

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY 6TH CODE OF PRACTICE: RESPONSE TO CONSULTATION

Introduction

1. The HFEA received 61 responses to our invitation to participate in the consultation process for the 6th Code of Practice:

- 22 from licensed centres/Persons Responsible
- 24 from professional/patient bodies
- 11 from inspectors
- 4 from the public/patients

2. Of the 61 respondents, 10 were completely happy with the new draft. The rest offered a range of comments covering most sections of the Code.

3. This document summarises the main comments received chapter by chapter and the changes made in response. A more detailed summary of changes made to the Code since the 5th edition is included in Chair's letter CH(04)01 dated 12th January 2004.

4. Further information is available from Charles Lister, Head of Policy, on 0207 539 3334 (charles.lister@hfea.gov.uk).

Style and Layout

5. Many commentators regarded the 6th edition as an improvement over its predecessor. In particular, the inclusion of the relevant sections of the Act was felt to be helpful. The one critical comment on layout was the inclusion at the head of each chapter of the boxed paragraph on interpretation of terms used in the Code. A number of people found the constant repetition annoying. This was therefore removed in the final version.

Part 1: Staff

6. 16 respondents commented on this chapter, reflecting a range of concerns but particularly:

- the lack of attention paid to the qualifications and experience required by nursing and midwifery staff;
- a concern that the Code permitted the use of unqualified counsellors;
- a need to stress the importance of continued professional training for all professional staff in centres.

These issues were addressed through changes to paragraphs 1.8, 1.9 and 1.17.

Part 2: Facilities & Administrative Procedures

7. 12 respondents commented on this chapter, mostly on the reporting of adverse incidents and the need for greater clarity on definitions and timescales for reporting. A new section on adverse incidents has therefore been added at paragraphs 2.23 to 2.26. New directions have also been issued on reporting of adverse incidents (see Chair's letter CH(04)01). The definition of an adverse incident has also been strengthened and reflects the definition used by the National Patient Safety Agency

Part 3: Welfare of the Child and the Assessment of Those Seeking Treatment

8. 11 respondents commented on this chapter. No major issues were raised, although one centre commented that a number of the requirements were impractical. As HFEA will be reviewing policy on welfare of the child in 2004 no further changes were made to this chapter following consultation.

Part 4: Assessing and Screening Potential Donors

9. 15 respondents commented on this chapter with a range of comments. The following amendments were made in response:

- Para 4.1 (i): now makes clear that potential donors should understand not just which tests must be carried out but why they are necessary;
- Para 4.1 (vii) is a new section recognising that donors and their partners should be given the opportunity to see an independent counsellor to explore the implications of the donation. This is further emphasised at paragraph 4.8;
- Para 4.4: has a new final sentence stating that centres are expected to record instances where a donor cannot give a full and accurate family history;
- Para 4.8 (v): adds a further a categories for centres to consider when assessing the suitability of potential donors - for childless donors, the implications for themselves and any future family;
- Para 4.9: now states that the possibility of people undergoing treatment donating gametes should be raised by the counsellor.

Part 5: Information

10. 20 respondents commented on this chapter raising a range of issues, many of which aimed to improve the accuracy/clarity of policy. The following amendments were made in response:

- Para 5.4(iv) was reworded to improve accuracy;
- Para 5.5 (i): adds ‘the centre’s policy on selecting patients’ to the list of information to be given to individuals seeking treatment;
- Para 5.5 (vi) (d): was extended to include the impact on the individual children in the family;
- Para 5.10: a new paragraph was added stating that specific consent should be obtained where any genetic research is to be carried out on identifiable samples.

Part 6: Consent

11. 20 respondents commented on this chapter with a variety of suggestions. Changes made include:

- Para 6.1: expands the list of relevant guidance on consent;
- Para 6.2: adds “mentally incapacitated” patients to the exceptional circumstances under which centres may examine or treat people without first obtaining their consent;
- Para 6.10-6.12: a new section was added on ‘consent by children and young people’. This section clarifies to centres that parents cannot consent on behalf of their children to any licensed procedure and that centres are expected to have written information that is accessible to children and young people given by a member of staff with competence in communicating with children;

Part 7: Counselling

12. 16 respondents commented on this section. Main themes emerging were:

- *the need to distinguish between counselling and advice/guidance.* This arose particularly where the Code talks about ‘implications counselling’. Commentators wanted the Code to make clear that counselling should only be undertaken by qualified counsellors.
- *the unacceptability of unqualified counsellors* – see Part 1 above.

