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Consultation response to the Department of Health

Review of the Human Fertilisation and Embryology Act: A public consultation

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-partisan, non-religious registered Scottish charity composed of doctors, lawyers, psychologists, ethicists and other professionals from disciplines associated with medical ethics.

The principles to which the Scottish Council on Human Bioethics subscribe are set out in the ***United Nations Universal Declaration of Human Rights*** which was adopted and proclaimed by the UN General Assembly by resolution 217A (lll) on 10 December 1948.

The views presented in the following response were initially drafted by an SCHB working party before being presented to the full 11 member Board of Directors of the SCHB for final comment and approval.

The SCHB is very grateful to the Department of Health of the UK Parliament for this opportunity to respond to the consultation on the Review of the Human Fertilisation and Embryology Act. It welcomes the Committee's intent to promote public consultation, understanding and discussion on this topic.

Questions and proposals for consultation

The model and scope of regulation

1. The Government believes that both the development and use of human reproductive technologies, and their regulation in response to public concerns, should continue to be subject to legislation. (Paragraph 2.7).

The SCHB agrees that the force of law remains justified in the distribution of permissions, rights, responsibilities and prohibitions for the development and use of human reproductive technologies. Law and regulation are necessary to set out a system of public oversight and accountability.

2. On balance, the Government believes that the current model of regulation, whereby Parliament sets the prohibitions and parameters within which an independent statutory authority licenses activities, has worked well and should continue. (Paragraph 2.14).

The SCHB is of the view that the current model of regulation, whereby Parliament sets the prohibitions and parameters within which an independent statutory authority licenses activities, has not worked well and should be tightened.

The Council is of the opinion that the current regulatory model, which provides the HFEA with a large amount of policy-making flexibility, should be replaced with a system which devolves clinical decision-making and technical standards down to patients and professionals while, at the same time, strengthening Parliamentary and ethical oversight.

The SCHB agrees that a Joint Parliamentary Bioethics Committee drawn from both Houses to consider legislation placed before Parliament and to identify inadequacies in existing legislation should be established. The relevant ethical debates will then be undertaken in parliament through a democratic process.

The SCHB concurs that specialist advisory committees could be set up to advise and inform legislators and society. In this regard, the remit of the Human Genetics Commission could be extended to embrace the advisory remit of the HFEA but parliament should continue to develop its consultation process in order to receive advice and information from as many relevant bodies and individuals as possible.

3. However, the Government also accepts that legislation should be more explicit and provide Parliament with greater powers to debate and amend the law. In particular, the Government accepts the need to clarify the extent of any policy-making role of the regulator. (Paragraph 2.15).

The SCHB agrees that legislation should be more explicit and provide Parliament with greater powers to debate and amend the law.

Concerning the balance between legislation prepared by Parliament and regulations which may be established by regulatory authorities or ministers, the SCHB is of the view that the former should take priority, where possible. This is because the drafting of legislation enables all sections of society to take part in the discussions through the parliamentary process.

Where regulations and/or legislation are being considered they should, in so far as possible, anticipate future biological possibilities, even though it may be difficult to determine these developments.

In order to address the problem of possible new developments, legal provisions should state only what is specifically acceptable, thereby prohibiting all other procedures. This will then avoid an enumeration of prohibitions which may, with time, become obsolete, unclear and vague. For example, new UK legislation with respect to reproductive cloning eventually enacted a provision indicating what was acceptable by stating that "A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence" (Section 1 of the Human Reproductive Cloning Act 2001). This was done in order to address misunderstandings resulting from only having prohibitions in existing legislation which did not specifically apply to human cloning.

The SCHB considers that the UK Parliament should ensure that it drafts all-encompassing legislation when preparing laws in the area of human reproduction. This would minimise the issues that would have to be regulated ad hoc by other bodies which may be less representative of society.

In addition, the SCHB is of the view that it would be impractical for the UK Parliament itself to act as a regulatory body. Thus there is a need for a body such as the HFEA to be appointed which has the appropriate expertise to consider the issues that arise. However, this body clearly needs to be accountable to Parliament and an appropriate parliamentary committee should be able to closely monitor any regulatory decisions. The SCHB is also concerned that the present HFEA may have too much power to act, without consultation with Parliament, in the important area of human reproductive technologies.

4. The Government believes that legislation should make clear that all human embryos outside the body are within the scope of regulation and subject to the control of the statutory licensing authority regardless of the manner of their creation. (Paragraph 2.20).

The SCHB agrees that legislation should make clear that all human embryos outside the body are within the scope of regulation and subject to the control of the statutory licensing authority regardless of the manner of their creation.

However, the SCHB does not agree that in establishing an ethical basis for the regulation and legislation of Human Reproductive Technologies, the Warnock Committee's gradualist approach to the status of the embryo is ethically sound.

The SCHB concurs that the precautionary principal should be applied concerning the status of the human embryo. In other words, until explicit scientific proof of the contrary can be provided, a human embryo, as soon as it is created, should be considered as having the same moral status as an adult human person. The Council also notes that it would be inappropriate not to address the debate relating to the moral status of the human embryo in any new enquiry. This is because the debate is crucial to the manner in which many consider the different biomedical procedures. In other words, it is not sufficient to dogmatically maintain that a conclusive and final decision has already been taken concerning this issue. It is because human personhood and dignity are not decided through majority votes that a considerable debate remains concerning the status of the early embryo!

For the same precautionary reasons, the SCHB believes that a definition of an embryo should be given. An example could be: *"The early biological stages in time of a person"*. It also supports the definition of an embryo given in German legislation which indicates that any isolated totipotent cell which may divide and develop into an individual human being, once the necessary further conditions are provided [1], is also an embryo. It would then be up to scientists and society to give evidence that an entity cannot be regarded as an embryo.

The Council notes, in this regard, that the process of human development is a continuous one in which any demarcation would be arbitrary and merely conventional as exemplified by the different upper time limits for abortions and embryological destructive research across Europe. Within the development process it is indeed impossible to indicate a non-arbitrary point of transition from human non-person to human person.

The SCHB agrees that the attempt to define an embryo in the HFE Act has proved counter-productive, but does not accept that any future legislation should resist the temptation to redefine it.

5. The Government considers that the best approach is to define the forms of embryo which may be placed in a woman and in what circumstances, and to regulate other forms of embryo insofar as these are created and used for research. (Paragraph 2.22).

The SCHB agrees that legislation should define the forms of embryo which may be placed in a woman and in what

circumstances and that all other forms of human embryos should not be created in conformity with the Council of Europe Convention on Human Rights and Biomedicine (European Treaty Series - No. 164) [2] which states in Article 18 (2) (Research on embryos in vitro) that:

"The creation of human embryos for research purposes is prohibited."

In addition, the SCHB concurs that the precautionary principal should be applied concerning the status of the human embryo. In other words, until explicit scientific proof of the contrary can be provided, a human embryo, as soon as it is created, should be considered as having the same moral status as an adult human person.

The Council also notes that it would be inappropriate not to address the debate relating to the moral status of the human embryo in any new enquiry. This is because the debate is crucial to the manner in which many consider the different biomedical procedures. In other words, it is not sufficient to dogmatically maintain that a conclusive and final decision has already been taken concerning this issue. It is because human personhood and dignity are not decided through majority votes that a considerable debate remains concerning the status of the early embryo.

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6. The Government proposes that eggs undergoing processes intended to result in the creation of embryos - whether fertilisation or other non-fertilisation processes - should continue to be subject to regulation. (Paragraph 2.27).

The current meaning of embryo also includes human eggs "in the process of fertilisation". This has been criticised on the basis that a unique genetic identity is not formed until the process of fertilisation is complete. However, the SCHB cannot state, without any supporting evidence, that the starting point from which the protection of law should apply is the stage when two cells have formed - generally at around 36 hours.

The SCHB is aware of the desires of biomedical scientists to undertake research or therapy before fertilisation is complete, which currently may be prevented by provisions in the HFE Act that apply to research on embryos. However, the SCHB believes that to remove eggs in the process of fertilisation from the scope of regulation could open up dangerous loopholes and uncertainty.

7. The Government believes that the potential use of artificial gametes raises safety issues and that some uses may also raise ethical concerns. Therefore the Government proposes that the use of artificial gametes in assisted reproduction treatment should not be permitted but that the HFE Act should contain a regulation-making power giving Parliament more flexibility to allow the use of artificial gametes in future should it wish to do so. (Paragraph 2.31).

The SCHB believes that the potential use of artificial gametes raises safety issues in addition to ethical concerns. Therefore the use of artificial gametes in assisted reproduction treatment should not be permitted.

8. The Government seeks views on the extent to which regulation should apply to the use of a couple's "fresh" gametes. Should this be limited to technical and safety issues only or should treatment involving a couple's fresh gametes be subject to the full requirements of the HFE Act where these are relevant? (Paragraph 2.37).

The SCHB is of the opinion that the use of a couple's "fresh" gametes should be subject to the full requirements of the HFE Act where these are relevant and where a third party is involved in the procedure.

