Code of Practice 2018 Update Working Group- minutes

13th December 2017 10:00-12:50

Church House, Westminster, London SW1P 3NZ

Working group members	Present	Ann Wilcox Carmel Dennehy David Ogutu Francoise Shenfield Jackie Hare Jason Kasraie Karen Pooley	Lisa Joels Mary Cawthron Melanie Lake Oksana Stidston Rebecca Cowie Rhonda Cowie Venessa Smith
	Apologies	Janine Fleming Smriti Bhatta	
Members of executive		Hannah Verdin (Chair) Erin Barton Rasheda Begum Niamh Marren Polly Todd Louise Winstone	Nhung Vu Lisa Whiting Jessica Watkin

1. Welcome and introductions

1.1. The Chair welcomed attendees to the meeting and members introduced themselves.

2. Terms of reference

2.1. The terms of reference were presented and approved by the group.

3. Overview of main proposed changes

Information provision for patients

3.1. The first topic of guidance to be discussed was “Information provision for patients” relating to Guidance Note 4. The group did not have any suggestions for changes to this area of the Code.

Screening requirements

3.2. The next topic for discussion was screening requirements. The Policy Manager outlined how the current guidance is confusing because different professional bodies and organisations have different screening requirements and recommendations. The European Commission is currently

consulting on an alternative interpretation to the EUTCD which may lead to a new set of requirements.

3.3. A point was raised regarding the way known donors are referred to on forms and in guidance, as often the word “donor” is not seen to accurately reflect the relationship. It was suggested that even if the screening requirements are the same, the special relationship of known donors should be reflected in forms.

3.4. One member noted confusion arising from recent NAT testing recommendations for sperm donors which involved a test which virologists said may not be able to be done.

Egg sharing

3.5. The Chair introduced the topic of egg sharing which involved two issues. The first related to “exceptional circumstances” cited in the guidance when it is acceptable for all eggs that have been collected in an egg sharing arrangement to be donated. The second issue is reviewing the information provision for patients entering a benefits in kind arrangement.

3.6. One member questioned why egg freezing was referred to in the guidance when it would be more appropriate to freeze embryos. Other members of the group suggested examples of when egg freezing would be appropriate for some patients. Members agreed that it is difficult to think of examples when egg freezing would not be available and therefore all eggs would be donated, rather than kept by the egg sharer. It was suggested that if such a rare situation arose the clinic could contact their inspector.

3.7. The discussion moved onto the second issue regarding information provision. Members noted the difficulties in being able to prove the correct information has been provided. It was agreed that a positive culture was important to ensure patients are provided with information in the correct way.

3.8. One member suggested a change to the Code to require patients to be told specifically about the implications of donating eggs to someone who then may have a successful pregnancy and the patient may not. The group recognised that this could not be required through counselling because counselling cannot be made mandatory, although it was agreed it would be useful to require clinics to discuss the implications of egg sharing with patients and that an implications checklist might be useful.

3.9. Members raised that the guidance is not clear about whether it is acceptable for someone to donate eggs and then for someone else to receive the benefits, for example a family member donating their eggs for their sibling to then receive discounted treatment. It was agreed that there could be further clarification on what constitutes “egg giving” and whether it is permissible for someone to donate and nominate someone else to receive the benefits.

3.10. It was noted that there are many variations within egg sharing arrangements and that this causes confusion about what is allowed. The Chair asked whether it would be useful to have guidance outlining different egg sharing arrangement scenarios and the group was positive about this idea.

3.11. One member suggested that the Code should refer donors to the HFEA to discover whether any children have been born as a result of their donation. There was disagreement over whether it was best for patients to contact their clinic or the HFEA. The Chair agreed to review our guidance.

Obtaining and retaining electronic consent

3.12. The Scientific Policy Officer introduced the topic of electronic consent, explaining how the NHS is moving towards a paperless record system and increasingly clinics are asking if they can use electronic forms.

3.13. Working group members cited caution around the use of electronic signatures due to recent legal cases which have scrutinised consent procedures. One attendee suggested the prevalence of forgeries in current consent practice was already high for consent to storage. The group agreed that the risk of forgery was higher with electronic consent.