13. As a consequence, the following changes were made:

- Para 7.4 (i): a sentence has been added to make clear that implications counselling provided by a qualified counsellor (see

paragraph 7.12) should be distinguished from implications advice or guidance provided by other members of the multidisciplinary team;

- Para 7.5: has been amended to reinforce the importance that all patients are offered counselling and they are made aware that this offer is a routine part of the treatment service;
- Para 7.6: now makes clear that, in providing counselling, centres are expected to be aware of the individual needs of patients including disability and language;
- Para 7.10: places an expectation on centres to invite those seeking treatment to consider their attitude to their own or partner's infertility and the possibility that treatment will fail;
- Para 7.19: adds people experiencing difficulty coping with a treatment cycle to the list of those who should be offered support counselling;
- Para 7.20: makes more explicit that all staff who are in contact with the patient should receive training in providing emotional support.

14. At the suggestion of respondents, this chapter has also been re-ordered into what we hope is a more logical sequence.

Part 8: Use of Gametes & Embryos

15. The main change in this chapter, and the focus of respondents' comments, was the issue of embryo transfer. In addition to the 10 respondents who were happy with the new Code in its entirety, a further 10 gave positive support to the proposed 2 embryo transfer limit 9 respondents were opposed. The remainder offered no comment on this issue. Many of those opposed to the strict two embryo policy acknowledged the need to reduce multiple pregnancies but expressed concern about the likely impact of such a policy on live birth rates in older women.

16. Following the consultation and further analysis of the HFEA's database, the Authority amended the original proposals (see paragraphs 8.17 to 8.22 of the Code). HFEA believes that the new policy is a reasonable balance between the overriding objective of reducing multiple births and the need to protect women's chances of having a healthy singleton baby.

Part 9: Storage & Handling of Gametes and Embryos

17. 10 comments were received, leading to the following changes:

- Para 9.3. reference was added to the *Guidance on the Microbiological Safety of Human Organs, Tissues and Cells Used in Transplantation* (Dept of Health 2000);

- Para 9.10. A new final sentence was added to provide greater clarity.
- Para 9.13. the words *have access to appropriate information and advice* were added.

Part 10: Research

18. 8 comments were received. The only change made was to remove the words *health authority* from para 10.7.

Part 11: Records

19. There were only 4 responses to this chapter. As a result, the second sentence of para 12.3 was amended to improve clarity.

Part 12: Confidentiality

20. 7 people commented on this chapter, 3 making the point that it would be more sensible for it to be adjacent to the chapter on Records (it was Chapter 5 in the consultation document). Other than that, only one change was made

- Para 12.9: which was extended to include gamete and embryo donation as well as egg sharing.

Part 13: Complaints

21. 8 comments were received. As a result para 13.4 now makes clear that information on centres' complaints procedures should be given to patients as well as displayed.

Part 14: Preimplantation Testing

22. 12 comments were received and two changes made in consequence:

- Para 14.12 Infertility counsellors were added to the list of people to be included in the multidisciplinary team.
- Para 14.23(i) For clarity, *the view of the people seeking treatment of the condition to be avoided* was added to the list.

Part 15: Witnessing Clinical and Laboratory Procedures

23. This section received 5 comments, including views from one body that some of the requirements were too prescriptive. However, given the importance of accurate witnessing, no changes were made to this section of the Code.

Part 16: ICSI

24. This section attracted only 3 comments. No changes were made.

Appendices

25. 11 comments were received on various aspects of the Appendices. The following changes were made:

- Appendix A General para 1(b) third bullet point was amended to say that, in egg sharing, counselling should be *offered* – rather than *given* - to all parties.
- Appendix B: at point 3 of the consent form a further box was added for patients to give informed consent for National Care Standards Commission inspectors to see their treatment records.

HFEA
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