



Department of Health Review of the Human Fertilisation and Embryology Act

White Paper (December 2006)

British Fertility Society Response

24th April 2007

The British Fertility Society (BFS) comprises a membership of over 800 healthcare professionals (doctors, scientists, nurses, counsellors and others) with involvement in fertility care provision and reproductive medicine research in the United Kingdom. The Society has the following aims and objectives:

- To promote high quality practice in the provision of fertility treatment.
- To provide a common forum for members of various disciplines having an interest in the science and treatment of infertility.
- To promote high quality scientific and clinical research in the causes and treatment of infertility.
- To provide professional leadership in the provision and regulation of infertility services.
- To promote the increase of NHS funding for, and equity of access to, fertility treatments.

The BFS has in the past and continues to make important contributions to debate in relation to advances in the human reproductive technologies. In recent times the Society:

- contributed to the House of Commons Science and Technology Committee review of the law relevant to assisted reproduction techniques (April 2005)
- responded to the Department of Health (DH) Public Consultation on the Review of the Human Fertilisation and Embryology Act (November 2005)
- Responded to the DH's Human Fertilisation & Embryology Act 1990 (Amendment) Regulations 2006 consultation (October 2006)

The Department of Health published a White paper in December 2006 in which the Secretary of State for Health set out proposals for revised legislation in relation to human reproductive technologies. These include the establishment of the Regulatory Authority for Tissues and Embryos. This paper sets out the considered views of the BFS Executive committee following consultation with the Society's membership.

The White paper outlines the Government's proposals for revision of the legislation which will be presented to Parliament in the form of a draft Bill. The BFS shares the Government's view that it is important that the legal and regulatory parameters in this area are publicly reviewed, removed where no longer required, and reinforced or replaced where necessary. Account needs to be taken of the European dynamics in the evolution of revised legislation as encompassed in the EU Tissues and Cells Directive.

KEY POINTS

- 1. Standards of clinical practice and research should be in the remit of the DH and professional organisations which have the relevant expertise, as already exists in other branches of medicine and science.**
- 2. The research assessment role of the regulator should be confined to determining whether the proposal is lies within the boundaries of the revised Act.**
- 3. Protocol modifications and training should not require a research licence.**
- 4. Clinics should not be required to submit laboratory data of every treatment cycle to the regulator.**
- 5. The definition of an embryo should be clarified. The Society suggests the first cleavage stage to be appropriate.**
- 6. Certain elements of the White Paper proposals should be removed from Primary Legislation and devolved to the regulatory body allowing flexibility to cope with clinical and scientific advances e.g. gene therapy, artificial gametes, pre-implantation diagnosis.**
- 7. Gametes and embryos for research should be allowed to be stored for longer than 10 years.**
- 8. Sex selection for non-medical reasons should be allowed in exceptional circumstances. A blanket ban in Primary Legislation is unnecessary.**
- 9. Consent to disclosure procedures should be removed from Primary Legislation.**
- 10. Thought should be given to how counselling services for donor conceived people after receipt of sibling information is resourced.**
- 11. Policy debate should not be a function of the Authority but should rather be conducted within and accountable to Parliament. The establishment of a National Bioethics Commission should be considered.**
- 12. The cost of regulation to patients should only include the cost of inspection and maintenance of the register.**
- 13. The constitution of the RATE and its advisory panels must be absolutely transparent and accountable.**