9. The Government intends to make the operation of internet services which involve the supply of gametes subject to regulation. Should the law (a) prohibit the operation of such services, (b) regulate the safety and quality aspects of such services, (c) regulate safety and quality and remove any anomalies with other methods of gamete donation? (Paragraph 2.42).

The SCHB is of the opinion that UK law should prohibit the operation of such services.

10. The Government seeks views on whether moving toward the transfer of a single embryo during a treatment cycle should (a) be a matter for legislation, (b) be a matter for the regulator, (c) be a matter

for the professional bodies only. (Paragraph 2.47).

The SCHB is of the view that the specifics of a procedure should be a matter for the regulator in consultation with professional bodies who should uphold best practice.

11. The Government invites views on what, if any, powers the regulator should have in relation to the costs of assisted reproduction treatments provided to private patients. (Paragraph 2.49).

12. The Government invites comments on the desirability of making the regulator's licensing powers more flexible, for instance (a) the ability to licence clinical trials, and (b) explicitly allow training of clinicians and researchers. (Paragraph 2.56).

The SCHB is very concerned with the proposal to make the regulator's licensing powers more flexible. At present, the regulator already has far too many powers.

The SCHB is of the opinion that the current HFEA does not adequately regulate new developments and seems to excessively support applications of technology, without adequate scientific understanding or weight being given to other views and considerations. In this respect, the SCHB notes that the absence of any minority reports often indicates a unanimous decision. This suggests that the composition of the HFEA does not adequately reflect the wide spectrum of views within society. Indeed, many believe that the members of the HFEA are selectively appointed to only represent certain views.

In addition there are conflicts between the HFEA's role as an enforcer of legislation and its duty, as an adviser, to identify flaws in the legislative framework. Thus the regulatory and advisory functions of the HFEA should be separated.

The SCHB agrees that decisions made by the regulator on assisted reproduction and embryo research should be evidence driven. The SCHB believes that certain HFEA decisions could be considered as reckless and irresponsible in the light of the proportionality principle.

Welfare of the child

13. The Government seeks views on whether taking account of the welfare of the child who may be born as a result of treatment and any other child who may be affected should remain an HFE Act *obligation* on persons providing treatment services. (Paragraph 3.19).

The SCHB is of the view that taking account of the welfare of the child who may be born as a result of treatment and any other child who may be affected should remain an HFE Act obligation on persons providing treatment services.

In the normal process of human reproduction, persons will generally decide for themselves the context in which they choose to have a child. They will thus choose their partners, the specific point in time when they want a child etc. However, as soon as a person or couple is prevented from having a child in a 'private' manner because of natural limitations and seeks assistance from the state to overcome these limitations, a discussion is then initiated concerning the conditions set by the public domain with respect to assisted reproduction.

For example, the House of Commons Science and Technology Committee indicated in its report entitled 'Human Reproductive Technologies and the Law' that:

> *"it might be argued that the mere fact of third party involvement is enough to render the behaviour in question public rather than private."[3]*

But the committee then went on to conclude that any prior conditions concerning the creation of a child set by regulations in assisted reproduction are arguably leading to inconsistency and discrimination against certain groups or individuals based on the cause of their infertility rather than on any other ethical basis [4].

The report fails however, to understand that society has always had a moral role in the provision of regulations when help is sought from the public domain. Legislation is indeed generally drafted from ethical principles which are themselves always the reflection of moral beliefs. And in the context of human reproduction, society has accepted that the ethical creation of children should also be based on the welfare of the prospective children and not only to fulfil the wishes of parents. Thus when society is asked (through its healthcare professionals) to assist a person or couple to create a child it then also has an inherent responsibility to make sure that the welfare of the child is taken into account through providing conditions which will protect the child from certain risks or harm.

This is similar to the legislation relating to adoption in the UK in which society has been given responsibility for children and

therefore seeks to provide the best outcome for these children in the consideration of their welfare.

In the Informal Summary of the House of Commons Science and Technology Committee Report it is also indicated that "[r]eproductive freedoms must be balanced against the interests of society but alleged or potential harms to society or to patients need to be demonstrated with evidence before technological developments are prohibited" it then goes on to state that "the HFEA's use of evidence falls short of these ideals" and that the HFEA "has employed an excessive use of the precautionary principle". But the MPs seem to have overlooked the proportionality principle when considering the precautionary principle. The proportionality principle indicates that, in any ethical analysis, the advantages should be examined against the risks (even when only limited evidence for these risks exist). In association with the precautionary principle this means that if any serious risks for the welfare of the future child exist resulting from a procedure in assisted procreation then this procedure should not take place.

In the House Commons report Professor John Harris from Manchester University indicates that *"[t]here are many arguments from many sides, which purport to give reasons for limiting access to reproductive technologies ... There is one reason to reject them all, and that is that they do not point to dangers or harms of sufficient seriousness or sufficient probability or proximity to justify the limitation on human freedom that they require"*.[5]

The SCHB, however, disagrees with this view and notes that there are indeed dangers or harms of sufficient seriousness or sufficient probability or proximity with respect to reproductive procedures which justify the limitation on human freedom. Thus it agrees with Professor Alastair Campbell who argues that when the state and the professions are involved in parenting decisions there is an obligation to avoid harm wherever possible [6]. In other words as soon as the Public Domain is involved in the creation of the child, the state becomes responsible with the parents for the welfare of the prospective child. This is the important difference with respect to couples who conceive naturally in which case the state does not interfere.

The SCHB notes that in the *Human Fertilisation and Embryology Act 1990*, the child's welfare should only be taken into 'account' before treatment is offered with the principle of the child's welfare being rejected as the paramount consideration by MPs and Peers during the passage of the Act through Parliament.

This contrasts with the *Adoption and Children Act 2002*, in which the welfare of the child is considered to be the *'paramount consideration of the court or adoption agency'* when making decisions about the care of a child. In this case, describing welfare as paramount means that all other considerations are of secondary importance to the best interests of the child concerned [7].

The previous HFEA consultation document suggests that the difference in welfare considerations between the two acts relates to the difference between the status of the prospective child in assisted conception, on the one hand, and its status in areas of practice relating to actual children already born for adoption, on the other. For example, it states that in assisted conception the treating clinician must balance the wishes of the prospective parents against the interests of a child who does not yet exist. In other words, the clinician must assess the harm that the child is likely to face if it is born to those patients, based upon what the family circumstances might be once the family is created [8].

But the SCHB takes issue with this analysis and questions the rationality of this argument without having seen any evidence to support this opinion. The relevant question, in this regard, is why do persons want children in the first place. Do they want a child primarily for themselves or do they also want a child for the child's sake?

If parents want children primarily for themselves and seek to obtain these children in order to address personal needs or wishes, then it is indeed difficult to see how any welfare of the child could take priority. Instead the autonomy and the wishes of the persons wanting to have a child would be the main factor in the decision and the interests of the child will always come second.

If, on the other hand, a child is seen as the product of a loving relationship between persons in which the love expands onto the potential child, then the circumstances would be quite different. Indeed, because a loving relationship is also about putting the other person first and making them a priority, then the welfare of the child to be created should be paramount to the prospective parents. In this case, the prospective children would be considered in a similar way to those children being considered for adoption, i.e. their welfare would be paramount and come first.

14. The Government seeks views on whether, if a welfare of the child requirement remains in the HFE Act, compliance with it should be a matter for "good medical practice" and the clinician's judgement, rather than be subject to HFEA guidance and regulation. (Paragraph 3.23).

The SCHB is of the view that if a welfare of the child requirement remains in the HFE Act, compliance with it should be subject to HFEA guidance and regulation and not be a matter for "good medical practice" and the clinician's judgement.

The Council is indeed of the opinion that most GPs are not qualified nor have the experience or expertise to gather the relevant information relating to the prospective child's welfare.

15. If you agree with this, do you think that clinicians should only be required by the legislation to take account of the medical welfare of the child? (Paragraph 3.24).

Whilst affirming that the medical welfare of children is of vital importance, the SCHB does not agree that this should be the only relevant consideration.

16. If a legal obligation to consider the welfare of the child is retained, should it be reformulated to refer to a risk of serious harm? For example, should it specify that treatment should not be provided where the clinician believes there is risk of significant harm? (Paragraph 3.26).

If a legal obligation to consider the welfare of the child is retained then the SCHB is of the opinion that that clinics should be expected to enquire about risk factors provided by the patient, plus follow-up to the GP and other agencies, such as social services, routinely in order to satisfy themselves that there is no foreseeable medical or social risk to the child.

The Council is indeed of the opinion that most GPs are not qualified nor have the experience or expertise to gather the relevant information relating to the prospective child's welfare. The GP's opinion should therefore be complemented with the views of bodies such as the social services.

The SCHB is also of the opinion that clinics should be required to take into account any risk of medical, physical or psychological harm, as well as a range of social factors which might affect a child's welfare. These social factors might include the age and health of the prospective parent(s), the stability of the family environment, the child's need for a father and the mother's ability to meet the child's needs.

17. Do you think that the requirement to take account of "the need of the child for a father", as part of considering the welfare of the child, should be removed from the Act? Alternatively, do you think that it should be replaced with "the need of the child for a father and a mother"? (Paragraph 3.32).

