

UK – Human Fertilisation and Embryology Authority
Comments and Observations

Date: 2007-01-15	Document: CWA_2_HFEA.doc
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#	1	2	(3)	4	5	(6)	(7)
	MB ¹	Clause No./ Subclause No./ Annex (e.g. 3.1)	Paragraph/ Figure/Table/ Note (e.g. Table 1)	Type of comment ²	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
1.	GB	3.1	Line 5	ge	It should be clarified that 'human cells or tissues' in the definition of 'donor' is inclusive of donated embryos. It is understood that some countries consider that the Directive does not apply to embryos and that therefore the coding and traceability requirements do not apply to donated embryos.		
2.	GB	4.2.1	Line 20 and 21	ge	The document makes a number of references which are not relevant to Assisted Reproductive Technology (ART). For instance, pool number and split number are not widely used terms. Similarly: <ul style="list-style-type: none"> • single and multi-tissue; • autologous and allogenic; and • living and deceased types of donation are not generally relevant to ART.		
3.	GB	4.3	Line 30 (page 18) Also Clause 13.6.2 (Line 19)	ge	Partner donation (both in-vitro fertilization and intra-uterine insemination) makes up the majority of assisted reproductive treatments in the UK. The definition of 'donor' is inclusive of partner donated gametes (Section 3.1) however in 4.3 and 13.6.2 it is stated that partner donations do not require a code. The latter is consistent with Article 10 of Commission Directive 2006/86/EC. The HFEA supports the exclusion of partner donated reproductive cells from the coding requirements, however this does raise the issue of ensuring traceability of these reproductive cells should they be subsequently donated for the use of others (i.e. non-partner donation) or transferred to another establishment. If it is proposed that all tissues and cells are covered by the coding system (i.e. including partner donated gametes), the HFEA opposes the inclusion of partner donated reproductive cells. The coding and tracing of such samples is not justified on a risk basis and would be burdensome on establishments.		
4.	GB	6.3	Line 15	ge	It is debatable whether the allocation and control of code allocation require central management and a register to		

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					avoid duplication. If each establishment is allocated a unique identifier alongside the country identifier then each establishment could be free to allocate donation IDs. The whole code would be unique given the country identifier combined with the establishment's identifier. Each establishment could ensure that they did not issue duplicate donation IDs. Note that the HFEA would ideally like existing establishment identifiers to be retained as they have been in place for over seventeen years.		
5.	GB	7.1	Line 23	ge	Further to comment #3, the HFEA questions whether the code should be applied at the point of procurement (as currently suggested) or at the point of donation for the use of others (i.e. non-partner donation). While the point of procurement and donation will be the same for many sectors, in the ART sector these may be two separate events. The code may also need to be applied at the point of transfer of the samples, should they be moved between establishments for patient use (without any donation for the use of others having taken place).		
6.	GB	7.2	Line 30	ge	The HFEA notes that the timeline for implementation of the Coding and Traceability System would appear to be unachievable. This is particularly the case if any form of regulation is required or if there are complex administrative/technical requirements.		
7.	GB	7.4	Line 29	te	This section states that maintaining anonymity is essential. While in most instances anonymity should be maintained, it should be noted that different restrictions apply to ART in the UK, and other countries, where anonymity of donors has been removed.		
8.	GB	7.6.3	Lines 5-15	te	The assumption that any establishment complying with the ECD will use computerised technology is somewhat flawed. Most establishments have not adopted computerised systems involving labelling, barcoding or RFID systems. This		

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					<p>may be because there is no conclusive evidence that barcode readers and RFID readers are entirely safe to use in conjunction with egg, sperm and embryo samples.</p> <p>There are a number of establishments in the UK ART sector that do not use computerised systems for record keeping. There has however been widespread adoption of an Electronic Data Interchange (EDI) system to enable rapid data provision to the HFEA Register. Establishments enter information about patient cycles etc so that they are immediately recorded by the HFEA. This could support elements of a coding system however establishments would have to make additional investment if they were required to have label printers, readers and additional software.</p> <p>Regardless of the preferred model, the implementation of a fully electronic coding and traceability system is likely to have significant resource implications for the sector.</p> <p>Any coding model should be able to be read visually and manually applied so that establishments have a choice about whether to implement an electronic system or not. It should be recognised that some ART establishments manage only a few donation events each year and therefore an electronic coding system would be unnecessarily burdensome.</p>		
9.	GB	7.6.7	Lines 28-30	ge	As stated in comment #8, the implementation of a coding system in the UK ART sector will have significant resource implications if it is technology dependant.		
10.	GB	8.2.3	Table 8.4	ge	<p>The consultation results do not reflect the variable opinions and priorities likely in the different tissue and cell sectors. This is due to the limited scope of the consultation.</p> <p>For the ART sector in the UK, low cost implementation is of great importance. Global applicability would however be of very little importance.</p>		
11.	GB	8.3.2.5	Line 25	ge	The HFEA is unclear what the value of the system is to the ART sector and is therefore not prepared to support the		