3.14. One member of the group raised the point that witnessing is the most key factor in ensuring consent is not forged and this was met with agreement. The current Code of Practice does not require that consent forms be signed and witnessed in a clinic.

3.15. A distinction was made between the method of signing and witnessing. Members did not see an issue with a patient signing a consent form via an iPad in a clinic if it is witnessed by a member of staff. This was considered different to copying an electronic signature.

3.16. One member raised the issue of witnessing consent to storage where the patient is living abroad. One suggestion was to request patients attend a clinic abroad to witness the consent being given, however other attendees felt that this would be too difficult. An alternative suggestion was to distinguish between consent to storage and consent to treatment. Another suggestion was to allow a GP to be a witness. It was agreed that the consent process should be discussed in further detail at the Code of Practice workshops.

3.17. One attendee raised the issue of consent to co-parenting as currently there is no appropriate form for this type of arrangement. Members were advised that clinics should discuss the difference between donating gametes and being treated together and encourage patients to seek legal advice.

Consent to data research

3.18. The Chair introduced the topic of consent to data research. Research has found that consent rates vary hugely across clinics and the project is exploring how patients can be encouraged to consent to data research. Ideas include a patient leaflet and allowing clinics to view their consent rate compared with the national average.

3.19. Members were positive about the idea of a patient leaflet however caution was raised over having a target of 100%. There was disagreement over the idea of showing consent to data research rate for clinics with some attendees fearing it would be made into a competition, and others saying that this information would be useful for clinics. It was clarified that the intention is that clinics will only be able to see their own rate and the national average.

3.20. The group was positive about the idea of the HFEA providing more information to clinics about research projects which have used the register so they can relay examples to patients when discussing consent to data research. The Chair mentioned the possibility of a workshop on data research at the Annual Conference.

3.21. Attendees agreed with the Chair's suggestion that this area of work is more related to information provision rather than changes to the Code of Practice.

Extending storage for gamete providers

3.22. The Policy Manager introduced the topic of extending storage, outlining how current guidance is misinterpreted to allow the extension of storage for gamete providers on the basis of their partner's infertility.

3.23. One suggestion was to have two separate sentences in the guidance; one for extending the storage of embryos, and one for extending storage of gametes.

3.24. Concerns were raised over the increasing number of patients freezing eggs for use in treatment later in life and the difficulty with the 10-year storage limit. However as this is a legal requirement, any change would require a change in the law and this is outside the scope of the working group.

3.25. The Chair explained that a definition of "premature infertility" is not given as it is felt it may be too restrictive, and it was felt best to rely on the expertise of medical professionals. There was disagreement over whether there are grounds to extend the storage of eggs for a woman who is not ready to use her eggs.

3.26. A further point was raised over whether we should be asking patients on their consent form whether they are "prematurely infertility" as this is a medical diagnosis. Attendees noted that often patients will not know whether they are or will be prematurely infertile when they store their gametes.

3.27. Members felt that there should be clarification in the guidance over which medical professionals are eligible to assess a patient as prematurely infertile. Members were also supportive of the idea that professional guidance should be used to inform this guidance.

Implementing the EU Directive on import and export of gametes or embryos

3.28. The purpose of the Directive is to ensure that there are procedures for verifying the standards of quality and safety of gametes and embryos that are imported into the UK from non-EU establishments. The importing relationships will need to be approved by the HFEA and we will also be reviewing consent and compensation requirements for overseas donors.

3.29. Members asked whether it would be possible for the HFEA to approve an importing relationship with an overseas clinic and for that clinic to then export gametes or embryos to any UK clinic. The Chair noted that this would not be acceptable because the HFEA must approve each importing relationship between a specific UK clinic and overseas clinic.

3.30. Members discussed the challenges with ensuring overseas donors have not been paid more than compensation.

3.31. The 10-family limit was raised as an issue for importing gametes and this was cited as a reason for the HFEA to become more involved in assessing overseas clinics before relationships are established.