The SCHB is of the view that the requirement to take account of "the need of the child for a father", as part of considering the welfare of the child, should be replaced with "the need of the child for a father and a mother" in the new legislation.

The SCHB notes that in the recent HFEA consultation document, it is indicated that [9]:

> *"Studies conducted over the past decade suggest that, despite initial concerns, children born to lesbian couples compare well with other assisted conception children in terms of emotional, behavioural and gender development."*

However, the SCHB notes that such a statement could lead to misconceptions since it is not because children born to lesbian couples compare well, psychologically, with other assisted conception children that there will not be any possible complications in the future. The studies undertaken so far are incomplete and have often only examined pre-adolescent children. These may not be as concerned about their identity or their family circumstances as when they grow older. It is possible that these children may only become aware of any psychological problems when they become adults or consider having children of their own later on in life.

In addition, the previous quote from the HFEA consultation may be misguided since the Department of Health's consultation document itself indicated that: *"research shows that children brought up in one parent families tend to score worse on a range of indices than children brought up by a mother and a father."*[10]

The SCHB notes that the need of a child for a father mentioned in Section 13, paragraph 5 of the *Human Fertilisation and Embryology Act 1990* was generally replaced and 'watered-down' in the Code of Practice with the need for 'persons' or 'partners' which is not indicative of any specific male gender. This is unfortunate since the indications enacted by the representatives of the general public in the Westminster Parliament do not seem to have been respected by the HFEA Code of Practice.

As a result, the SCHB was concerned about the undemocratic manner in which the Code of Practice was being drafted. Indeed, Section 26 (3) of the Human Fertilisation and Embryology Act 1990 indicates that:

> *Before preparing any draft, the Authority shall consult such persons as the Secretary of State may require it to consult and such other persons (if any) as it considers appropriate.*

But who were these persons who were consulted? Was a broad public or stakeholder consultation undertaken before the preparation of the different editions of the Code of Practice? If this was not undertaken, then the Code of Practice cannot really reflect the democratic will of the people in the UK.

The use and storage of gametes and embryos

18. The Government believes that on balance, the HFE Act's existing requirements for written consent remain proportionate and appropriate, and provide a valuable protection of the wishes of patients and donors. Do you agree? (Paragraph 4.10).

The SCHB agrees that the HFE Act's requirements for written consent should remain proportionate and appropriate, and provide a valuable protection of the wishes of patients and donors.

19. Should the requirement for *written* consent be extended to apply to all assisted conception treatments provided in licensed clinics, including treatment using a couple's own 'fresh' gametes such as IUI and GIFT? (Paragraph 4.11).

The SCHB is of the view that written consent should be extended to apply to all treatments provided in licensed clinics. This would ensure that actors have thought through the procedures and their possible consequences in an appropriate manner.

20. The Government proposes that the law should allow the *storage* of gametes without the consent of a person lacking capacity where the gametes were lawfully removed. Do you agree? (Paragraph 4.16).

In the case of an individual lacking the capacity to make a decision, an intervention should only be carried out with the authorisation of the individual's representative, or an authority or a person or body provided for by law.

21. The Government proposes that a person's gametes stored in these circumstances may only be *used* with the consent of that person. Do you agree? (Paragraph 4.17).

The SCHB agrees that a person's gametes stored in these circumstances may only be used with the consent of that person.

22. The Government invites views on whether the law should be changed to require the withdrawal of the consent of *both* parties whose gametes were used to create an embryo in order to allow a stored embryo to perish, and that such an embryo should otherwise continue in storage until the statutory maximum storage period is reached. (Paragraph 4.21).

The SCHB notes that patients should be asked to think about what they want to do with their potential leftover embryos before they are created. This is in agreement with Dr Richard Kennedy, secretary of the British Fertility Society and consultant gynaecologist at the Centre for Reproductive Medicine in Coventry, who indicated that *"it would be helpful to raise the issue of 'what will you do with these embryos?' before they are created."*[11]

The SCHB is of the view that an embryo belongs to both parties whose gametes were used to create an embryo. Both parties are therefore responsible for the embryo. Where possible, the continued existence of a frozen embryo should be preferred over destruction.

The SCHB is also surprised that the Government seems to consider that the alternative to implantation is to leave the embryo to perish when other solutions such as embryo adoption can be examined.

Concerning the creation of human embryos *in vitro*, the SCHB notes that in countries such as Germany, Austria, Italy and Ireland it is considered unethical to create human embryos *in vitro* if they are not immediately implanted into the mother. This happens in order to avoid the difficult problem, which exists in the UK, of having an ever increasing stock of frozen, unwanted and supernumerary embryos generally destined for destruction.

The SCHB recognises that even though an unacceptable large number of stored embryos does unfortunately exist in the UK, it would be preferable for these embryos to be given for adoption instead of being destroyed. Though some of the problems relating to the important biological 'bonds' that should exist between parents and children do not exist in this case, the adoption of embryos, in a similar way as the adoption of children, is a very positive solution to an already existing difficult situation. This is in contrast to *creating* difficulties in kinship identities and the related biological 'bonds' which is what is happening in donor insemination.

The SCHB would thus like to encourage the adoption by infertile couples of supernumerary embryos [12].

23. Do you think that the law should continue to set statutory maximum storage periods for gametes and embryos and if so how should these be determined? (Paragraph 4.25).

The SCHB is of the opinion that supernumerary embryos should not be created and that couples should be appropriately counselled concerning the use and destiny of their embryos before they are created.

24. If you think that the law should continue to set statutory maximum storage limits, should the storage limits for donation be brought into line with the storage periods for treatment? (Paragraph 4.26).

25. The Government invites views on whether the requirement on licensed centres to provide "such relevant information as is proper" should remain a legal requirement. (Paragraph 4.35).

The SCHB is of the opinion that licensed centres should have a legal requirement to provide "such relevant information as is proper".

26. If so, should that requirement be extended to require clinics to be specific about which treatments they provide are outside the National Institute for Clinical Excellence's clinical guideline on infertility treatment? (Paragraph 4.36).

The SCHB is of the view that clinics should be specific about which treatments they provide and which are outside the National Institute for Clinical Excellence's clinical guideline on infertility treatment.

27. The Government invites views on whether the requirement on licensed centres to offer a suitable opportunity to receive counselling should remain a legal obligation. (Paragraph 4.40).

The SCHB is of the view that the requirement on licensed centres to offer a suitable opportunity to receive counselling should remain a legal obligation.

28. Alternatively, should the legal requirement to offer a suitable opportunity to receive counselling apply only in the case of treatment involving donated gametes and embryos? (Paragraph 4.41).

The SCHB is of the view that the requirement on licensed centres to offer a suitable opportunity to receive counselling should remain a legal obligation for all procedures.

29. The Government invites views on whether the appropriate level of compensation for donors should be set by the regulator or by Parliament by means of regulations, rather than by the HFEA as now. (Paragraph 4.45).

The SCHB is of the view that appropriate levels of compensation should be set by Parliament by means of regulation. This would enable a democratic decision to take place which would not be possible with the HFEA.

The SCHB notes that the following national and international legal instruments have addressed the topic of compensation in the context of the donation of human organs, tissue and cells:

European Union - Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [13],[14]

Article 12 *(Principles governing tissue and cell donation), paragraph 1:*

> *Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells. Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted.*

Council of Europe - Additional Protocol to the European Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of human origin (ETS No. 186) [15],[16]

Article 21 *(Prohibition of financial gain), paragraph 1:*

> *The human body and its parts shall not, as such, give rise to financial gain or comparable advantage.*
>
> *The aforementioned provision shall not prevent payments which do not constitute a financial gain or a comparable advantage, in particular:*

- compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations;

- payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;

Thus, the SCHB notes that, in the light and in the spirit of what is mentioned above, there should never be any risk of a donation taking place (even once) as a result of compensation being considered by a person as a financial incentive. In other words, no compensation should ever be given to a donor if he or she can perceive this compensation as a financial incentive to donate. Accordingly, the SCHB believes that in order to ensure that a compensation is never seen as an incentive to donate cells, it is important to prohibit all payments other than the reimbursement of necessary and verifiable expenses and loss of earnings. In other words, no fixed sum should be considered. This means that, in a similar manner to the donation of blood in the UK, no compensation for inconvenience should be considered in the donation of human cells.

Relationships between children resulting from donor gametes and their parents

1. In addressing the issues raised by the regulation of donor-assisted conception, the SCHB believes that it is very important to examine the deep bonds that exist between parents and their offspring. For example, many parents, as the responsible partners in the creation of life, know that in some way they belong to the child and the child in receiving life belongs to them i.e. there exists a sort of mutual belonging. The deep sense of loss or incompleteness felt by parents, unable to be directly responsible for the creation of life in their child, is the essential reason for their interest in assisted reproduction as opposed to, for example, adoption. In other words, the costly and sensitive procedures considered by all families seeking artificial conception are a pointer to the importance they attach to the biology of creation. They apprehend the possibility of their own inability to feel a sense of belonging with the child and the difficulties the child itself may experience in feeling that it did not belong to them.

