified counsellor.

**Ovarian Hyperstimulation Syndrome:**

Q22: Do you think that taken together, these proposed changes will be effective in supporting the care and follow up of patients affected by OHSS?

YES, THEY WILL GO SOME WAY TO IMPROVING CARE

Q23: Do you think that taken together, these proposed changes will be feasible for
clinics to implement?

YES

Q24: Any comments

27.1 and 27.8 A link to the RCOG Green Top Guideline, or the extract relevant to the classification of OHSS should be included, to remove any confusion as to what constitutes moderate or severe OHSS

1. 15.1 (i)
   A mechanism should be required of licensed centres that ensures the patient carries written information with them, that they are given by the licensed centre that carries out treatment, and that they are made aware that they must present this written information to any doctor who takes over their care after licensed treatment, at any hospital, local or otherwise.

2. Centres should be asked to proactively try and maintain contact with women identified as high risk of OHSS after the trigger injection. This will allow centres to better track their patients and identify those who have needed care elsewhere.

3. "seeking to put into place" is perhaps too vague a requirement; the CoP should state that licensed centres should put in place mechanisms for communication around related appropriate information and data sharing.

Surrogacy

Q25: Do you think that the requirements set out above in 3.7 - 3.9 will be effective in ensuring that surrogates, intended parents, and their partners, where applicable, fully understand the implications of entering into a surrogacy arrangement and have a sufficient opportunity to ask any questions and voice any concerns?

Yes, but see below

Comments:

1. We consider that the Code should reflect that more than one appointment may be needed for proper counselling of the surrogate and her partner.
2. In section 3.8, the word ‘surrogate’ in the last sentence should be replaced by ‘intended parents’
3. Section 3.9 - In keeping with the views of BICA, it is reasonable that the counsellors professional judgment be used to decide whether or not a joint counselling appointment for surrogate and intended parents is required. More generally, we consider that having similar counselling requirements for surrogacy and donor gametes is rational and will promote good practice.

Q26: Are guidance notes 3.7 - 3.9 sufficiently clear about what a clinic needs to provide in terms of implications counselling for surrogacy arrangements?

Yes

Q27: Does the new text above offer appropriate guidance to help clinics ensure that a surrogate and intended parent are suitable to enter into an appropriate and medically safe surrogacy arrangement?

YES, however, the requirement to obtain information about the surrogate from her GP is more than the requirement for other patients seeking licensed treatment. We are concerned as to whether this may be deemed disproportionate and discriminatory.

Q28: Is the new guidance sufficiently clear about what is needed from a surrogacy SOP?

NO

Comment: Legal Parenthood is not a matter for individual clinic SOPs. Rather the SOP should include ensure that intending parents and surrogates understand the situation with regard to legal parenthood. We consider that it should not be up to fertility clinics to explain the minutiae of legal parenthood to intended parents, but it is reasonable for clinics to advise them to seek their own independent legal advice.

Q29: Does this guidance do enough to protect the interests and wellbeing of surrogates and intended parents?

NO

Q30: Any comments:
The interests of surrogates and intended parents can only be protected to some extent by the centre carrying out the fertility treatment. Adequate protection requires that intending parents should seek their own independent legal advice to understand legal parenthood and other issues. The same could be said to apply to surrogates. The licensed centre has a role in ensuring that intended parents and surrogates understand the proposed treatment and there is no coercion. However, surrogacy is only the start of the process and it is unrealistic to expect licensed fertility clinics to be responsible in any meaningful way for events and eventualities in later pregnancy and after delivery.

**Data protection**

**Q31: Is the new guidance sufficiently clear?**

**YES**

**Q32: Any comments**

None

*For information: EU Directives on the import and export of gametes*

**Q33: Any comments**

None

**Q34: Any comments**

None

**Q35: Any comments**

None

**Q36: Any comments**

None

**Quality management system**

**Q37: Any comments**

None
Data submission
Q38: Any comments

We would ask for a review of the timescales for information to be returned to the HFEA. This should be realistic and in keeping with the timescales for when the information is needed. The authority recognises this with the extended time allowed for reporting of OHSS for instance.

For information: format and usability
Q39: Any comments or suggestions

None