3.32. The Chair asked the group what they thought about assessing consent for overseas donors. Concerns were raised that forcing overseas clinics to use HFEA consent forms could lead to mistakes or forgeries if the forms are not in the correct language. An alternative suggestion was put forward to allow the UK clinic to check the overseas clinic has a consent process which fulfils the statutory consent requirements. One member asked the group whether UK clinics fill in forms from overseas clinics when exporting gametes or embryos and multiple members said that they do. The Chair suggested that this topic be revisited at the Code of Practice workshops.

Leadership

3.33. The HFEA are focussing on leadership in clinics over the next year which will involve changes to the Code of Practice, particularly Guidance Note 1. The Policy Manager introduced the topic by showing members the framework used by CQC and NHS Improvement in their assessment of whether a service is 'well-led'. Members agreed that the principles within the framework were relevant and could not think of any other aspects of leadership specific to the fertility sector.

3.34. Some members suggested introducing the role of a deputy PR as the Licence Holder is not always present or involved in the running of the clinic.

3.35. Concerns were raised about assessing leadership although clarifying responsibilities is useful. Members were cautious about the idea of introducing any form of mandatory training. However optional training and support was welcomed.

3.36. One member noted the importance of focussing on creating a leadership culture rather than focussing just on the PR. They also mentioned that the work on leadership is an opportunity to help ensure the PR has the leadership authority necessary to perform their responsibilities as reporting arrangements differ in clinics.

3.37. Members asked in what circumstances would someone be deemed unsuitable for the role of PR. The Policy Manager advised members that the PR entry programme test will be reviewed as part of the wider work on leadership.

3.38. The discussion moved onto evidence that a clinic is poorly led. There was general agreement that it is likely to be clear in a clinic if there is not strong leadership because there will be a lack of improvement and continual learning. Some examples could be high levels of OHSS, a low take-up of counselling, a high level of abandoned cycles, repeat incidents and a repeated failure to meet KPIs.

3.39. A further point was raised about whether there is distinction between leadership in NHS clinics and private clinics, with one member from an NHS background highlighting that it is sometimes difficult to find suitable people for the role within the NHS.

3.40. Further discussion focussed on how to assess good leadership and there was agreement that information such as patient feedback and staff feedback could be used to assess leadership in a clinic, although members did recognise the difficulty in obtaining honest feedback from staff employed at the centre.

3.41. One member suggested that further detail could be added to the Code about the duties of the PR, separate from the responsibilities which are legal requirements.

Emotional Support

3.42. It was noted that often it seems like the provision of counselling is a tick box exercise. Members discussed whether this is due to cost for patients and whether it would be useful to understand how many patients should be receiving counselling.

3.43. The Policy Manager suggested that although the guidance note on counselling would be reviewed as part of this work, the project is looking beyond counselling to how patients are treated at different stages within their treatment by different members of clinic staff. One member responded by highlighting how patients respond to people and behaviours differently and it is therefore difficult to have regulations for being supportive.

3.44. The group generally agreed that resources and best practice examples would be helpful, although some members felt strongly that this should not be incorporated into the Code of Practice.

3.45. One member outlined their experience using an app in their clinic which helps monitor the progress of patients throughout their treatment and offers helping strategies, and has been successful in making patients feel supported.

3.46. Members agreed that emotional support is related to the work on leadership. When asked whether there should be someone responsible for looking out for emotional support in a clinic, the group felt that everyone in a clinic has that responsibility. If there was to be someone responsible it would make sense for this to be the PR or someone they delegate to.

3.47. Members agreed that it would be beneficial to require centres to have a strategy for emotional support which includes evaluation of effectiveness by analysing information collected from patients including feedback and complaints. However, the group felt that complaints are not always particularly helpful when assessing emotional support.

3.48. The idea of training and support was viewed positively.

4. Ways of working: SharePoint

4.1. The Policy Manager outlined how SharePoint would be used to share documents going forward and the group was happy with this method.

5. AOB

5.1. The Chair thanked attendees for their participation and concluded the meeting.

The next meeting will be held Wednesday 10th January.

Signature

Name

Hannah Verdin

Date

22nd January 2018