2. This apprehension is also reflected in published reports which suggest, for example, that when Assisted Insemination by Donor (AID) has been used, the commissioning (non-genetic) father is significantly more reticent than the commissioning (genetic) mother of informing the child of its biological origins. Moreover, it has been indicated that only 21% of AID parents, in the Netherlands, have decided to inform their child of the way in which they were conceived compared to 94% of parents who have not used AID [17].

More recently, researchers found that in 46 families in England with a child up to age of 8 who had been conceived through sperm donation only 13% had already told their child and 26 % said they intended to. But 43 % had decided against it and 17 % were still unsure what they would do [18],[19]. And an earlier European study of donor insemination families in the UK, Italy, the Netherlands and Spain found that only 12% of the mothers had planned to tell the child about his or her conception procedure, while 75% had decided not to do so. By the time the children reached 11-12 years old, only 8.6% of parents had told their children about their conception procedure [20]. This is all the more worrying since 50% of donor insemination children suspect, when growing up, that their social father may not be their genetic one before being told [21].

But why do so few parents inform their children of the manner in which they were conceived? An answer may be found when the deep and important bonds which exist between the parents and their child are considered.

Other perspectives of the strength of the parent-child bond can be noted in the following examples:

3. The dilemma faced by the two women Natallie Evans and Lorraine Hadley who lost their High Court battle, in 2003, to use the frozen embryos created with the help of their former but now estranged partners against their will [22]. It was, indeed, very clear to all that one of the main reasons why both men had refused to give permission was that they felt that some kind of bond would exist between them and the child which they did not want.

4. The assumed strength of the biological parent-child bonds which is reflected in the fears that many gamete donors have concerning the lifting of anonymity. For example, 90 % of UK clinics are already reporting a shortage of donors, and fertility experts expect the situation to get worse since April 2005, when donors lost their right to anonymity [23].

5. Recent research results which show that more than four out of five US children conceived using donor insemination with an identifiable sperm donor would be likely to ask the identity of their donor and try to contact him. This would happen either when that information was available to them at the age of 18 or sometime later in their lives. Many said that they would also like to contact any other children of the donor [24]. But why do they want this contact?

6. The fact that UK clinics are expected to strive, as far as possible, to match the ethnic background and physical characteristics of gamete donors to those of an infertile partner; thus, in a way, making sure that the possible child is seen (in a visual sense) to 'belong' to its parents.[25] In this regard, Olivia Montuschi from the Donor Conception Network, which represents families of children conceived after sperm or egg donations, insisted that it was vital for children to share physical characteristics with their parents. She also indicated that *"If a child is significantly different in any way, either in physical characteristics or intellectual attainment, then it can make it harder for them to feel part of that family"*[26]. But why is it so important that children feel part of the family? Does this not reflect a deep sense of bonding or communality which

should exist between the biological parents and the child?

7. The extremes to which some persons, such as Mr. David Blunkett, will go in order to prove their paternity over a child. But what, exactly, do these people feel towards the child they claim is 'theirs' and why do they go to such lengths? Moreover, it is interesting to note that, in Mr. Blunkett's case, the judge indicated that it was in the child's best interests to have his parentage determined at the earliest opportunity by a court ordering scientific tests [27].

8. The more than 116,000 frozen human embryos that are presently stored in UK clinics resulting from IVF. This has arisen because parents may [28],[29]:

(1) want to implant these embryos at a later date into the biological mother,

(2) be unsure of the moral status of these human embryos and therefore not want to see them destroyed either outright or in research,

(3) not want to give these embryos up for adoption because of the 'bonds' that exists between them and the embryos. In the UK, despite the high number of left-over embryos, only around 190 embryos/year are donated to infertile couples who cannot create their own [30].

In this respect, Professor Ian Craft, director of the London Fertility Centre, said: *"It surprises me that so few couples agree to donate spare embryos if you consider the desperation of infertile couples to have children."* Adding that *"there are very few babies to adopt and so I would have thought these couples, who have been through infertility treatment themselves and who have completed their families, would be more sympathetic to others".* He also indicated that society should be making people more aware of the benefits that these supernumerary embryos may represent to childless couples [31].

Concerns of the SCHB relating to Donor-Assisted Conception

1. The SCHB notes that Donor-Assisted Conception is not risk free for the woman giving the eggs since many eggs must be retrieved from female patients and this is not without the risks of ovarian hyperstimulation syndrome following aggressive hormonal treatments [32].

2. It remains the Council's concern that some media-highlighted cases of obvious gamete insemination and embryo implantation errors have taken place. This has arisen when obvious racial differences were noticed. It is not known how often other true mistakes have occurred when racial characteristics were not present.

3. The SCHB notes that parents who use donor insemination are often bringing a child into the world in order for him or her to relate to themselves while often ignoring the relationship the child may want to have with his or her genetic parents. Though the parents may concede to tell their child the truth when they are older, they would then have to understand that the child may wish to see and know his or her genetic parents and express a sort of a 'love' which he or she may already experience. The child may also experience difficulties towards his or her genetic or social parents with the possibility of feeling a sense of rejection.

4. The SCHB is, therefore, of the opinion that until the above questions are answered satisfactorily concerning:

(1) the important bonds that exist between the biological parents and the child, and

(2) the unease the general population has concerning donor insemination,

then the possibility of promoting donated gametes in order to address infertility should not be envisaged. Accordingly, the SCHB cannot reply to the other questions posed by the this consultation without undermining its stance that such procedures should not proceed until further investigations are undertaken and the serious doubts concerning these procedures are addressed.

30. The Government invites views on whether payments for the supply of gametes (other than compensation for expenses or inconvenience) should be prohibited in all circumstances, including research that is currently outside the scope of the HFE Act. (Paragraph 4.47).

The SCHB is of the view that payments of any kind or form for the supply of human biological cells should be prohibited in all circumstances, including research that is currently outside the scope of the HFE Act.

Reproductive choices: screening and selection

31. The Government invites views on whether legislation should set out the general criteria under which embryo screening and selection can be undertaken. If so, what should those general criteria be?

(Paragraph 5.19).

The SCHB is of the opinion that embryo screening and selection result in the following concerns:

EUGENIC TRENDS

The SCHB is of the view that new developments in human reproductive procedures are very likely to result in eugenic consequences or lead to eugenic trends. Furthermore, it is of the opinion that eugenics, defined as *"the science of improving stock, not only by judicious mating, but by whatever tends to give the more suitable races or strains of blood, a better chance of prevailing over the less suitable"* [33] is associated with a number of very serious ethical concerns. These are:

1. The destruction of embryos or foetuses

The first serious ethical concern, that may be associated with eugenics, is the methodology in which the selecting-out of disorders is undertaken. Prenatal screening for diagnosis of potential disorders lends itself to limited management i.e. selecting out via destruction of any affected embryo or foetus. This procedure creates serious ethical problems for the people who believe that a human embryo or foetus has the same moral status as a person who is born alive. For this section of the general public the act of willingly terminating an innocent human life undermines human dignity to such an extent that the act becomes unacceptable.

For those, on the other hand, who believe that an embryo or foetus does not have the same moral status as a person who is born alive, there are probably less ethical problems in this respect.

2. The possible discrimination against persons with genetic disorders

The second ethical problem, which may arise with eugenic selection, relates to the possible undermining of the social acceptability of genetic disorders and/or disability. In other words, eugenic selections may encourage a perspective of discrimination towards those who are not 'up to standard' or who are not as good or as capable as others in certain aspects. Our world is a competitive one and it is often difficult for governments or other bodies to address any possible discrimination that may arise because of a perceived weakness on the part of an individual.

Egalitarian anxieties do have a genuine basis: a society divided between those possessing enhanced abilities as a result of eugenic selection and those conceived naturally with the ordinary range of abilities might well develop consequential divisions which make life more difficult for ordinary people. But much depends on the assumed social and political context. If a democratic context exists, whereby political institutions and culture are organised in such a way that the public as a whole, and in particular those who are less talented, benefit from the exceptional abilities of a few especially talented individuals, then there may be no good reasons for thinking that things will get worse with eugenic selections. On the other hand, if society is considered as one in which a talented elite enjoy their good fortune and privileges without any commensurate benefits for the rest of society, then there is no reason to believe that the latter should welcome the creation of a larger and correspondingly more powerful elite [34].

3. The lack of the parent-child bond

Another concern with eugenics would arise if one or both parental gametes were not used to create a desired embryo. This would happen, for example, if a couple used donated sperm (or a donated cell nucleus in the case of cloning) to improve the biological 'quality' of the embryo or the future child. A 'quality' that the parents believe would not be present if they just used their own gametes or cells.

But this gives rise to serious consequences with regard to the relationship which exists between the child and his or her parents. Indeed, many parents, as the responsible partners in the creation of life, know that in some way they belong to the child and the child in receiving life belongs to them. As already mentioned, the deep sense of loss or incompleteness felt by parents, unable to be directly responsible for the creation of life in their child, is the essential reason for their interest in assisted reproduction as opposed to, for example, adoption. In other words, the costly and sensitive procedures considered by all families seeking artificial conception are a pointer to the importance they attach to the biology of creation. They apprehend the possibility of their own inability to feel a sense of belonging with the child and the difficulties the child itself would experience in feeling that it did not belong to them. In other words, the establishment of such bonds of mutual belonging between the parent and the child are seen as being extremely important. Indeed the idea that blood ties (or gene bonds) are unbreakable, no matter what happens in a family or between parents and children, is often present in the security people obtain from these ties.