**THE 25 PROPOSALS INCORPORATED IN THE WHITE PAPER ARE LISTED BELOW
TOGETHER WITH COMMENT FROM THE BFS.**

Proposal	BFS view
<p>1. The current model of regulation, whereby Parliament sets the prohibitions and parameters within which a statutory authority licenses activities should continue.</p>	<p>We believe the main roles of the regulator are:</p> <ul style="list-style-type: none"> • To protect patients and offspring by monitoring safety and efficiency of procedures/clinics. • To reassure the public with respect to concerns about the creation and manipulation of human embryos. • To protect those working in the field from public criticism through rigorous monitoring and controls. <p>When laws are set, it is the role of the regulator to ensure compliance with the law. Standards of treatment and professional skills should be within the remit of professional bodies, not the regulator which does not have the expertise within its membership, and is not accountable to the professional groups. It would be essential for these organisations to have effective communication channels with RATE. The regulator in effecting its role in accreditation and inspection of clinics should take account of published standards incorporated in a revised Code of Practice for clinics.</p> <p>There is support within the BFS for a Bioethics Commission which is accountable to Parliament in the evolution of policy matters relevant to the human reproductive technologies.</p>
<p>2. Activities involving the creation, keeping and use of embryos outside the body, or the use of donated gametes, should continue to be subject to licensing by an independent regulator.</p>	<p>The BFS agrees that clinics producing embryos or working with donated gametes should be subject to inspection by the regulator.</p> <p>With respect to research, the role of the regulator should be limited only to considering whether applications that it receives conform to the wishes of Parliament. Information sheets and governance could reasonably be left to COREC procedures. Further comments on research are included at the end of this document.</p>
<p>3. All human embryos outside the body, regardless of the manner of their creation, will be within the scope of regulation.</p>	<p>The Society agrees that human embryo creation should be regulated. However, the Government has not made a case to support the need for a central database of laboratory data relating to all embryos created. Presently this generates an unnecessary administrative burden of doubtful value. It is however the view of the BFS that it would be essential that the regulator have access to clinic records to validate reported treatment outcomes. This should be facilitated through the inspection process.</p> <p>It should be noted that IVF is now mainstream clinical treatment contributing to over 1% of births in the UK each year. Some take the view that the routine nature of treatment argues against the need for a register. Others believe that the unique nature of IVF, where there may be unknowns in relation to genomic effects, e.g. risks of imprinting disorders argue for the retention of a register of children conceived following ART. It is not the role of the regulator to facilitate research but a central register of children conceived may permit linkage of an IVF database to other registries including childhood cancer.</p>

	<p>It remains essential that clinics maintain their own databases in accordance with good clinical practice. This enables regular audit of outcome (validation of processes under EU Tissue Bank regulation) and individual staff performances (CME and appraisal). This will be more detailed data than is currently collected by the HFEA. Outcome data from these records can be audited as part of the accreditation process and published centrally if required by regulations.</p>
<p>4. The law will continue to treat “eggs in the process of fertilisation” in the same way as embryos, and this will also apply to eggs undergoing other processes of embryo creation.</p>	<p>The current Act defines an “embryo” in order to provide a legal entity. This has little relationship to the scientific meaning and carries an unhelpful relationship with a baby in the public’s mind. The BFS agrees with the 14 day upper limit for in vitro embryo growth but many consider that the lower limit for regulation should be set at the first cleavage stage since there is no unique genetic identity present until this stage. It should be remembered that the original draft of the HFE Act suggested that the first cleavage stage be the appropriate point for specific regulation to be implemented. The regulation of stem cell, chimera/cybrid research is dealt with below.</p>
<p>5. Artificial gametes. The Government proposes a ban on the use of non-naturally occurring gametes (cells not originating in the testes or ovaries) in assisted reproduction treatment.</p>	<p>The BFS agrees with this but urges the Government to place this restriction within regulation rather than Primary Legislation. At the present time there is no evidence of efficacy or safety in this work. However it is possible that evidence of potential benefit may emerge. It is important therefore to retain some flexibility within the regulatory framework, which would allow for the potential to translate basic scientific research in to clinical research trials without recourse to amendment of Primary Legislation.</p>
<p>6. The Government proposes to retain a duty of treatment centres to consider the welfare of the child who may be born as a result of treatment (or any other child who may be affected).</p>	<p>The lighter touch which has come about in the last 2 years has been welcomed. The BFS suggests that Welfare of Child procedures should be subject to guidelines rather than Primary Legislation.</p>
<p>7. On balance, the Government has decided to propose that the reference to the need for a father (in consideration to the welfare of the child) should be removed from the Act.</p>	<p>Again the BFS welcomes this proposal in line with evolved Welfare of Child procedures in the last 2 years. This should be subject to guidelines only.</p>
<p>8. The law will enable the <i>storage</i> of gametes from persons lacking capacity where the gametes have been lawfully removed in the best interests of that person, without written consent, where medical opinion indicates that the person is likely to gain/regain capacity.</p>	<p>The BFS is uncomfortable with the notion of removing gametes without consent. We are concerned that in some instances this might be construed as assault and we are unclear as to whether gamete removal would always be in the best interests of the person concerned. It would be absolutely essential that there be a process of obtaining consent to use gametes, separate to any proxy consent to removal.</p>
<p>9. There should be a “cooling off” period for up to one year following the withdrawal of consent to embryo storage by one of the persons whose gametes were used in the creation of the embryo.</p>	<p>This is agreed.</p>