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					<p>proposition that cost of implementation is a low priority.</p> <p>It would seem that the proposal has not involved extensive involvement of the ART sector and therefore the practical implications for the sector have not been fully considered.</p>		
12.	GB	10.5.2	Line 5 (page 48)	ge	<p>The HFEA charges establishments in the UK a licence fee. The ICCBBA fee would be in addition to this.</p> <p>In the survey conducted by the Workshop financial cost was considered to be a low to medium priority. However, it would be considered to be a higher priority in the ART sector in the UK. This is because the majority of patients self-fund their treatment. A cost-benefit analysis should be carried out to assess the true value of the system over the cost.</p> <p>The HFEA has not recorded a noteworthy number of adverse incidents involving identification of samples or transport of samples. It is therefore unclear what efficiency or benefit the electronic coding system would realise for the ART sector in the UK. A manual system covering the required information, building on existing establishment codes, may be sufficient.</p>		
13.	GB	11.2.1	Line 4 (page 58)	ge	<p>While ISBT 128 is widely used in other sectors, there is no experience of the system or a similar system in ART. It may be useful to gain an insight into how the system would work for ART. This would enable the identification of any issues relevant to its application in assisted conception establishments.</p>		
14.	GB	11.2.1	Line 14	ge	<p>It should be clarified that ICCBAA would not retain information about the donation for which codes are issued. Any provision of information to ICCBAA would raise issues about confidentiality of information under UK legislation.</p>		
15.	GB	11.2.2	Line 20	ge	<p>Option 2 - The HFEA is concerned about the burden on regulators in allocating unique donation identifiers. There would be no significant burden however if establishment's received their own identifier and then allocated donation</p>		

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					<p>identifiers themselves. The HFEA would ideally like existing establishment identifiers to be retained.</p> <p>Coordination of requests for information could be dealt with by maintaining a readily accessible list of establishment identifiers. Enquiries could then be fielded directly by the establishment involved.</p> <p>As noted above, ART establishments in the UK already have unique identifying numbers. These would ideally be retained with the country code differentiating any duplication between Member States. Any requirement to re-allocate establishment numbers would be administratively burdensome and require ongoing cross-referencing of records.</p>		
16.	GB	11.2.3	Line 5-10 (page 59)	ge	Member States could ensure uniqueness of identifiers by allocating establishment identification numbers (the HFEA has already done this) and allowing each establishment to allocate donation identifiers. In the ART sector product identifiers should not be complex or varied.		
17.	GB	13.5	Line 40	ge	<p>It is noted that it is proposed to implement the codes would be implemented based on the Italian Transplant Information System. The practical nature of this system is not discussed however. The HFEA considers that further details about the system and how it would be implemented in Member States should be provided to allow more comprehensive comment.</p> <p>The proposal is largely silent on the traceability requirements that will follow the implementation of the coding system. The coding system and its traceability cannot be divorced from each other. The coding system must be practical and support traceability.</p>		
18.	GB	13.6	Line 20	ge	While it is recognised that labelling is beyond the scope of the Workshop, the HFEA considers this to be a key issue that needs to be addressed (in terms of practicality) prior to a decision being made about the coding system. The HFEA considers that it needs to be determined whether labels (if		

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					required as part of the coding and traceability system) will withstand long-term cryopreservation and physically fit on the straws used to store samples for ART. With the increased use of vitrification in the sector, the label size in relation to the container size may be a key issue.		
19.	GB	13.6.5	Lines 5-10	ge	As noted in 13.6.2, any requirement to retrospectively label ART samples in storage could seriously compromise the sample's viability. The suggestion that samples in storage may be subject to retrospective coding and labelling ignores this risk. Re-labelling by removing samples from storage presents a risk of losing viability if the sample warms. It would also be a administrative burden on establishments. Furthermore, it does not seem to have been conclusively demonstrated that RFID tags and barcodes remain operational after extended periods of cryopreservation. The HFEA is aware of difficulties using RFID tags in cryopreservation.		
20.	GB	13.6.7	Lines 25-30	ge	As noted in comment #8, the requirement to use an electronic based coding system will have significant resource implications for the ART sector in the UK. This is particularly the case given that a number of establishments would have to invest in significant enhancements to current systems. The HFEA also has concerns about the possible requirement for dual labelling during the implementation phase. Implementation at different times in different Member States should be avoided. Dual labelling is onerous and impractical in the ART sector.		

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