4. The lack of unconditional acceptance

An intuitive objection to eugenic selection is that it 'interferes with nature'. Thus the 'conservative' opponents to eugenics will argue that the kind of interference involved in selection undermines the proper relationship between the parents and their child. In other words, by inviting parents to exercise their preferences in making a selection, one introduces an element of

control over the result of conception, which makes the experience of parenthood very different from the current situation. At present and in the majority of cases, parents are content to just accept their children as they are. Because there is no possibility of choice, there is therefore no possibility of regret and unconditional acceptance is sustained [35]. The parents are also not under any pressure to make a choice which they can later regret.

For example, when adults 'fall in love', they exercise some degree of choice in selecting their partner, i.e. the person they love. But adults can also regret the choice they have made and seek to terminate the relationship. Parental love for children, on the other hand, does not include a similar element of choice. If it did the whole relationship between the parents and the child could be undermined [36]. This is also reflected in that, at present, parents accept their children as they are in an attitude of 'natural humility' or unconditional acceptance. This attitude is an important feature of parental love, the love that parents owe to their children as individuals in their own right; for this is a love that does not have to be earned and is not dependent on a child having characteristics that the parents hoped for. In the future, it is the very existence of new procedures in medically assisted procreation that will provide parents with a choice and therefore, undermine this unconditional acceptance.

Moreover, if eugenic decisions were to be made by parents, it is very probable that they would find it difficult to make 'cold' and theoretical decisions which may be in agreement with their real feelings and desires. Indeed, the final decisions may be very different from the ones they thought they would make since parents may choose to conform to societal pressures and decide for increasing amounts of selection.

PRE-IMPLANTATION GENETIC DIAGNOSIS

Because the definition of an embryo as well as its legal status are so dissimilar between countries, the SCHB would like to note that very different legislations in Europe have been developed concerning Preimplantation Genetic Diagnosis (PGD). These different legislations also reflect the reality that only a limited amount of scientific information is currently available concerning the 'potency' of human totipotent cell(s) taken from the embryo in PGD. These are then used (and thereby destroyed in the process) to test the 'quality' of the original embryo.

But though no consensus regarding the exact ethical nature of totipotent cells has yet been reached internationally, the fact that these differences exist when considering PGD has frequently been overlooked in some countries. For example, in the UK, there has often been a nearly unanimous acceptance by scientists and the general public that the moral status of totipotent cells used for PGD has finally been resolved after the 1990 Act. But this is unfortunate since it must be remembered that UK legislation was decided through the means of democratic votes and not after any unanimous scientific demonstration which everyone could accept. Indeed, an increasing number of persons in the UK remain uncertain as to whether the right decisions were made at all [37].

In summary, as long as our whole scientific and ethical decision making process continues to be based on democratic majorities rather than on rational and logical demonstrations, politicians, scientists, healthcare professionals and many amongst the general public will remain uneasy as to what is really being considered. Because of this, legislation with respect to totipotent cells should never be seen as being built on unquestionable solid foundations to be used for future discussions concerning embryological research. Instead it should simply be considered as the views of the majority at the time which could prove to be inappropriate when further results and understandings of the biological process are defined.

The SCHB is thus of the opinion that appropriate and responsible discussions relating to the ethical perspective of prenatal screening should not only be limited to the medical practices in the UK. This is because the UK cannot be considered as being the repository of the right unquestionable ethical standards. What may be considered as ethical in the UK by relevant bodies may be considered as completely unacceptable and even as a criminal offence in other European countries.

THE COMPLEXITY OF GENETIC TESTING

The SCHB notes that the probability of being able to select for children with certain characteristics is very much overestimated. Very few personal characteristics are regulated by a single gene with most of them being multifactorial i.e. determined by the joint effect of many genes and environmental factors: in particular aspects such as height, weight and intelligence. Therefore, the SCHB is concerned that attempts to select for a child with attributes like these may fail with the resultant child being put at risk.

EUROPEAN CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE

Finally, The SCHB would like to see the UK sign and ratify the European Convention on Human Rights and Biomedicine which has already been signed by 31 and ratified by 19 Council of Europe Member States. If this is not done, the reputation of the UK abroad in the field of biomedical ethics would be seriously undermined.

32. Do you think that there should be a prohibition on deliberately screening *in*, or selecting *for* impairments and disabilities - as opposed to screening *out*, or selecting against? (Paragraph 5.20).

See answer to question 31. As soon as a third party (such as the stated) is asked to be involved in medically assisted procreation, this third party then has responsibilities in the creation process of the prospective child. If this third party considers that the creation process or outcome is irresponsible, this party should then not assist in the procedure.

33. Should the particular uses of embryo screening and selection remain a matter for decision and licensing by a statutory regulator in accordance with the general criteria set by Parliament? (Paragraph 5.21).

See answer to question 31. Furthermore the views of those directly being selected against should be taken into account.

34. Alternatively, should the particular uses of embryo screening and selection be a matter for patients and clinicians, within the legal limits set by Parliament? (Paragraph 5.22).

See answer to question 31. Furthermore the views of those directly being selected against should be taken into account. Parliament should be able to regulate Medically Assisted Procreation more directly.

35. What are your views on the regulation of PGD with tissue typing? Should the legislation set out criteria under which this should be allowed? If so what should they be? Beyond that should particular uses need to be approved by the regulator - or should patients with their clinicians be free to make their own decisions? (Paragraph 5.23).

The SCHB notes that recent trends giving ever more choice in the field of reproductive technologies have also increased the number of embryos and foetuses being destroyed. For example, with PGD a number of embryos are created with only a few being selected and implanted (or frozen) resulting in a significant number of embryos being considered as 'waste'. Such a development took place in the case of the Hashmi couple, who fought for the right to have a tissue-matched IVF baby to save the life of their older son. In this case, six IVF cycles were undertaken and a significant number of embryos created but without any success [38]. In the same way, the SCHB is very concerned that PGD may enable parents, in the future, to enter into a kind of 'embryonic creation and destruction relentlessness', whereby ever more embryos are created and destroyed with the aim of saving the life of one of their existing children.

36. The Government invites views on what statutory controls, if any, should apply to the screening and selection of gametes. (Paragraph 5.27).

See answer to question 31. Furthermore the views of those directly being selected against should be taken into account. As soon as a third party is involved, regulation is necessary in the field of medically assisted procreation.

37. The Government seeks views on sex selection for non-medical reasons. In particular, should this be banned? Or should people be allowed to use sex selection techniques for family balancing purposes as the Science and Technology Committee suggest? If so, how many children of one gender should a couple already have before being allowed to use sex selection techniques to try for a child of the other gender? (Paragraph 5.32).

An intuitive objection to sex selection is that it 'interferes with nature'. Thus the 'conservative' opponents to sex selection will argue that the kind of interference involved in selection undermines the proper relationship between the parents and their child. In other words, by inviting parents to exercise their preferences in making a selection, one introduces an element of control over the result of conception, which makes the experience of parenthood very different from the current situation. At present and in the majority of cases, parents are content to just accept their children as they are. Because there is no possibility of choice, there is therefore no possibility of regret and unconditional acceptance is sustained [39]. The parents are also not under any pressure to make a choice which they can later regret.

This is also reflected in that, at present, parents accept their children as they are in an attitude of 'natural humility' or unconditional acceptance. This attitude is an important feature of parental love, the love that parents owe to their children as individuals in their own right; for this is a love that does not have to be earned and is not dependent on a child having characteristics that the parents hoped for. In the future, it is the very existence of new procedures in medically assisted procreation that will provide parents with a choice and therefore, undermine this unconditional acceptance.

Moreover, if sex selection decisions were to be made by parents, it is very probable that they would find it difficult to make 'cold' and theoretical decisions which may be in agreement with their real feelings and desires. Indeed, the final decisions may be very different from the ones they thought they would make since parents may choose to conform to societal pressures.

38. The Government proposes that the prohibition in the HFE Act on genetic modification of embryos for reproductive purposes should continue and be extended to gametes used in treatment. We invite views as to whether the legislation should include a power for Parliament to relax this ban through regulations (rather than primary legislation) if assured of safety and efficacy. (Paragraph 5.38).

The SCHB is of the view that the current ban should be maintained due to serious but unpredictable risks of random insertional mutagenesis and inevitable lack of consent on the part of affected individuals. Any envisaged change in the law should be left to Parliament only after consideration of overwhelming evidence from exhaustive animal studies that risks had been completely eliminated. Leaving such a decision open to regulation by an unelected body carries the grave risk that such a change in policy would be made prematurely and in the absence of sufficient evidence.

Information and the HFEA Register

39. The Government believes that it is essential to maintain a central register of donor treatment to which donor-conceived people can have access for information about their donor, and to find out if they are related to someone they intend to marry. Do you agree? (Paragraph 6.14).

Whilst opposing donor assisted conception, the SCHB agrees with the above statement.