<p>10. The Government proposes to extend the statutory storage period for embryos from five to ten years, bringing embryos in line with gametes.</p>	<p>This is agreed in the context of clinical treatment, though flexibility to store in some cases beyond this time is suggested whether for the patients' own use, for donation to other patients or for research.</p> <p>A time limit of 10 years on embryos stored for research will present problems. It is often the case that patients defer decisions on allowing research on their embryos until a short time prior to the end of the statutory storage period, and consequently the effective use of these embryos in research may be impeded. It is suggested that the limits for storage of eggs, sperm, embryos and any other tissue stored for research be removed, provided that ethics committee approval has been gained for the research and the institution where they are stored has an appropriate licence. This would allow the material to be stored between projects as well as when active research is taking place.</p>
<p>11. The law will include explicit criteria for the testing of embryos. Legitimate purposes will be:</p> <ul style="list-style-type: none"> i. Screening out genetic or chromosomal abnormalities leading to serious medical conditions, disabilities or miscarriage ii. Tissue typing to provide umbilical cord blood to treat a sibling suffering life threatening illness. <p>Deliberately screening-in a disease or disorder will be prohibited. The regulator will license these activities to ensure consistency, and will consider tissue typing applications on a case by case basis.</p>	<p>It is unnecessarily proscriptive to insist that the regulator should have the final say as to whether a specific genetic condition can be screened. This does not happen with pre-natal screening. Why should PGD be any different? The regulator should be able to challenge clinics to justify their practice if it was suspicious that the clinic was not working within the law. The responsibility for clinical decisions in this way should remain with clinicians, not regulators.</p> <p>It should also be borne in mind that certain diseases/disorders can occasionally confer health benefits for individuals e.g. heterozygote for sickle cell trait providing malarial resistance. Consideration might therefore be given to avoiding blanket prohibition in primary legislation. Some would argue that fully informed prospective parents are in the best position to judge issues relating to the welfare of their children.</p>
<p>12. Sex-selection for non-medical reasons within treatment services will be prohibited, including for "family balancing".</p>	<p>It is the view of the Society that sex selection for non-medical reasons should not be banned in primary legislation. The Code of Practice should be permissive in exceptional circumstances. There is no evidence to suggest that there is likely to be an enormous uptake of this kind of service. Use of sex selection techniques should be monitored.</p>
<p>13. The Government proposes that the law will clearly ban genetic modification of the nuclear DNA of embryos and gametes for reproductive purposes.</p>	<p>The Society agrees with this position, but under what circumstances can in vitro research be translated in to in vivo research? It is suggested that this be placed within the scope of regulation rather than in Primary Legislation.</p>
<p>14. For research purposes only, the restriction on altering the genetic structure of a cell while it forms part of an embryo will be removed.</p>	<p>Agreed, but it is suggested that this be placed within the scope of regulation rather than in Primary Legislation.</p>

<p>15. The government proposes to revise the confidentiality restrictions in the HFEA Act relating to the use of data on assisted reproduction treatments, so that it is more accessible for activities such as research.</p>	<p>There are two distinct views on the place of the register in future legislative requirements. The first takes the view that there is no justification for keeping a central identifying register of all patients who have received treatment regardless of the outcome.</p> <p>The argument for maintaining a register of donor conceived children garners more support. Current regulations require that every egg mixed with sperm be accounted for in returns to the HFEA. Some would suggest that this be removed as a requirement by the RATE. The requirement to keep accurate records within clinics will be consistent with standards of accreditation under the EU Directive. It is difficult to see what benefit could be gained or avoided by keeping a central record of the outcome of each embryo created. Summary data from clinics, verified at accreditation inspections, can be submitted as annual returns to RATE. This would remove some of the regulatory burden and hence the cost.</p> <p>A second view is that the register serves a useful function for follow up studies and research. However there is a strong view from some that the regulatory authority should not function as a research facilitator. Routine data collection has been used to create league tables which are a major disincentive to good practice, in particular the move to single embryo transfer.</p> <p>The majority view is in favour of retention of the register but to reduce the paperwork involved by restricting detailed returns to those treatments which result in a birth.</p> <p>The present consent to disclosure arrangements are unnecessarily restrictive and impede communication between healthcare professionals and researchers. These should be eased.</p>
<p>16. The law will make clear that gamete donors will be able to access limited, non-identifying information about children conceived as a result of donation. Donors will be able to be informed when their identifying details have been requested by those children (from age 18).</p>	<p>It is the view of the BFS that gamete donors should be able to find out non-identifying information as to whether their donations have resulted in a live-birth. Donor conceived people should be able to find out about potential siblings. There is a need for pre-HF & E Act (1990) donors to have their legal status identified.</p> <p>Some members regret the removal of anonymity protection for donors and point out that the short term effect of the change in legislation has been that the cost of DI has risen enormously in many centres. It has effectively been removed from the NHS as standard practice in most areas, and increased the numbers of patients seeking treatment abroad. Reduced access to treatment, while retaining the right of children to know their biological father, has meant that fewer patients now access treatment in the UK. There is a view that had parallel programmes of anonymous and non-anonymous donation as previously recommended by the BFS been facilitated it is possible that the present situation could have been avoided. The BFS urges the Government to resource a nationally co-ordinated approach to gamete donation services in the UK.</p> <p>The BFS is curious to know as to whether the DH has audited the consequences of the change in legislation.</p>
<p>17. Donor-conceived children will be able to find out if they have donor-conceived siblings, as part of the information accessible to them from age 18.</p>	<p>This is agreed, however there is a concern within clinics with respect to the availability of counselling and support services after this information is provided. Clinics are anxious that they may not have the resources to accommodate these needs.</p>

	Consideration should be given to the numbers of families derived from single donors. In some countries this is higher than 10, the figure in the UK.
18. Persons intending to form civil partnerships will be able to find out whether they are related as a result of gamete donation.	Agreed.
19. The extent to which not-for-profit organisations may undertake activities for the facilitation of surrogacy arrangements will be clarified.	Agreed.
20. The status and legal parenthood provisions of the HFE Act will be revised to enable a greater range of persons to be recognised as parents following assisted conception.	Agreed.
21. Legislation will make clear that basic (as well as applied) embryo research is permissible subject to the controls of the HFE Act. Also, the law will make clear that research into serious injuries (such as spinal cord injuries) is permissible, as well as research into serious diseases as at present.	Agreed but it is suggested that the legislation is not too proscriptive.
22. The Government proposes to remove the restriction on replacing the nucleus of a cell of an embryo for research purposes only, subject to the controls of the HFE Act.	Guidance on the translation of such basic research in to clinical trials required as in 13 & 14.
23. The Government proposes that the use of embryos for training in treatment and research techniques will clearly be permissible under the authority of a licence.	<p>We strongly support the use of embryos for training purposes without the need to issue a research licence i.e. under a treatment licence only. No clinic should be allowed to provide a new treatment without having embryos, eggs and sperm available for training. This should only relate to cells which are not needed or wanted for clinical treatment and which would otherwise be discarded. No additional licensing procedures should be required for such training.</p> <p>This also should relate to the modification of lab protocols e.g. performing a comparison of two different media, or the application of new laboratory method already in use elsewhere e.g. vitrification. Introduction of new lab methods should not require a research licence but rather be a function of an existing treatment licence. Such work would be assessed in the context of the new style EU Tissue Directive inspection process.</p>