40. The Government invites views on whether people should be able to obtain information about whether they were donor-conceived and about their donor (including identifying information where lawful) from the age of 16 rather than, as now, from the age of 18. (Paragraph 6.18).

Whilst opposing donor assisted conception, the SCHB agrees that people should be able to obtain information about whether they were donor-conceived and about their donor (including identifying information where lawful) from the age of 16 rather than, as now, from the age of 18.

41. The Government proposes to enable donor-conceived people to access information to discover whether they are related to someone with whom they intend to form a civil partnership, and would welcome comments. (Paragraph 6.20).

Whilst opposing donor assisted conception, the SCHB agrees that donor-conceived people should be able to access information to discover whether they are related to someone with whom they intend to have children.

42. The Government invites views on whether the law should specify what non-identifying information about offspring can be released to gamete and embryo donors. (Paragraph 6.23).

Whilst opposing donor assisted conception, the SCHB agrees that non-identifying information about offspring could be released.

43. The Government seeks views on whether donor-conceived people should be able to access information about their donor-conceived siblings (where applicable). If so should this be limited to non-identifying information? (Paragraph 6.25).

Whilst opposing donor assisted conception, the SCHB agrees that donor-conceived people should be able to access information about their donor-conceived siblings (where applicable).

44. Should the natural children of donors be able to access information about their donor-conceived siblings (where applicable) and vice-versa? If so should this be limited to non-identifying information? (Paragraph 6.26).

Whilst opposing donor assisted conception, the SCHB agrees that natural children of donors should be able to access information about their donor-conceived siblings and vice-versa. This information should include identifiable details.

45. The Government seeks views on what measures would be appropriate, if any, to ensure that parents tell children conceived through gamete or embryo donation that they are donor-conceived? (Paragraph 6.31).

The SCHB is of the opinion that any element of secrecy in conception is detrimental to the relationships between (1) members of a couple and (2) the parents and the child.

46. The Government invites views on whether, in future, the HFEA's data register should continue to record and publish information on all licensed treatments including outcome data (where it is satisfied that they are not misleading). (Paragraph 6.39).

The SCHB is of the view that the HFEA's data register should continue to record and publish information on all licensed treatments including outcome data (where it is satisfied that they are not misleading).

47. If the HFEA's data register is to continue to collect information on all licensed treatments, should the dataset be expanded to facilitate more effective follow-up research? (Paragraph 6.40).

The SCHB agrees that more effective follow-up research should be facilitated as definitive conclusions are unavailable regarding the long-term medical or sociological consequences of many current practices.

48. Alternatively, if the HFEA's data register is to be restricted to information on licensed treatments involving donated gametes or embryos, should licensed clinics be required to maintain local databases of additional information for research? (Paragraph 6.41).

The SCHB agrees that restricting the HFEA's data register to treatments involving donated gametes and embryos would not provide a suitable control group with which comparisons regarding the effects of donation might be made.

49. The Government proposes that the confidentiality provisions of the HFE Act should be revised so that information about assisted reproduction treatment is treated in the same way as other medical information and subject to the same safeguards. Do you agree? (Paragraph 6.44).

The SCHB agrees that that the confidentiality provisions of the HFE Act should be revised so that information about assisted reproduction treatment is treated in the same way as other medical information and subject to the same safeguards. However, the law does allow exceptions to exist. For example, donor anonymity has now been lifted.

Surrogacy

50. The Government invites views on what, if any, changes are needed to the law and regulation as it relates to surrogacy. (Paragraph 7.17).

In agreement with a number of other countries in Europe, the SCHB is of the opinion that surrogacy should be prohibited because of the grave psychological and social risks that may be created by such a procedure. These include psychological and social risks for (1) the comissioning parents, (2) the surrogate mother, her eventual partner and existing children in addition to (3) the child created.

51. If changes to the law and regulation on surrogacy are necessary, do the recommendations of the 'Brazier Report' represent the best way forward? (Paragraph 7.18).

See answer to question 50.

52. If changes to the law and regulation on surrogacy are necessary, should they be taken forward as part of the review of the HFE Act, or in separate legislation? (Paragraph 7.19).

The SCHB is of the view that surrogacy arrangements should be prohibited as part of the review of the HFE Act.

Status and legal parenthood

53. The Government invites views as to whether the HFE Act should treat an unmarried man as the father of a child resulting from treatment in the same way it treats a married man. If so, how would this be achieved given that there is no legal definition of an unmarried couple? (Paragraph 8.16).

The SCHB opposes the use of medically assisted procreation for unmarried men. Marriage is also a sign of responsible commitment towards the prospective child.

54. Should a court be able to make a parental order in favour of unmarried as well as married couples in surrogacy cases? (Paragraph 8.18).

The SCHB is of the view that surrogacy arrangements should be prohibited as part of the review of the HFE Act.

55. The Government seeks views on whether:

- **a court should be able to make a parental order (following surrogacy) in favour of civil partners, subject to the same rules and requirements that apply to married couples**
- **where one of the civil partners carries a child as the result of assisted reproduction treatment, the other civil partner should be treated in law as the parent of the child in line with married couples. (Paragraph 8.22).**

The SCHB is of the view that surrogacy arrangements should be prohibited as part of the review of the HFE Act.

56. The Government seeks views on whether the status and legal parenthood provisions in the HFE Act should apply to same-sex couples who do not form a civil partnership. If so, how would any automatic recognition of parenthood be achieved given the lack of legal ties between the couple? (Paragraph 8.24).

In the absence of legal ties, a lack of evidence regarding the commitment of a partner to another may constitute a similar lack of evidence regarding his or her commitment to parenthood.

Research

57. In common with the Science and Technology Committee, the Government believes that there is no case at present for either an extension or a reduction to the 14 day time limit for keeping an embryo. Any change would remain a matter for Parliament. (Paragraph 9.15).

The SCHB notes that UK legislation concerning embryo research is generally a lot more liberal than elsewhere in the world and that it would be highly desirable for UK legislation to encompass relevant international declarations and conventions. In this regard, the SCHB is of the opinion that possible new legislation in the UK relating to Human Fertilisation and Embryology should be amended so that it becomes compliant with the following provisions of international declarations, legislation and regulation:

United Nations Educational, Scientific and Cultural Organization:

- The draft Universal Declaration on Bioethics (currently being prepared by UNESCO)

- The Universal Declaration on the Human Genome and Human Rights [40]

- The International Declaration on Human Genetic Data [41]

Council of Europe

- Convention on Human Rights and Biomedicine (European Treaty Series - No. 164) [42] : Article 18 (2) (Research on embryos in vitro) which states that:

> *"The creation of human embryos for research purposes is prohibited."*

- Additional Protocol on the Prohibition of Cloning Human Beings (European Treaty Series - No. 168) [43] : Article 1 which states that :

> *(1) "Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited."*
>
> *(2) "For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set."*

European Union

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and

safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

Finally, the SCHB concurs that the precautionary principal should be applied concerning the status of the human embryo. In other words, until unambiguous scientific proof to the contrary can be provided, a human embryo, as soon as it is created, should be considered as having the same moral status as an adult human person.

For the same precautionary reasons, the SCHB supports the definition of an embryo given in German legislation which indicates that any totipotent cell, extracted from an embryo which may divide and develop into an individual human being once the necessary further conditions are provided [44], is also an embryo.

The Council notes, in this regard, that the process of human development is a continuous one in which any demarcation would be arbitrary and merely conventional, as exemplified by the different upper time limits for abortions and embryological destructive research across Europe. Within the development process it is indeed impossible to indicate a non-arbitrary point of transition from human non-person to human person.

58. The Government believes that research undertaken on embryos using the cell nuclear replacement technique for the purpose of studying mitochondrial diseases should be permissible in law, subject to licensing. (Paragraph 9.22).

The SCHB notes that UK legislation concerning embryo research is generally a lot more liberal than elsewhere in the world and that it would be highly desirable for UK legislation to encompass relevant international declarations and conventions.

In this regard, the SCHB is of the opinion that possible new legislation in the UK relating to Human Fertilisation and Embryology should be drafted so that it becomes compliant with the Council of Europe *Convention on Human Rights and Biomedicine (European Treaty Series - No. 164)[45] : Article 18 (2) (Research on embryos in vitro)* which states that:

> *"The creation of human embryos for research purposes is prohibited."*

59. Further, the Government invites views on removing the current prohibition on "replacing a nucleus of a cell of an embryo with a nucleus taken from the cell of any person, another embryo or a subsequent development of an embryo" for research purposes, subject to licensing. (Paragraph 9.23).

The SCHB is opposed to removing the current prohibition on "replacing a nucleus of a cell of an embryo with a nucleus taken from the cell of any person, another embryo or a subsequent development of an embryo" for research or any other purposes.

60. The Government invites views on whether the law should permit altering the genetic structure of an embryo for research purposes, subject to licensing. (Paragraph 9.28).

One should note that this proposal appears inconsistent with the Government's earlier proposal that the prohibition in the HFE Act on genetic modification of embryos for reproductive purposes should continue and be extended to gametes used in treatment. If individuals performing such research should have no whatsoever foreseeable treatment applications in mind, then how could such research be justified?