<p>24. Revised legislation will clarify the extent to which law and regulation applies to embryos combining human and animal material. The Government will propose that the creation of hybrid and chimera embryos <i>in vitro</i> should not be allowed. However the Government also proposes that the law will contain power enabling regulations to set out circumstances in which the creation of hybrid and chimera embryos <i>in vitro</i> may in future be allowed under licence, for research purposes only.</p>	<p>Currently the mixing of human and animal gametes is only allowed (under licence) for testing the fertility or normality of human sperm, and the product of the mixed gametes must be destroyed when the test is complete and no later than the two cell stage. The BFS strongly supports the case for research using hybrids and chimeras to further knowledge of human embryo cell pluripotency and embryonic stem cell derivation and testing.</p> <p>As with some of the comments above it is suggested that this work should not be banned in Primary Legislation but governed by the delivery of regulation within the revised Code of Practice.</p>
<p>25. The Government proposes to replace the HFEA and the HTA with a single regulator – the Regulatory Authority for Tissues and Embryos. RATE will be the single competent authority acting as the regulator under the EU Blood, and Tissue and Cells Directive.</p>	<p>See below.</p>

THE ESTABLISHMENT OF THE NEW REGULATOR: RATE.

A number of issues are of concern to the Society in relation to the establishment, responsibilities and effective functioning of the new regulator.

i. Standards

It should be made clear that the regulator should not have a role in the setting of clinical and laboratory standards in the sector. The Authority will not have the appropriate membership to do this and are not accountable to the Professional Groups (BFS/ACE/RCOG and others). Standards should be set by the professional bodies themselves in consultation with their members. It would be the responsibility of RATE to ensure that the documentation of clinics/laboratories demonstrates compliance with recommended good practice of the professional groups and assessment in this regard should be a fundamental component of the inspection process.

ii. Regulatory role and policy setting

There continues to be vigorous public and political debate about human reproductive technologies. Recent examples include donor anonymity, screening for adult onset disorders, egg donation for research, sex selection The BFS believes that there should be a clear separation between this necessary open debate and the regulatory process. The debates should involve all relevant stakeholders. They should afford the articulation of views by those with particular subjective interest in matters of controversy e.g. patients and providers as well as those with wider interests e.g. ethics, social policy, politics, religion, philosophy. Consideration should be given to the establishment of a National Bioethics commission, based within and accountable to Parliament, which could facilitate recommendations in respect of policy. As things stand at present there may be a conflict of interest between the regulatory function of the Authority and its policy

making role. An example of this is the current situation where clinics are discouraged by the regulator (e.g. via licence committees) from adopting practices which reduce clinical pregnancy rates, while at the same time the policy making arm of the HFEA is engaging clinics and professionals in a discussion on how best to promote single embryo transfer.

iii. The cost of regulation

Regulatory costs in the IVF sector are far greater than in comparative areas e.g. blood transfusion services (BTS), the activities of the Health Care Commission. Unlike in other areas of regulated clinical practice such as abortion services and BTS, it is IVF patients who pay for regulation. It is questionable as to whether patients should pay for activities over and above the basic duties of the regulator i.e. inspection and the maintenance of the register. Efficiency savings underpinned the Health Secretary's decision to rationalise the number of regulatory bodies under the arms length review. It is not clear to the BFS how such savings are likely to be passed on to clinics and patients.

iv. Information giving

The BFS is not certain that this needs to be within the statutory competence of the Authority and, with the plethora of information available from clinics, the internet and other sources, wonders whether this offers a potential for cost saving.

v. Reporting results

The way in which data from clinics is presented to the public is a matter of concern to the BFS. The Society continues to work with the regulator in determining the best way in which such data should be presented. The conversion of presently reported success rates in to National League tables are a major disincentive to good clinical practice such as the promotion of single embryo transfer policies.

vi. Research

Research poses particular problems within the sector. The BFS acknowledges that this is a particularly sensitive point politically. There are some within the research community within the UK who are of the opinion that regulatory inefficiencies have inhibited innovation and progress. Complex scientific knowledge is required to understand the issues involved in relation to reproductive technologies and to other scientific research which is currently not regulated. The current "cybrid" controversy is an example. Lack of expertise within the new regulatory authority is a potential continuing hazard. An alternative to the current regulatory procedures might be to establish a specific, Research Ethics Committee under updated COREC procedures to process research applications. Any such committee would need to have the required scientific membership to understand work conceptually and also have legal advice to ensure compliance with the law. Given the small scientific field in the UK and the potential for conflicts of interest, it would be advised that membership of such a committee, in addition to lay members, would consist of senior scientists and clinicians who are not directly working in the field but would understand the science. The

cost to clinics and researchers in maintaining separate additional licensing procedures for research seem hard to justify. There would be the potential for RATE to be represented on such a committee but it need not be within the regulatory authority's remit to regulate research. Were research regulation to remain solely within the remit of the new authority, then fundamental improvements in the processing of applications is required, and the Society's concerns re expertise and efficiency addressed.

vii. The scope of regulation

There is currently a regulatory gap for the culture and use of human embryonic stem cells derived from human embryos. The HFEA regulates the use of human embryos and the derivation of new ES cell lines, but not their continuing culture, storage and therapeutic use. The HTA do not currently cover this area, as they do not cover the use of cell lines grown outside the body. It is vital that RATE encompasses this area, which currently appears to lie between the HFEA and HTA.

viii. Accountability

The BFS understands that the new RATE Board will be served by several Expert Advisory Panels including one for assisted reproduction and embryology. The constitution of each advisory panel will be crucial to the effective functioning of the new authority. It is not clear to the BFS how these panels will be appointed and whether members will be accountable in any way for their deliberations. It would seem likely that the RATE members will be unlikely to be in a position to counter any recommendations made by an advisory panel and thus it has been suggested in some quarters that the Authority would merely rubber stamp any such recommendations. There is a concern that the reliance on the Advisory Panel in advance of any authority decisions may delay the regulatory process unnecessarily.

CONCLUSION

Reproduction is a very personal aspect of our lives. Any measure which intrudes on this privacy should be resisted unless there is evidence of threat to the wellbeing of the rest of society. It is now nearly 30 years after the birth of Louise Brown and IVF has become an established routine part of medical treatment

The HFE Act which outlines the legal framework of IVF and Assisted Conception has served us well, but now should be modified by removing those clauses which discriminate against infertile couples e.g. the requirement to demonstrate suitability for parenthood and the need for a father. It is difficult to justify why the infertile should be subject to regulations more restrictive than those applied to the general population.

The incorporation of the HFEA into RATE provides an opportunity to review its functions and current practice. The regulator should concentrate on ensuring, by inspection and requiring reports from centres, that the conditions of the Act are adhered to. It should refrain from setting guidelines on areas which are outside the Act.

The time has come to stop treating couples with infertility as “special cases”. The BFS strongly recommends a reduction in the burden of excessive regulation and with the introduction of the European Directive we have the opportunity for a more logical approach to regulation through strict accreditation of clinics and audit of compliance.

The key points in our response are commended to the Secretary of State for Health.

KEY POINTS

- 1. Standards of clinical practice and research should be in the remit of the DH and professional organisations which have the relevant expertise, as already exists in other branches of medicine and science.**
- 2. The research assessment role of the regulator should be confined to determining whether the proposal is lies within the boundaries of the revised Act.**
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Mark Hamilton
Chair, British Fertility Society
m.hamilton@abdn.ac.uk
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