The SCHB is also of the opinion that possible new legislation in the UK relating to Human Fertilisation and Embryology should be drafted so that it becomes compliant with Article 13 (Interventions on the human genome) of the European Convention on Human Rights and Biomedicine which indicates that:

> *"An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants."*

61. The Government invites views on whether the law should permit the creation of human-animal hybrid or chimera embryos for research purposes only (subject to the limit of 14 days culture in vitro, after which the embryos would have to be destroyed). (Paragraph 9.35).

To begin with, one should emphasise the pronounced lack of scientific justification for such research. Anyone interested in studies with animal-human chimera is only interested in examining the fate of cells during development, so limiting such studies to a 14 day time window would satisfy neither the relevant researchers nor those opposed in principle to the creation of chimeras.

In addition, when the Human Fertilisation and Embryology Act (1990) was put through parliament in the UK, the 'Hamster Egg Penetration Test' (HEPT) in which human sperm is mixed with a hamster's egg, was one of the few valid tests available to measure the viability of some patients' sperm. However, the introduction of Intra Cytoplasmic Sperm Injection

(ICSI) and other treatments has now made HEPT effectively obsolete for testing sperm prior to treatment. A similar technique has sometimes been used in the UK for research into the viability of sperm. However, the most recent treatment licence ended in 2003. In effect the UK Human Fertilisation and Embryology Authority no longer offers licences for HEPT to any treatment centres. The most recent research licence expired in 2003.

The SCHB also agrees with many other European countries that the creation of human-animal hybrid or chimera embryos for research purposes should be prohibited. In addition, the SCHB is of the opinion that:

1. The placing of a live human embryo into an animal should be prohibited.

2. The placing of live human sperm into an animal should be prohibited.

3. The placing of a live animal embryo into a woman should be prohibited.

4. The placing of live animal sperm into a woman should be prohibited.

5. The creation of an embryo containing cells made up of both human and animal chromosomes should be prohibited.

6. The insertion of a human cell nucleus or chromosomes into a non-human egg stripped of its chromosomes enabling an embryo to exist should be prohibited.

7. The mixing of animal and human gametes should be prohibited.

8. The incorporation of human pluripotent stem cells into post-natal animals should proceed with extreme caution. Moreover, such a procedure should only take place if it can be demonstrated that the cells cannot contribute to the germline or give rise to specifically human brain functions in the animals.

9. Because pluripotent stem cells might be expected to participate in the tissue of the germline and in the brain, the incorporation of (1) human pluripotent cells into post-blastocyst stages of non-human embryos and (2) non-human pluripotent cells into post-blastocyst stages of human embryos should be prohibited until it can be demonstrated that such possibilities cannot take place.

10. The incorporation of (1) human pluripotent stem cells into a non-human blastocyst or its preliminary embryonic stages and (2) non-human pluripotent stem cells into a human blastocyst or its preliminary embryonic stages should be prohibited.

62. The Government invites views on whether the current list of legitimate purposes for licensed research involving embryos remains appropriate. (Paragraph 9.38).

The SCHB is of the opinion that possible new legislation in the UK relating to Human Fertilisation and Embryology should be amended so that it becomes compliant with the Council of Europe *Convention on Human Rights and Biomedicine (European Treaty Series - No. 164) [46] : Article 18 (2) (Research on embryos in vitro)* which states that:

> *"The creation of human embryos for research purposes is prohibited."*

63. The Government believes that the purposes for which research using embryos may legitimately be undertaken should, as now, be defined in law and research projects should continue to be approved by a national body in order to ensure compliance with the law, national consistency and appropriate ethical oversight. (Paragraph 9.41).

As in most other European countries [47], the SCHB is of the view that any research involving the creation of embryos for the express purpose of performing destructive research should be prohibited.

The SCHB also agrees that all research involving the human being should, as now, be defined in law and research projects should continue to be approved by a national body in order to ensure compliance with the law, national consistency and appropriate ethical oversight.

64. The Government invites views on what, if any, additional regulatory requirements should apply to the procurement and use of gametes for purposes of research. (Paragraph 9.45).

Payment for human cells or other inducements to encourage donation should be prohibited.

65. The Government invites comments on the desirability of allowing the creation of embryos for the *treatment* of serious diseases (as distinct from *research* into developing treatments for serious diseases

which is already allowed). (Paragraph 9.47).

The SCHB is of the opinion that allowing the creation of embryos for the *treatment* of serious diseases (as distinct from *research* into developing treatments for serious diseases which is already allowed in the UK) should be prohibited.

Indeed, the use and destruction of embryos for treatment would be considered as completely unethical and extremely offensive to millions of people in the UK.

In addition the ramifications regarding the potential exploitation of women, either in order to create the required number of supernumerary embryos of clinical quality or to obtain sufficient eggs for nuclear transfer should be considered.

Finally, there is a health risk associated with the use of embryos for the treatment of serious diseases such as the potential for tumorigenesis arising form the proposed transplantation of ES cells.

The Regulatory Authority for Tissues and Embryos

66. The Government proposes that RATE, in common with the HFEA and HTA, will be headed by a lay chairperson, and have substantial lay representation among its membership. The membership will also need to have, or have access to, sufficient medical and scientific expertise in relation to the activities that come within its remit. (Paragraph 10.4).

The balance between legislation, regulation and reproductive freedom

Concerning the balance between legislation prepared by Parliament and regulations which may be established by regulatory authorities or ministers, the SCHB concurs that the former should be preferred, where possible. This is because the drafting of legislation enables all sections of society to take part in the discussions through the parliamentary process.

Where regulations and/or legislation are being considered they should, in so far as possible, anticipate future biological possibilities, even though it may be difficult to determine these developments.

In order to address the problem of possible new developments, legal provisions should state only what is specifically acceptable, thereby prohibiting all other procedures. This will then avoid an enumeration of prohibitions which may, with time, become obsolete, inappropriate, unclear and vague. For example, new UK legislation with respect to reproductive cloning eventually enacted a provision indicating what was acceptable by stating that "A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence" (Section 1 of the Human Reproductive Cloning Act 2001).

This was done in order to address misunderstandings resulting from only having prohibitions in existing legislation which did not specifically apply to human cloning.

The role of Parliament in the area of human reproductive technologies

The SCHB considers that the UK Parliament should ensure that it drafts all-encompassing legislation when preparing laws in the area of human reproduction. This would minimise the issues that would have to be regulated ad hoc by other bodies which may be less representative of society.

In addition, the SCHB is of the view that it would be impractical for the UK Parliament itself to act as a regulatory body. Thus there is a need for a body such as the RATE to be appointed which has the appropriate expertise to consider the issues that arise. However, this body clearly needs to be accountable to Parliament and an appropriate parliamentary committee should be able to closely monitor any regulatory decisions. The SCHB is also concerned that the present HFEA may have too much power to act, without consultation with Parliament, in the important area of human reproductive technologies.

The SCHB is of the opinion that the current HFEA does not adequately regulate new developments and seems to excessively support technological applications, without either adequate scientific expertise or suitable weight being given to other views and considerations. In this respect, the SCHB notes that the absence of any minority reports often indicates a unanimous decision. This suggests that the composition of the HFEA does not adequately reflect the wide spectrum of views within society. Indeed, some believe that the 18 members of the HFEA are selectively appointed to only represent certain views.

Therefore, the SCHB proposes that RATE should include individuals representing very different viewpoints, thereby better reflecting society. If this is not done, a false and misleading impression of unanimity will be presented with RATE only making decisions 'for' society without being representative of society.

New solutions should be considered to enable the general public to become better informed and more engaged in decision-

making relating to what should be acceptable. In other words, a body, such as RATE, should undertake sufficient and appropriate consultations of the general public. Moreover, the Houses of Lords and Commons, as the bodies representing the UK members of society, should be more involved in the decisions of RATE.

Concerning the dual role of RATE relating to its licensing and regulatory powers, the SCHB is of the opinion that the licensing of interventions and procedures should remain the responsibility of RATE but that policy decisions regarding the regulation of any new biological or reproductive possibilities should take place in collaboration between the experts of RATE and the democratic representatives of Parliament.

67. The Government proposes that:

- **• RATE will be an executive non-departmental public body. Its primary function will be to consider applications for licences to undertake those activities which Parliament decides should be subject to licensing. It will be funded principally from fees levied on licence-holders**
- **• RATE will be responsible for regular inspections of premises where licensable activities are carried on.**
- **• RATE will issue codes of practice giving guidance to persons undertaking those activities within its remit**
- **• RATE will maintain a central database of, at least, information relating to the use of donated gametes and embryos, and children born as a result. (Paragraph 10.5).**

See answer to question 66.

68. Both the HFEA and the HTA currently have statutory functions including to monitor or review developments relating to the activities within their remits, and to provide advice to the Secretary of State where appropriate or where asked to do so. The Government believes that a similar 'advisory' function would be appropriate for RATE as this body will be well placed to observe and monitor developments through its licensing and inspection procedures and its information gathering function. (Paragraph 10.6).

See answer to question 66.

69. The Government proposes that:

- **• the chairperson and members of RATE will be appointed by the NHS Appointments Commission**
- **• RATE will publish an annual report, which must be laid before Parliament**
- **• legislation will set out requirements for consultation and approval of codes of practice**
- **• RATE will publish summaries of embryo research licence applications received. (Paragraph 10.7).**

See answer to question 66.

70. The Government invites views on whether legislation should define a formal role for the professional bodies in advising RATE on the content of technical standards for assisted reproduction and embryo research. (Paragraph 10.10).

The SCHB believes that professional bodies should not have a formal role in advising RATE on the content of technical standards for assisted reproduction and embryo research. This would otherwise enable these bodies to have an undue and undemocratic influence on the decisions of RATE. It would also be seen as discriminatory to any other stakeholders who would seek to work with RATE.

71. The Government invites views on what sanctions should be available to the regulator to ensure compliance whilst promoting service improvement. (Paragraph 10.13).

72. The Government invites views on whether the maximum penalty of ten years imprisonment under the HFE Act should be altered, and if so, what should the maximum penalty be? (Paragraph 10.16).

The SCHB is of the view that the penalty should be commensurate with the gravity of the anticipated consequences for affected individuals or society at large.

Miscellaneous

73. The Government invites views on the extent to which the principles of good regulation are upheld in the Government's proposals, and any other comments or information about the regulatory impact of the measures described in this consultation document. (Paragraph R1.16).

74. Finally, we would welcome your views on any other issues that you feel should be considered or changes that you would like to see made to the HFE Act 1990.

In a similar manner to Article 4 of the UN Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography, the SCHB agrees that UK legislators should consider the possibility of drafting bioethical extra-territorial provisions making it an offence for UK nationals and habitual residents going abroad to undertake procedures which are prohibited in the UK.

The SCHB notes that UK legislation concerning embryo research is generally a lot more liberal than elsewhere in the world and that it would be highly desirable for UK legislation to encompass relevant international declarations and conventions.

In this regard, the SCHB is of the opinion that possible new legislation in the UK relating to Human Fertilisation and Embryology should be amended so that it becomes compliant with the following provisions of international declarations, legislation and regulation:

United Nations

- United Nations Declaration on Human Cloning

United Nations Educational, Scientific and Cultural Organization:

- The draft Universal Declaration on Bioethics (currently being prepared by UNESCO)

- The Universal Declaration on the Human Genome and Human Rights [48]

- The International Declaration on Human Genetic Data [49]

Council of Europe

- Convention on Human Rights and Biomedicine (European Treaty Series - No. 164) [50]: Article 14 (Non-selection of sex):

> *The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.*

Article 18 (Research on embryos in vitro):

> *(1) Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.*
>
> *(2) The creation of human embryos for research purposes is prohibited."*

- Additional Protocol on the Prohibition of Cloning Human Beings (European Treaty Series - No. 168) [51]: Article 1 which states that :

> *(1) Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.*
>
> *(2) For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set.*

European Union

- Charter of Fundamental Rights of the European Union: Article 3 (Right to the integrity of the person)

> *1. Everyone has the right to respect for his or her physical and mental integrity.*
>
> *2. In the fields of medicine and biology, the following must be respected in particular:*
> *- the free and informed consent of the person concerned, according to the procedures laid down by law,*
> *- the prohibition of eugenic practices, in particular those aiming at the selection of persons,*
> *- the prohibition on making the human body and its parts as such a source of financial gain,*

- the prohibition of the reproductive cloning of human beings.

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

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1. Section 8 of the German Embryo Protection Act of 13 December 1990.

2. Signed by 31 of the 45 Council of Europe Members States, http://conventions.coe.int/Treaty/en/Treaties/Word/164.doc

3. House of Commons Science and Technology Committee, Human Reproductive Technologies and the Law, Volume 1, 2005, The Stationery Office Ltd, paragraph 35, http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/702.htm

4. House of Commons Science and Technology Committee, Human Reproductive Technologies and the Law, Volume 1, 2005, The Stationery Office Ltd, paragraph 35, http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/702.htm

5. House of Commons Science and Technology Committee, Human Reproductive Technologies and the Law, Volume 1, 2005, The Stationery Office Ltd, paragraph 31, http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/702.htm

6. House of Commons Science and Technology Committee, Human Reproductive Technologies and the Law, Volume 1, 2005, The Stationery Office Ltd, paragraph 36, http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/702.htm

7. Tomorrow's children: A consultation on guidance to licensed fertility clinics on taking in account the welfare of children to be born of assisted conception treatment, Human Fertilisation and Embryology Authority, 2005, paragraph 2.1.-2.2. , http://www.hfea.gov.uk/AboutHFEA/Consultations/Welfare%20of%20the%20child%20Tomorrows%20Children.pdf

8. Tomorrow's children: A consultation on guidance to licensed fertility clinics on taking in account the welfare of children to be born of assisted conception treatment, Human Fertilisation and Embryology Authority, 2005, paragraph 2.1.-2.2. , http://www.hfea.gov.uk/AboutHFEA/Consultations/Welfare%20of%20the%20child%20Tomorrows%20Children.pdf

9. Tomorrow's children: A consultation on guidance to licensed fertility clinics on taking in account the welfare of children to be born of assisted conception treatment, Human Fertilisation and Embryology Authority, 2005, paragraph 2.3., http://www.hfea.gov.uk/AboutHFEA/Consultations/Welfare%20of%20the%20child%20Tomorrows%20Children.pdf

10. Review of the Human Fertilisation and Embryology Act: A Public Consultation, Department of Health, 2005, paragraph 3.28.

11. Sarah-Kate Templeton, Spare embryos 'should be donated to infertile couples', The Sunday Herald, 21 September 2003: http://www.sundayherald.com/36912

12. This should take account of the risk of incest if many embryos are adopted in a common location.

13. This includes haematopoietic peripheral blood, umbilical-cord (blood) and bone-marrow stem cells, reproductive cells (eggs, sperm), foetal tissue and cells and adult and embryonic stem cells. The Directive does not include organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body. After receiving EU legal advice it is also thought to cover human embryos but only with respect to their quality and safety aspects.

14. Comes into force on the 7th of April 2006.

15. The provisions of this Protocol, applicable to tissues, also apply to cells, including haematopoietic stem cells. However, the Protocol does not apply (1) to reproductive organs and tissue (comprising ova, sperm and their precursors); (2) to embryonic or foetal organs and tissues including embryonic stem cells; (3) to blood and blood derivatives.

16. Additional Protocol to the European Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of human origin (ETS No. 186): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=186&CM=8&DF=12/10/04&CL=ENG

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18. Sperm donation - should you tell your child?, Reuters, http://www.msnbc.msn.com/id/6866305/

19. Poor couples 'want IVF anonimity', BBC News, 26 January 2005, http://news.bbc.co.uk/1/hi/health/4205661.stm

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21. Mary Braid, Your daddy was a donor, The Observer, 20 January 2002, http://observer.guardian.co.uk/review/story/0%2C6903%2C636020%2C00.html

22. Women lose embryo battle - BBC - 1 October 2003, http://news.bbc.co.uk/1/hi/health/3151762.stm

23. A. Frean, Couples may get chance to design the 'ideal' IVF baby, TIMESONLINE, 12 November 2004: http://www.timesonline.co.uk/article/0,,2-1355182,00.html

24. Children Positive about Sperm donors, BioNews No. 284, 15 November 2004

25. This is also reflected in paragraph 18 of the HFEA consultation which states that: Clinics usually offer recipients gametes or embryos from donors who are a close physical match to the people receiving treatment. This is thought to be in the interests of the family concerned so that donor-conceived members of that family do not 'stand out' and risk becoming socially stigmatised as a result. Additionally, some recipients want donors with a certain background for non-genetic reasons, for example because they want a donor who shares their religion.

26. A. Frean, Couples may get chance to design the 'ideal' IVF baby, TIMESONLINE, 12 November 2004: http://www.timesonline.co.uk/article/0,,2-1355182,00.html

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29. Couples' feelings mixed about extra embryos, 14 October 2003 (Reuters Health): http://www.stjudemedicalcenter.org/healthnews/reuters/20031014elin022.htm

30. G Fuscaldo, J Savulescu, Spare embryos: 3000 reasons to rethink the significance of genetic relatedness, Reproductive BioMedicine Online, Volume 10, No 2 February 2005, http://www.rbmonline.com/4DCGI/Article/Detail?38%091%09=%201550%09 Studies reviewing the fate of surplus human embryos reveal that close to 90% of couples choose to discard their excess embryos and that hundreds of embryos are disposed of annually. It has been argued that human embryos are a valuable resource and that there is a need to consider educational programmes to encourage couples to donate spare embryos to other infertile couples, rather than discard them. Surveys show that one reason that so few embryos are donated is that couples attach great significance to genetic parenthood. Advances in reproductive technology may necessitate a review of biological definitions of family and the importance of genetic relatedness. It can be argued that it is unreasonable to conclude that genetic ties are so significant that embryos should be discarded rather than donated and raised by non-genetically related parents. It is suggested that education programmes should encourage reflection on people's beliefs about the importance of genetic relatedness with regard to what makes a family. Open embryo donation or directed embryo donation programmes might cause couples to change their minds, or alleviate their anxiety about donating embryos to others.

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